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, 2018

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.)**

7575 Gateway Blvd., Suite 110
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 Global Select 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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark 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, a smal ler reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act):

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the 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 Global Select Market on June 30, 2018, was $782,202,455. This excludes 673,613 shares of the registrant's Common Stock held by executive officers, directors and stockholders affiliated with directors outstanding at June 30, 2018. 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 January 31, 2019, was 59,470,368

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2019 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, 2018, 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, 2018

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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, that 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 that 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

Overview

We are a clinical-stage biopharmaceutical company focused on developing and providing access to innovative therapies for patients with liver and other chronic diseases with high unmet medical need.

Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPARδ), a nuclear receptor that regulates genes directly or indirectly involved in the synthesis of bile acids/sterols, metabolism of lipids and glucose, inflammation and fibrosis. We are currently developing seladelpar for the treatment of primary biliary cholangitis (PBC), an autoimmune disease that causes progressive destruction of the bile ducts in the liver resulting in impaired bile flow (cholestasis) and inflammation. We are also developing seladelpar for the treatment of nonalcoholic steatohepatitis (NASH), a prevalent and serious chronic liver disease caused by excessive fat accumulation in the liver that results in inflammation and cellular injury that can progress to fibrosis and cirrhosis, and potentially liver failure and death.

We reported net losses of approximately $72.5 million, $27.6 million, and $26.7 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had cash equivalents and marketable securities totaling $178.7 million, which we believe is sufficient to fund our current operating plan into 2021.

Strategy

Our goal is to become a leading biopharmaceutical company focused on developing and providing access to innovative therapies for patients with liver and other chronic diseases with high unmet medical need. Key elements of our strategy are to:

- Advance clinical development of seladelpar for patients with PBC and NASH,
- Strengthen our patent portfolio and other means of protecting exclusivity, and
- Evaluate other product candidates.

Recent Events

In February 2019, we completed enrollment of a placebo-controlled Phase 2b proof-of-concept study to evaluate seladelpar at three doses in biopsy-proven NASH. The primary efficacy outcome is the change from baseline in liver fat content at 12 weeks measured by magnetic resonance imaging using the proton density fat fraction method (MRI-PDFF). The study also includes pathology assessments of liver biopsy samples at baseline and at 52 weeks to examine the potential of seladelpar treatment to resolve NASH and/or decrease fibrosis.

In October 2018, we commenced enrollment of a global, Phase 3 registration study to evaluate seladelpar in patients with PBC. Data from two Phase 2 studies of seladelpar in PBC established seladelpar's anti-cholestatic and anti-inflammatory effects and identified doses we believe have the potential to offer patients improved efficacy and better tolerability over the only approved second-line treatment available today, in addition to reductions in markers of cholestasis including alkaline phosphatase (AP), seladelpar also improved inflammatory and metabolic markers with patients experiencing decreases in levels of transaminases, high sensitivity C-reactive protein, and low-density lipoprotein cholesterol. Many PBC patients suffer from pruritus, or itching, which can significantly impact their quality of life. Based on data from our Phase 2 studies, and unlike the only approved second-line treatment currently available, seladelpar has not been associated with drug-induced pruritus.

CymaBay Pipeline Overview

Our pipeline includes two clinical stage product candidates: seladelpar (MBX-8025) and MBX-2982*. We have one preclinical stage product candidate, CB-001.

Product Candidates	Disease/condition	Status	Description
Seladelpar	Primary Biliary Cholangitis (PBC)	Phase 3	52-week study to evaluate seladelpar in PBC patients with inadequate response or intolerance to ursodeoxycholic acid (UDCA) (NCT03602560)
Seladelpar	Nonalcoholic Steatohepatitis (NASH)	Phase 2	52-week study to evaluate safety, tolerability, and effect of seladelpar in patients with NASH (NCT03551522)
MBX-2982 (GPR 119 agonist)	Gut/Liver	Pre-IND	Undisclosed indication(s)
CB-001 (GPR 120 agonist)	Gut/Liver	Preclinical	Undisclosed indication(s)

* Phase 2 in discontinued indication supported safety and pharmacokinetic profile, currently being explored pre-clinically for other indication(s).

Seladelpar (MBX-8025)

Seladelpar is a selective agonist for the peroxisome proliferator-activated receptor delta (PPARδ). The PPARδ receptor is a nuclear receptor that regulates genes involved in bile acid/sterol, lipid, and glucose metabolism, and regulation of certain inflammatory cells. Seladelpar has the potential to treat certain diseases of the liver and a variety of disorders of lipid metabolism.

Seladelpar was initially developed for treatment of mixed dyslipidemia, which is characterized by elevated low-density lipoprotein (LDL-C) and triglycerides (TGs). Results from our Phase 2 clinical study of seladelpar in patients with mixed dyslipidemia established effects that we believe have the potential to benefit patients affected with other conditions, these benefits including:

- Significant reductions in markers of cholestasis, such as alkaline phosphatase (AP) and gamma-glutamyl transferase (GGT),
- Decreases in high-sensitivity C-reactive protein (hs-CRP), a marker of inflammation,
- Lowered LDL-C and raised high-density-lipoprotein (HDL-C), and
- Decreased triglycerides and free fatty acids.

We believe seladelpar may provide a significant benefit for patients with rare cholestatic liver diseases, such as PBC, and NASH, a more prevalent liver disease with no currently approved therapy.

In February 2019, the Food and Drug Administration (FDA) granted seladelpar Breakthrough Therapy Designation for the treatment of early stage PBC, and in October 2016, seladelpar received the European Medicines Agency (EMA) PRIority MEdicines (PRIME) designation for the treatment of PBC. In November 2016, the FDA granted orphan drug designation to seladelpar for the treatment of PBC. In September 2017, EMA's Committee for Orphan Medicinal Products (COMP) granted orphan drug designation to seladelpar for the treatment of PBC.

To date, we have completed six-month and twelve-month toxicity studies of seladelpar in rats and monkeys, respectively, as well as two-year carcinogenicity studies in mice and rats. In addition, nine Phase 1 and three Phase 2 clinical studies with seladelpar have been completed. In addition to the Phase 2b NASH study, a 52-week Phase 2 clinical study is currently ongoing in patients with PBC. A long-term safety extension study for PBC patients is currently enrolling patients as they complete 52 weeks of treatment in the aforementioned Phase 2 PBC study.

Seladelpar Clinical Development

Primary Biliary Cholangitis (PBC)

Summary

PBC is a rare, chronic progressive autoimmune liver disease that predominantly affects middle-aged women. A T-cell mediated immune response is thought to damage, and ultimately destroy, the interlobular and septal bile ducts. The loss of bile duct function leads to decreased bile secretion and retention of toxic substances, including bile acids, within the liver parenchyma. This retention may ultimately cause liver cirrhosis and liver failure in PBC patients.

PBC primarily affects an estimated one in 1,000 women over the age of 40. Due to its low prevalence, PBC has been recognized as an orphan disease in the U.S. and E.U., meeting its respective FDA and EMA orphan designation criteria. Diagnosis of PBC is confirmed by elevated serum AP presence and/or magnitude of antimitochondrial antibody (AMA presence), and liver biopsies, although biopsies are no longer required for diagnosis in most patients.

The most common clinical symptoms of PBC include fatigue and pruritus (up to 70% occurrence), which adversely affects many patients' quality of life. PBC patients are also frequently affected by conditions including jaundice, hyperlipidemia (notably hypercholesterolemia), hypothyroidism, osteopenia and osteoporosis, and coexisting autoimmune diseases. Late complications of PBC include portal hypertension, malabsorption, deficiencies of fat-soluble vitamins, and steatorrhea (excess fat in feces). Left untreated, PBC disease progression can lead to the need for liver transplantation and liver-related mortality. Despite being a rare disease, PBC is one of the top six indications for liver transplantation in the U.S. and E.U. Recurrence of PBC following liver transplantation is reported in 11-46% of transplantations, with an estimated prevalence of 30% at 10 years following transplantation, further demonstrating a need for effective therapies.

Retrospective analyses of PBC clinical outcomes data have shown that elevated levels of AP and bilirubin are associated with worsened clinical outcomes including liver transplantation and death associated with PBC. These analyses supported the use of AP and bilirubin as elements of a clinical surrogate reasonably likely to predict outcomes that was used for the approval of obeticholic acid as a second line therapy for PBC.

Competition/Industry

We face competition from pharmaceutical and biotechnology companies. The FDA-approved treatments for PBC are ursodeoxycholic acid (UDCA), also known as ursodiol, a generic drug, and obeticholic acid (Ocaliva®). UDCA is a natural bile acid that decreases serum levels of AP, bilirubin, alanine transferase, aspartate aminotransferase, cholesterol, and immunoglobulin M, which are all elevated in patients with PBC and can serve as biochemical markers of disease. Ocaliva® is a synthetic bile acid analog that binds to and activates the farnesoid X receptor, or FXR, and received orphan designations in the U.S. and the E.U.

Studies of Seladelpar in PBC

Phase 3 ENHANCE

In October 2018, we commenced enrollment of a global, Phase 3 registration study (ENHANCE) to evaluate seladelpar in patients with PBC. The Phase 3 study is a double-blind, randomized, placebo-controlled 52-week study evaluating the safety and efficacy of 5 mg and 10 mg of seladelpar versus placebo in patients with PBC who have had an inadequate response or are intolerant to first-line treatment with ursodeoxycholic acid (UDCA). An inadequate response is defined as a patient having AP greater than 1.67 times the upper limit of normal (ULN). Approximately 240 patients will be randomized to receive placebo, 5 mg of seladelpar, or 10 mg of seladelpar. Patients on 5 mg will have the potential to increase the dose, in a double-blinded manner, to 10 mg after 6 months if they have not yet met the primary endpoint. The primary endpoint is a composite response defined as a patient achieving an AP level below 1.67 times the upper limit of normal, with at least a 15% reduction from baseline, and a normal total bilirubin at 52 weeks. The primary analysis will compare response rates of treatment groups to those of the placebo. Key secondary endpoints will be AP normalization rate and changes in pruritus, as measured by the numerical rating scale, or NRS. We expect to complete enrollment in this program at the end of 2019.

Safety Extension Study

Our long-term safety extension study of seladelpar is open to patients participating in current or future PBC studies in the PBC clinical development program. Patients completing the low dose Phase 2 study (discussed immediately below) began transferring into the long-term safety extension study in December 2017.

Phase 2 Low Dose

In December 2016, we initiated a second Phase 2 study of seladelpar in patients with PBC. The study is an open label, randomized, dose-ranging study evaluating lower doses of seladelpar and the primary efficacy endpoint is the percent change in AP. Secondary outcomes are to evaluate other markers of cholestasis, inflammation, and lipid parameters, as well as clinical symptoms such as pruritus and quality of life.

Following positive results from our planned interim analysis in early 2018, we released updated data from the Phase 2 Low Dose study in November 2018 that continued to show sustained anti-cholestatic and anti-inflammatory effects with no worsening of pruritus through 52 weeks. Results highlight the potential for seladelpar to offer patients an efficacious and safe second line treatment option.

Specifically, efficacy data was released on the first set of patients treated for 52 weeks and safety data on patients that received at least one dose of seladelpar in the study. Eligible PBC patients with either an inadequate response or intolerance to ursodeoxycholic acid (UDCA) were randomized to daily seladelpar at 5 or 10 mg. After 12 weeks, patients on 5 mg could escalate to 10 mg if their AP treatment goal was not met (5/10 mg group). The primary efficacy outcome was the AP % change from baseline. At 52 weeks, the mean decreases in AP were -47% and -46% in the 5/10 and 10 mg groups, respectively. A key secondary outcome was the composite response measured at week 52 where a responder was defined as a patient with AP <1.67 x ULN, ≥15% decrease in AP, and total bilirubin ≤ULN. At 52 weeks, 59% and 71% of patients met the composite endpoint in the 5/10 and 10 mg groups, respectively. The anti-cholestatic effect of seladelpar was further substantiated with normalization of AP levels at 52 weeks in 24% and 29% of patients in the 5/10 and 10 mg groups, respectively. Treatment with seladelpar also demonstrated a robust anti-inflammatory activity with median transaminase decreases of -31% and -33% in the 5/10 and 10 mg groups, respectively.

A 26-week analysis from the study was also shared on the effect of seladelpar on pruritus, or itching, which is a common clinical symptom of PBC that adversely effects a patient's quality of life. After 26 weeks, the median changes in the pruritus visual analog scale (VAS) was -50% and -55% in the 5 /10 and 10 mg groups, respectively. These data suggest that seladelpar is not associated with drug-induced pruritus and support further evaluation of seladelpar's potential benefit on pruritus.

Overall, seladelpar appeared safe and well tolerated. Of the 119 patients that received at least one dose of seladelpar, 11 serious adverse events were documented, and none were considered related to seladelpar. Three patients discontinued seladelpar, of which only one discontinuation, for a grade 1 gastroesophageal reflux, was deemed related to seladelpar. There was no transaminase safety signal, and importantly, there was no indication that seladelpar was associated with drug-induced pruritus.

Phase 2 High Dose

Initial proof-of-concept for seladelpar in PBC was established in a Phase 2 study evaluating higher doses of seladelpar (50 mg and 200 mg daily). The Phase 2 high dose study was initiated in November 2015. The study was a placebo-controlled, double-blind, dose ranging study of 12 weeks duration in patients who had an inadequate response to UDCA. 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.

During the study, three cases of asymptomatic increases (5-8 times the upper limit of normal) in transaminases were observed (two in the 200 mg and one in the 50 mg cohorts) and the study was discontinued. All three cases were reversible on discontinuation of treatment and were not accompanied by elevation of total bilirubin. After unblinding the study data, changes in the primary endpoint AP were analyzed using data available for the 38 subjects enrolled in the study that had completed at least two weeks of treatment. The mean decreases from baseline in AP 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 the two seladelpar groups. All patients on seladelpar who received treatment for 12 weeks (three on 50 mg and two on 200 mg) normalized their AP levels. Thus, in this study seladelpar demonstrated a rapid and potent anti-cholestatic effect in patients with PBC. The lack of a dose response suggested that lower doses could be effective as well.

Nonalcoholic Steatohepatitis (NASH)

Summary

Nonalcoholic fatty liver disease (NAFLD) is the most common chronic liver disease worldwide and encompasses a spectrum of conditions that arise from fat accumulation in the liver of individuals that cannot otherwise be attributed to alcohol consumption. The prevalence of NAFLD has increased and is reported to account for approximately 25% of the general population worldwide. It is widely believed that the increase in NAFLD prevalence is a consequence of the obesity epidemic, and studies associate NAFLD with visceral obesity, Type 2 diabetes, hypertension, dyslipidemia, and hypothyroidism.

The accumulation of fat in combination with hepatic inflammation, can cause chronic liver injury leading to nonalcoholic steatohepatitis (NASH). NASH is the progressive form of NAFLD and increases patient risk of developing advanced liver fibrosis, cirrhosis, decompensated cirrhosis, the need for liver transplantation, hepatocellular carcinoma (HCC), and/or death. Serum markers that are often elevated in NASH patients include the transaminases alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST). Liver biopsies are performed to confirm a NASH diagnosis. Approximately 10-20% of individuals with NAFLD progress to NASH.

Competition/Industry

There are currently no drugs approved in the U.S. or E.U. for the treatment of NASH. However, several clinical studies have been completed or are underway with drug candidates that may affect disease outcomes in patients with non-cirrhotic NASH, including Phase 3 studies with OCA, an FXR-agonist (Intercept Pharmaceuticals), elafibranor (GFT505), a PPARα/δ agonist (Genfit SA), cenicriviroc, a CCR2/5 receptor antagonist (Allergan), and selonsertib, an ASK1 inhibitor (Gilead). Over two dozen other compounds are currently in Phase 2 development in NASH.

Studies of Seladelpar in NASH

Phase 2b NASH Study

In May 2018, we initiated a randomized, placebo-controlled, parallel, dose-ranging Phase 2b study to evaluate seladelpar in patients with NASH. In February 2019, we announced full enrollment of 181 patients with liver biopsy proven NASH at specialized U.S. investigational centers. Seladelpar at doses of 10, 20, and 50 mg per day will be studied versus placebo in a 2:2:2:1 randomization. The primary efficacy outcome is expected to be released in the second quarter of 2019 and will reflect the change from baseline in liver fat content at 12 weeks as measured by magnetic resonance imaging using the proton density fat fraction method (MRI-PDFF). Among the secondary measures of efficacy, most notable is the evaluation of histological improvement in NASH and fibrosis as assessed by comparing liver biopsy samples taken at baseline and 52 weeks. Additional important planned assessments include MRI-PDFF measurements at 26 and 52 weeks of treatment, as well as biochemical markers and non-invasive imaging that reflect inflammation, fibrosis and liver health.

Pre-clinical Studies

The mode of action for seladelpar in NASH was established in a diabetic and dyslipidemic obese mouse model (the *foz/foz* mouse model; Haczeyni et al., 2017). These mice develop liver pathology similar to humans with NASH consisting of steatohepatitis complicated by pericellular fibrosis (Van Rooyen et al., 2011; Haczeyni et al., 2015). The pathogenic progression of NASH and seladelpar's actions in this model are broadly summarized as follows: (1) The accumulation of fat with an accompanying development of insulin resistance: seladelpar reduced hepatic steatosis by increasing expression of genes associated with mitochondrial fatty acid oxidation, which was accompanied by restoration of full insulin sensitivity; (2) Cell stress and injury response: seladelpar reduced hepatocellular toxic species, including lipotoxic lipids and free cholesterol, with strong reductions in apoptosis and cell regeneration response to injury. There was a complete abrogation of cellular ballooning (necroinflammation), which is a defining characteristic of NASH; (3) Initiation and perpetuation of inflammation: seladelpar treatment led to strong reductions in liver macrophages, which was accompanied by reductions in inflammatory mediators; (4) Extracellular matrix deposition and remodeling: seladelpar reduced collagen deposition and characteristic fibrogenic transcripts that accompany stellate cell activation and fibrosis.

Recently, we have confirmed many of the features of the mechanism of seladelpar for NASH in a second mouse model, a diet-induced biopsy-confirmed NASH model in obese mice (Choi et al., 2018). This independent model employed feeding mice a diet with high levels of trans-fat, fructose and cholesterol to create a more aggressive NASH with fibrosis. Reduction in hepatic fat and improvement in NASH pathology, including abrogation of ballooning, were also observed. Fibrosis was reduced as measured by total collagen content in the liver.

MBX-2982

Summary

MBX-2982 targets G protein-coupled receptor 119 (GPR119), a receptor that interacts with bioactive lipids known to stimulate glucose-dependent insulin secretion. Preclinical data indicate that MBX-2982 is a potent selective orally-active GPR119 agonist that functions through a unique dual mechanism of action that acts directly on the beta cell to increase insulin secretion and stimulates release of the incretin GLP-1 from the gut. We have previously conducted clinical studies for MBX-2982 as a potential treatment for diabetes, demonstrating MBX-2982 was safe and well tolerated.

We believe MBX-2982 may have utility in various diseases impacting the gut, liver or gut-liver axis and are currently exploring potential opportunities to advance development.

CB-001 (GPR120)

Summary

CB-001 targets G protein-coupled receptor 120 (GPR120), a receptor for omega-3 fatty acids such as docosahexaenoic acid (DHA). Pharmacodynamic effects include insulin sensitization, stimulation of GLP-1 release, glucose sensitive insulin secretion (GSIS), improvement in hepatic steatosis and lipid profile, and anti-inflammatory activity. Preclinical target validation has been achieved.

We believe CB-001 may have utility in various diseases impacting the gut, liver or gut-liver axis and are currently exploring potential opportunities to advance development.

Arhalofenate

Summary

Arhalofenate is a dual-acting anti-inflammatory and uric acid lowering agent being developed for the treatment of gout. In 2016, we entered into an exclusive licensing agreement granting Kowa Pharmaceuticals America, Inc. the rights to develop and commercialize arhalofenate in the U.S. (including all possessions and territories). Under the terms of the agreement with Kowa, we received an up-front payment of $5.0 million, and in January 2018 we received a $5.0 million milestone payment for the initiation of a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment. We were also entitled to receive additional milestone payments based upon the achievement of specific development and sales milestones and royalties on future sales of arhalofenate products. On October 24, 2018, we received a notice from Kowa terminating the license agreement for the development of arhalofenate, effective on January 22, 2019. As a result of the termination, the rights licensed to Kowa through the agreement reverted to us on the termination date and we are no longer eligible to receive additional milestone payments or royalties from Kowa.

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. Our current significant collaborations are summarized below:

Johnson & Johnson: In June 2006, we entered into a license agreement with Janssen Pharmaceutical NV (Janssen NV), an affiliate of Johnson & Johnson, in which we received an exclusive worldwide, royalty-bearing license to seladelpar and certain other PPARδ compounds (the PPARδ Products) with the right to grant sublicenses to third parties to make, use and sell such PPARδ Products. Under the terms of the agreement, we have full control and responsibility over the research, development and registration of any PPARδ 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 certain patents related to the PPARδ Products. Janssen NV has a right of first negotiation under the agreement to license PPARδ Products 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 PPARδ Product. Under the terms of the agreement Janssen NV is entitled to receive up to an 8% royalty on net sales of PPARδ 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 PPARδ Product, such action would constitute a default under the agreement. In addition, if we fail to use diligent efforts to promote, market and sell any PPARδ Product under the agreement, such action would constitute a default under the agreement. In the event of such default, or upon our termination of the agreement, we are obligated to grant Janssen NV a worldwide, exclusive, irrevocable license under the agreement in all information that is controlled, developed or acquired by us that relates to a PPARδ compound or PPARδ Product and in all patents that are filed during the term of the agreement with a priority date after the effective date of the agreement and relate to a PPARδ compound or PPARδ Product.

In June 2010, we entered into two development and license agreements with Janssen Pharmaceuticals, Inc. (Janssen), an affiliate of Johnson & Johnson, under which Janssen obtained the right to further develop undisclosed metabolic disease target agonists for the treatment of Type 2 diabetes and other disorders, and we received a one-time nonrefundable technology access fee related to the agreements. These development and licensing agreements were terminated as of 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.

Research and Development

We do not currently own or operate research and development facilities. 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 also 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.

Intellectual Property

We own or co-own approximately 45 United States patents and 170 foreign patents, as well as 20 United States patent applications and 100 foreign and Patent Cooperation Treaty applications that are counterparts to certain United States patents and patent applications. In addition, we license from third parties approximately 20 United States patents and 2 United States patent applications, 350 foreign patents and 40 foreign and Patent Cooperation Treaty applications that 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 certain PPARδ agonists (including seladelpar), their compositions and uses both alone and in combination with other drugs, arhalofenate crystal forms, methods of use and methods of manufacture, and certain GPR119 and GPR 120 agonist compositions and uses.

The seladelpar portfolio consists of approximately 400 issued patents and 100 pending patent applications related to composition and method of use that we believe protect it through at least 2025-2035, 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 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 with established manufacturing firms that are responsible for sourcing and obtaining the raw materials necessary for the finished products. The raw materials necessary to manufacture the API for seladelpar are available from more than one source.

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 have significantly greater financial, technical and human resources than we have.

We are currently developing seladelpar for the treatment of patients with PBC and NASH. 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 AP, bilirubin, alanine aminotransferase, aspartate aminotransferase, cholesterol, and immunoglobulin M, all of which are elevated in patients with PBC and can serve as biochemical markers of the disease. In a study that combined data from three controlled trials with a total of 548 patients, ursodiol significantly reduced the likelihood of liver transplantation or death after four years. Ursodiol also delayed the progression of hepatic fibrosis in early-stage PBC, but was not effective in advanced disease. It is also known that up to 50% of PBC patients fail to respond 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 AP < 1.67 times upper limit of normal with a decrease in AP 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 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. Liver transplantation however is problematic because of its costs, the limited availability of donor organs, and by the fact that the disease may recur after an initially successful transplantation. 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.

Additional potential therapies in early stage clinical development for PBC include FXR agonists that act through the same mechanism of action as Ocaliva (tropifexor (LJN452, Novartis Pharmaceuticals Corp.), GS-9674 (Gilead Sciences, Inc.) and EDP-305 (Enanta Pharmaceuticals, Inc.)), the mixed PPARα/δ agonist elafibranor, the dual PPARα/γ agonist saroglitazar, the selective NOX inhibitor GKT137831, the oxy-sterol sulfate DUR-928, and the selective S1P receptor modulator etrasimod (APD334) (Arena Pharmaceuticals, Inc.). GSK23306772 (GlaxoSmithKline) is an inhibitor of the Intestinal Bile Acid Transporter (IBAT) and is being evaluated for the treatment of itch associated with PBC and maralixibat, another IBAT inhibitor, was recently discontinued for this indication due to lack of efficacy. NGM-282 (NGM Biopharmaceuticals), a FGF-19 variant was also studied in PBC, but the clinical program has been re-focused towards the treatment of NASH.

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 GLP. 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 a Phase 2 trial 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, who are 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

Pre-Approval Requirements

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.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. A product intended to treat a serious or life-threatening disease or condition may be eligible for breakthrough therapy designation to expedite its development and review. A product can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation provides opportunities for frequent interactions with the review team during product development and, once an NDA is submitted, the product may be eligible for priority review. The NDA may also be eligible for rolling review, where the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted.

EMA's recently established PRIME regulatory initiative similarly provides early enhanced regulatory support to facilitate regulatory applications and accelerate the review of medicines that address a high unmet need.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. A comparable orphan drug program is provided under EU law.

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 (HHS) 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 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, marketing expenditures, and drug pricing. Certain state and local laws also require the registration of pharmaceutical sales representatives.

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 coverage and adequate 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 coverage 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 now agree to offer 70% 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 & Medicaid Innovation at the Centers for Medicare & Medicaid Services (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 PPACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA such as removing penalties, starting January 1, 2019, for not complying with the PPACA's individual mandate to carry health insurance, delaying the implementation of certain PPACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, President Obama 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 2027 unless additional congressional action is taken. In January 2013, President Obama 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 and enacted federal and state legislation 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. At the federal level, Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. On January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our business.

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 7575 Gateway Blvd., Suite 110, 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 website our 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 of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Employees

As of January 31, 2019, we had 43 full-time employees.

Executive Officers of the Registrant

As of January 31, 2019, our executive officers and key other officers were as follows:

Name	Age	Position Held With CymaBay
Executive Officers		
Sujal Shah	45	President & Chief Executive Officer
Pol Boudes, M.D.	61	Chief Medical Officer
Charles A. McWherter, Ph.D.	63	Chief Scientific Officer
Klara Dickinson	51	Chief Regulatory and Compliance Officer
Paul T. Quinlan	56	General Counsel and Corporate Secretary
Daniel Menold	49	Vice President, Finance
Key Other Officers		
Robert L. Martin, Ph D	56	Senior Vice President, Manufacturing and Nonclinical Development
Patrick J. O'Mara	57	Senior Vice President, Business Development

Biographical Information

Executive Officers

Sujal Shah has served as our President and Chief Executive Officer since November 2017. Prior to that he served as our Interim President and Chief Executive Officer from March 2017 to November 2017. From December 2013 to March 2017, Mr. Shah served as Chief Financial Officer. 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 currently serves on the Executive Advisory Board of the Chemistry of Life Processes Institute at Northwestern University. 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.

Charles A. McWherter, Ph.D. has served as our Chief Scientific Officer since 2013 and served as our Senior Vice President, Preclinical Research and Development from 2007 to 2013. 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.

Klara Dickinson has served as our Chief Regulatory and Compliance Officer since January 2019, and was previously our Senior Vice President of Regulatory Affairs and Compliance. Prior to joining CymaBay in June 2017, she served as Senior Vice President, Chief Regulatory Officer of Anthera. From 2007 to 2014, she was Senior Vice President of Regulatory Affairs and Compliance at Hyperion Therapeutics Inc. Ms. Dickinson also spent three years at CoTherix, Inc. as Vice President, Regulatory Affairs and Healthcare Compliance Officer, and held various positions at biopharmaceutical companies Scios, Inc. and DEY Laboratories, a subsidiary of Mylan, Inc. Ms. Dickinson holds a B.S. in Biology from the College of Great Falls in Montana and is certified by the Regulatory Affairs Certification Board.

Paul T. Quinlan has served as our General Counsel and Secretary since December 2017. Previously, he served as General Counsel and Secretary at TerraVia Holdings, Inc. (formerly Solazyme, Inc.) since 2010, where he was responsible for the general supervision of the company's legal affairs. From 2005 to 2010, Mr. Quinlan was General Counsel and Secretary at Metabolex, Inc. and from 2000 to 2005, Mr. Quinlan held various positions in the legal department at Maxygen, Inc., most recently that of Chief Corporate Securities Counsel. Prior to joining Maxygen, Mr. Quinlan was an associate at Cooley LLP and Cravath, Swaine & Moore LLP. Mr. Quinlan obtained a law degree from Columbia University Law School and a M.Sc. in Medical Biophysics from the University of Toronto.

Daniel Menold has served as our Vice President, Finance since April 2017, and was previously our Corporate Controller since January 2014. Prior to joining CymaBay, Mr. Menold served as Corporate Controller for technology firm Zoosk, Inc., from 2011 to 2013, where he was responsible for the accounting and financial reporting functions and as Controller and Director of Accounting at Affymetrix. Prior to 2005, he also held accounting and finance positions of increasing responsibility at public and private life sciences and high technology companies in the Silicon Valley. Earlier in his career, Mr. Menold was at Ernst & Young where he was an audit manager and served on audits of life sciences and high technology companies. Mr. Menold received a M.S. in accounting and B.S. in finance from The University of Virginia McIntire School of Commerce.

Key Other Officers

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.

Patrick J. 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.

Item 1A. Risk Factors

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

Risks Related to Our Financial Condition and Capital Requirements

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

We have incurred significant net losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability. As of December 31, 2018, we had cash, cash equivalents and marketable securities of approximately $178.7 million, which we believe is sufficient to fund our current operating plan into 2021. If appropriate opportunities become available, we intend to seek to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development. 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 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 affect 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 and Phase 3 studies of seladelpar;
- 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 U.S. Food and Drug Administration (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.

Recent U.S. federal government shutdowns resulted in reduced staffing at the SEC that caused some disruption to the ability of companies to raise capital. If further shutdowns occur when we would otherwise desire to raise capital, our ability to raise such capital could be impaired and/or delayed.

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.

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:

- obtaining favorable clinical trial 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. If appropriate opportunities become available, we intend to seek to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development.

To raise additional funds to support our operations, we may sell additional equity or debt securities, enter into collaborations, strategic alliances, or licensing arrangements or other marketing or distribution arrangements. For example, in July 2017 we completed the issuance of 14,950,000 shares of our common stock at a public offering price of $6.50 per share and in February 2018, we completed the issuance of 13,340,000 shares of our common stock at a public offering price of $10.80 in underwritten public offerings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, and declaring dividends, and may impose limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

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

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

We have incurred and will continue to incur increased costs as a result of operating as a public company, and we will devote substantial time to meet compliance obligations.

We have incurred and will continue to incur legal, accounting and other expenses as a result of operating as a public company. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Stock Market, or Nasdaq, that impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated from time to time. We expect to incur expense and devote management effort toward ensuring compliance with Section 404 of the Sarbanes-Oxley Act, or Section 404, including but not limited to system and process evaluation and testing of our internal controls over financial reporting, as required by Section 404. Pursuant to Section 404(c) of the Sarbanes-Oxley Act, our independent registered public accounting firm is required to deliver an attestation report on the effectiveness of our internal control over financial reporting. Our future testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Implementing certain appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate consolidated financial statements or other reports on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and/or we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Recent U.S. tax legislation and future changes to applicable U.S. tax laws and regulations may have a material adverse effect on our business, financial condition and results of operations.

Changes in laws and policy relating to taxes may have an adverse effect on our business, financial condition and results of operations. For example, the U.S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses, and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

Risks Related to Clinical Development and Regulatory Approval

We depend on the success of our product candidates, in particular seladelpar, 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 multiple Phase 1 and Phase 2 clinical trials. There is no guarantee that our clinical trials will be completed or, if completed, will be successful. In July 2017 and April 2018, we announced positive interim results from an ongoing low-dose Phase 2 study of seladelpar in patients with primary biliary cholangitis, or PBC. During the fourth quarter of 2017, we initiated enrollment in a long-term extension study of seladelpar in patients with PBC. In February 2019, we completed enrollment in a Phase 2b study of seladelpar in patients with nonalcoholic steatohepatitis, or NASH, and in October 2018 we commenced enrollment of a global Phase 3 study to evaluate seladelpar in patients with PBC. The success of seladelpar will depend on many factors, including the following:

- successful enrollment and completion of clinical trials;
- recognition by the FDA and other regulatory authorities outside of the United States 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 United States 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 marketing approval; and
- obtaining, maintaining, enforcing and defending intellectual property rights and claims.

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

We have completed numerous Phase 1 and Phase 2 clinical studies with seladelpar. However, we have not completed a Phase 3 clinical trial, have never obtained regulatory approval for a drug and we may be unable to obtain, or may be delayed in obtaining, initial or full 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, we may have to compete with other clinical trials to enroll eligible subjects, or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- 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 expenses to increase in connection with our ongoing activities, particularly as we undertake additional clinical trials of seladelpar. We also will need to raise substantial additional capital in the future to complete the development and commercialization of seladelpar. 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 or other regulatory authorities to require that we repeat or conduct additional clinical studies. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates may be adversely impacted.

We have commenced testing of seladelpar in clinical studies for the treatment of PBC and NASH. If seladelpar does not demonstrate safety or efficacy in 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 PBC and NASH. Seladelpar may not be demonstrated to be effective in these indications or other indications we may target. Although we believe that seladelpar may be beneficial to address PBC and/or NASH, 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 that 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 a reported safety event;
- an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining required institutional review board (IRB) approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- changes to treatment guidelines or the introduction of a new standard of care;
- delays caused by clinical sites dropping out of a trial;

- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials; and
- delays in importing clinical trial materials into foreign countries where our clinical trials are being conducted.

If initiation or completion of any 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 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) plan;
- regulatory authorities may require the addition of labeling statements, such as black box or other warnings or contraindications that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we may choose to discontinue sale of the product;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

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

We have obtained orphan drug designation for seladelpar for the treatment of PBC, but not for 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 treatment of PBC by both the FDA and EMA. These exclusivities, or any other orphan exclusivity we may receive for another product 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. Additionally, the EMA can withdraw its orphan-drug designation even after market authorization if it determines that the drug has not demonstrated a significant benefit over other drugs for the same condition.

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 coverage and adequate reimbursement by third party payors 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 with principal investigators for our clinical studies and any related compensation with respect to clinical studies could adversely affect the drug approval process.

Principal investigators for our clinical studies may serve as scientific advisors or consultants to us or may be affiliated with our other service providers, including clinical research organizations or site management organizations, 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 or in the applicable study may be questioned or jeopardized.

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

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

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

We cannot commercialize our product candidates, 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 and foreign regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for any indication;
- regulatory authorities may not find the data from nonclinical studies and clinical studies sufficient or may differ in the interpretation of the data;
- regulatory authorities may require additional nonclinical or clinical studies;
- 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 authority 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 United States;
- 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 new drug application (NDA), marketing authorization or other equivalent submission, or to obtain regulatory approval in the United States or elsewhere.

In addition, events raising questions about the safety of certain marketed pharmaceuticals may result in increased caut ion 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 or 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 United States, the FDA may still impose significant restrictions on the indicated uses or marketing of seladelpar and our other product candidates 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 United States, we may never obtain approval for or commercialize seladelpar or any of our other product candidates outside of the United States, which would limit our ability to realize their full market potential.

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

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

Health care professionals and third party payors 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 Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal health care programs such as Medicare and Medicaid;
- the federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, 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, marketing expenditures, or drug pricing. Certain state and local laws also require the registration of pharmaceutical sales representatives. 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.

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

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

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

For example, the Patient Protection and Affordable Care Act (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 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 as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the PPACA such as removing penalties, starting January 1, 2019, for not complying with the PPACA's individual mandate to carry health insurance, delaying the implementation of certain PPACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the PPACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the PPACA will impact the PPACA and our business. 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.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, President Obama 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 2027 unless additional congressional action is taken. In January 2013, the President Obama 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, there have been several recent congressional inquiries, proposed bills and other proposals designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products including instituting reference pricing. At the federal level, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket

costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. On January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We are not sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

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

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

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

It is our current expectation that only one supplier of drug substance for seladelpar and one supplier of drug product for seladelpar will be initially 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, time consuming and could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new drug substance or drug product supplier is relied upon for commercial production. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our products, and cause us to incur additional costs. Furthermore, if our suppliers fail to deliver the required

commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, the supply chain for our products may be delayed, which could inhibit our ability to generate revenues.

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

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

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

- the inability to meet our product specifications, including product formulation, and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues, including those related 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 quality standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for key materials, such that if we are unable to secure a sufficient supply of these key materials, we will be unable to manufacture and sell our 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;
- disruption of the distribution of chemical supplies between the U.K. and E.U. due to Brexit;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver our products under specified storage conditions and in a timely manner.

Any of these events could lead to 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 that could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our confidential information, including our intellectual property, by CSPs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology, among other things. If our CSPs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

Risks Related to Commercialization of Our Product Candidates

The commercial success of 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 be unable to gain sufficient market acceptance by physicians, patients, health care payors and others in the medical community. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any of our 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. In addition, approval of seladelpar in multiple indications (such as PBC and NASH), or the approval of other drugs in NASH that might be effective in PBC could lead to negative pricing pressure on any commercialization of seladelpar in PBC, which could have a material adverse effect on our financial condition.

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 sales and marketing functions, we may be unable to compete successfully against these more established companies.

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product 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 United States, 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 United States, 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;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, pandemics, or natural disasters including earthquakes, typhoons, volcanic eruptions, floods and fires.

We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the European Union and many of the individual countries in Europe with which we 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 treatments the we are seeking to treat. Our competitors generally have significantly greater financial, manufacturing, marketing and drug development resources. Large pharmaceutical companies, in particular, have extensive experience in the clinical testing of, obtaining regulatory approvals for, and marketing of, drugs. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

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

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

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

Formulary approval and reimbursement may not be available for 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 seladelpar, into our target markets. Failure to obtain timely formulary approval will limit our commercial success.

Furthermore, market acceptance and sales of seladelpar or any other product candidates that we or our collaborators 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 United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and approval process apart from Medicare determinations.

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. For example, we expect the approval pathway for seladelpar for the treatment of PBC and/or NASH to be governed by Subpart H of the Food and Drug Act. As such, any approvals will initially be conditional and require confirmatory trials. Such trials may be costly and time consuming and may be unsuccessful in confirming the benefits of the conditionally approved product, potentially resulting in the withdrawal of approval and withdrawal of the product from the market. 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 plan, 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 United States 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 or a group of individuals may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in the following:

- decreased demand for our 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 United States 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 United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be 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 United States. As a result, we may encounter significant problems in protecting and defending our intellectual property abroad. We may also fail to pursue or obtain patents and other intellectual property protection relating to our products and product candidates in all foreign countries.

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party re-examination proceedings before the United States Patent and Trademark Office (U.S. PTO) and its foreign counterparts. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we 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 that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product 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 that might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

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

We are a party to a number of technology licenses that are important to our business and expect to enter into additional licenses in the future. For example, we rely on an exclusive license to certain patents and know-how from Janssen Pharmaceutical NV (Janssen NV), which include seladelpar and certain other PPARδ compounds (the PPARδ Products). Under the exclusive license with Janssen NV we have full control and responsibility over the research, development and registration of any PPARδ 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 PPARδ 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 PPARδ Product under the agreement, such action would constitute a default under the agreement and Janssen NV may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, including in the case of the Janssen NV license, seladelpar, which would have a materially adverse effect on our business.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is 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 United States 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. 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 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.

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

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

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

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

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

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

Risks Relating to Owning Our Common Stock

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

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

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

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

- adverse results or delays in preclinical testing or clinical trials;
- inability to obtain additional funding;
- any delay in filing an investigational new drug application (IND) or NDA for any of our future product candidates and any adverse development or perceived adverse development with respect to the FDA's review of an IND or NDA;
- failure to 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;
- changes in the structure of payment systems;
- 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;
- announcements of significant or potential equity or debt sales by us;
- announcements of clinical trial plans or results by us;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or management personnel;
- significant lawsuits, including patent or stockholder litigation;
- changes in the market valuations of similar companies;
- sales of our common stock by us or our stockholders in the future; and
- trading volume of our common stock.

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

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

We expect that significant additional capital will be needed in the future to continue our planned product development efforts, in particular clinical trial, and operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. For example, in July 2017 we completed the issuance of 14,950,000 shares of our common stock at a public offering price of $6.50 per share in an underwritten public offering for net

proceeds to us of approximately $91.3 million. In February 2018 we completed the issuance of 13,340,000 shares of our common stock at a public offering price of $10.80 per share in an underwritten public offering for net proceeds to us of approximately $135.5 million. In addition, in December 2018 we filed a $200 million shelf registration statement on Form S-3 with the SEC. 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 January 31, 2019, was 1,925,994 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.

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

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

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 extended our corporate office lease in April 2018, with a new expiration date of January 15, 2024 and an option to extend the lease for an additional five years. We believe that our current facilities are sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings

We are not a party to any legal proceedings.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

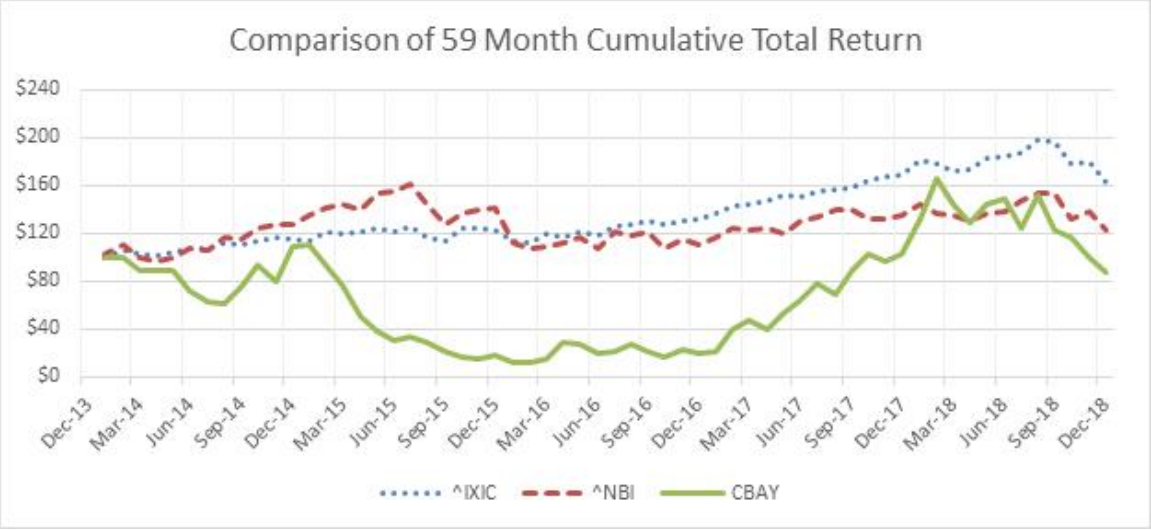
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market for Common Equity

Our common stock is listed on the Nasdaq Global Select Market under the symbol "CBAY". As of January 31, 2019, there were approximately 250 holders of record of our common stock, although there are a substantially greater number of "beneficial holders", whose shares are held of record by banks, brokers and other financial institutions in "street name".

Performance Graph

The following graph assumes an initial investment of $100 in our common stock on January 27, 2014, the first date that a trade occurred for our stock over-the-counter, as well as the stocks comprising the Nasdaq Composite Index (^IXIC), and the stocks comprising the Nasdaq Biotechnology Index (^NBI). All results assume the reinvestment of dividends, if any, and are calculated as of each month end. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.



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.

Item 6. Selected Financial Data

The following tables provide selected consolidated financial data. We have prepared this information using our audited consolidated financial statements as of and for the years ended December 31, 2018, 2017, 2016, 2015, and 2014. The following consolidated financial data should be read in conjunction with our consolidated financial statements and related notes and Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2018	2017	2016	2015	2014
Consolidated Statements of Operations Data	(in thousands, except per share amounts)				
Collaboration revenue	$ -	$ 10,000	$ -	$ -	$ -
Operating expenses:					
Research and development	58,124	18,938	15,941	17,026	15,823
General and administrative	14,381	12,387	9,645	8,871	8,185
Total operating expenses	72,505	31,325	25,586	25,897	24,008
Loss from operations	(72,505)	(21,325)	(25,586)	(25,897)	(24,008)
Other income (expense):					
Interest income (expense), net	3,652	(459)	(1,161)	(753)	(681)
Loss on extinguishment of debt	(407)	-	-	-	-
Other (expense) income, net	(3,288)	(5,773)	76	11,121	(7,228)
Net loss	$ (72,548)	$ (27,557)	$ (26,671)	$ (15,529)	$ (31,917)
Basic net loss per common share	$ (1.25)	$ (0.79)	$ (1.14)	$ (0.82)	$ (2.65)
Diluted net loss per common share	$ (1.26)	$ (0.79)	$ (1.14)	$ (0.83)	$ (2.65)
Weighted average common shares outstanding used to calculate:					
Basic net loss per common share	57,808	34,904	23,447	18,900	12,049
Diluted net loss per common share	57,838	34,904	23,447	18,917	12,049

	As of December 31,				
	2018	2017	2016	2015	2014
Consolidated Balance Sheets Data	(in thousands)				
Cash and cash equivalents, marketable securities	$ 178,664	$ 97,210	$ 16,994	$ 41,480	$ 34,795
Total assets	186,747	104,247	19,359	43,079	37,474
Working capital	167,147	87,234	9,217	36,648	16,770
Warrant liability	-	6,091	1,145	1,220	13,596
Facility loan, noncurrent	-	2,990	6,098	8,799	3,152
Accumulated deficit	(523,064)	(450,516)	(422,959)	(396,288)	(380,759)
Total stockholders' equity	170,418	84,947	3,937	28,115	13,850

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

Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPARδ), a nuclear receptor that regulates genes directly or indirectly involved in the synthesis of bile acids/sterols, metabolism of lipids and glucose, inflammation and fibrosis. We are currently developing seladelpar for the treatment of primary biliary cholangitis (PBC), an autoimmune disease that causes progressive destruction of the bile ducts in the liver resulting in impaired bile flow (cholestasis) and inflammation. We are also developing seladelpar for the treatment of nonalcoholic steatohepatitis (NASH), a prevalent and serious chronic liver disease caused by excessive fat accumulation in the liver that results in inflammation and cellular injury that can progress to fibrosis and cirrhosis, and potentially liver failure and death.

Seladelpar

Primary Biliary Cholangitis (PBC)

In October 2018, we commenced enrollment of a global, Phase 3 registration study to evaluate seladelpar in patients with PBC. Data from two Phase 2 studies of seladelpar in PBC established seladelpar's anti-cholestatic and anti-inflammatory effects and identified doses we believe have the potential to offer patients improved efficacy and better tolerability over the only approved second-line treatment available today. In addition to reductions in markers of cholestasis including alkaline phosphatase (AP), seladelpar also improved inflammatory and metabolic markers with patients experiencing decreases in levels of transaminases, high sensitivity C-reactive protein, and low-density lipoprotein cholesterol. Many PBC patients suffer from pruritus, or itching, which can significantly impact their quality of life. Based on data from our Phase 2 studies, and unlike the only approved second-line treatment currently available, seladelpar has not been associated with drug-induced pruritus.

Data from our completed Phase 2 High Dose and our ongoing Phase 2 Low Dose studies of seladelpar in patients with PBC have established seladelpar's anti-cholestatic and anti-inflammatory effects. In November 2018, we released updated data from the Phase 2 Low Dose study that continued to show sustained anti-cholestatic and anti-inflammatory effects with no worsening of pruritus through 52 weeks. Specifically, efficacy data was released on the first set of patients treated for 52 weeks and safety data on patients that received at least one dose of seladelpar in the study. Eligible PBC patients with either an inadequate response or intolerance to ursodeoxycholic acid (UDCA) were randomized to daily seladelpar at 5 or 10 mg. After 12 weeks, patients on 5 mg could escalate to 10 mg if their AP treatment goal was not met (5/10 mg group). The primary efficacy outcome was the AP % change from baseline. At 52 weeks, the mean decreases in AP were -47% and -46% in the 5/10 and 10 mg groups, respectively. A key secondary outcome was the composite response measured at week 52 where a responder was defined as a patient with AP <1.67 x ULN, ≥15% decrease in AP, and total bilirubin ≤ULN. At 52 weeks, 59% and 71% of patients met the composite endpoint in the 5/10 and 10 mg groups, respectively. The anti-cholestatic effect of seladelpar was further substantiated with normalization of AP levels at 52 weeks in 24% and 29% of patients in the 5/10 and 10 mg groups, respectively. Treatment with seladelpar also demonstrated a robust anti-inflammatory activity with median transaminase decreases of -31% and -33% in the 5/10 and 10 mg groups, respectively.

A 26-week analysis from the study was also shared on the effect of seladelpar on pruritus, or itching, which is a common clinical symptom of PBC that adversely effects a patient's quality of life. After 26 weeks, the median changes in the pruritus visual

analog scale (VAS) was -50% and -55% in the 5 /10 and 10 mg groups, respectively. These data suggest that seladelpar is not associated with drug-induced pruritus and support further evaluation of seladelpar's potential benefit on pruritus.

In February 2019, the FDA granted seladelpar Breakthrough Therapy Designation for the treatment of early stage PBC, and in October 2016, seladelpar received EMA PRIority MEdicines (PRIME) designation for the treatment of PBC. In November 2016, the FDA granted orphan drug designation to seladelpar for the treatment of PBC, and in September 2017, the EMA's Committee for Orphan Medicinal Products (COMP) granted orphan drug designation to seladelpar for the treatment of PBC.

Nonalcoholic Steatohepatitis (NASH)

We believe that seladelpar could also have utility in the treatment of NASH. Seladelpar was found to reverse NASH pathology, decrease fibrosis, inflammation, hepatic lipids and reverse insulin resistance in the *foz/foz* mouse which is a diabetic obese model of NASH. In February 2019, we completed enrollment of a placebo-controlled Phase 2b proof-of-concept study to evaluate seladelpar at three doses in biopsy-proven NASH. The primary efficacy outcome is the change from baseline in liver fat content at 12 weeks measured by magnetic resonance imaging using the proton density fat fraction method (MRI-PDFF). The study also includes pathology assessments of liver biopsy samples at baseline and at 52 weeks to examine the potential of seladelpar treatment to resolve NASH and/or decrease fibrosis.

Arhalofenate

Arhalofenate is a dual-acting anti-inflammatory and uric acid lowering agent being developed for the treatment of gout. In 2016, we entered into an exclusive licensing agreement granting Kowa Pharmaceuticals America, Inc. (Kowa) the rights to develop and commercialize arhalofenate in the U.S. (including all possessions and territories). Under the terms of the agreement with Kowa, we received an up-front payment of $5.0 million, and in January 2018 we received a $5.0 million milestone payment for the initiation of a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment. We were also entitled to receive additional milestone payments based upon the achievement of specific development and sales milestones and royalties on future sales of arhalofenate products. On October 24, 2018, we received a notice from Kowa terminating the license agreement for the development of arhalofenate, effective on January 22, 2019. As a result of the termination, the rights licensed to Kowa through the agreement reverted to us on the termination date and we are no longer eligible to receive additional milestone payments or royalties from Kowa.

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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these consolidated 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 consolidated 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 we describe our significant accounting policies in more detail in Note 2 of our consolidated 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 consolidated financial statements.

Revenue Recognition

As part of our drug development strategy, we periodically enter into collaboration arrangements with third party collaborators, under which we may license certain rights to our intellectual property to permit collaborators to further develop, manufacture and/or otherwise commercialize our drug candidates. The terms of these agreements typically include, but are not limited to, payments to us of one or more of the following: nonrefundable, upfront license fees; development and commercial milestone payments whose payment is typically contingent upon milestone achievement; funding of research and/or development activities; and royalties on net sales of licensed products.

Effective January 1, 2018, we adopted Accounting Standards Codification, or ASC Topic 606, *Revenue from Contracts with Customers* (ASC 606) using the modified retrospective method, for all contracts that had not been completed as of that date. As of the adoption date, we had entered into one out-licensing agreement that was within the scope of ASC 606, under which we have licensed certain of our product candidate rights to a third party. The terms of this arrangement included a non-refundable, up-front license fee, development and commercial milestone payments, and royalties on net sales of licensed products. Any revenues resulting from these payments are collectively classified as collaboration revenue, except for royalties on net sales of licensed products, which are classified as royalty revenues.

At the inception of an arrangement, we evaluate if a counterparty to a contract is a customer, if the arrangement is within the scope of revenue from contracts with customers guidance, and the term of the contract. We recognize revenue when the customer obtains control of promised goods or services in a contract for an amount that reflects the consideration we expect to receive in exchange for those goods or services. For contracts with customers, we apply the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including any constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. As part of the accounting for contracts with customers, we must develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. We then allocate the total transaction price to each performance obligation based on the estimated standalone selling prices of each performance obligation. We recognize the amount of the transaction price as revenue that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, our performance obligations are transferred to customers at a point in time, typically upon delivery.

Upfront License Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, we apply an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Development and Regulatory Milestone Payments: Depending on facts and circumstances, we may conclude that it is appropriate to include a milestone payment in the estimated transaction price using the most likely amount method or that it is appropriate to fully constrain the milestone. A milestone payment is included in the transaction price in the reporting period that we conclude that it is probable that recording revenue in the period will not result in a significant reversal in amounts recognized in future periods. We may record revenues from certain milestones in a reporting period before the milestone is achieved if we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We record a corresponding contract asset when this conclusion is reached. Milestone payments that have not been included in the transaction price to date are fully constrained. These milestones remain fully constrained until we conclude that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. We re-evaluate the probability of achievement of such development milestones and any related constraint each reporting period. We adjust our estimate of the overall transaction price, including the amount of collaborative revenue that was recorded, if necessary.

Sales-based Milestone and Royalty Payments: Our collaborators may be required to pay us sales-based milestone payments or royalties on future sales of commercial products. We recognize revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the collaborator's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the license our intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

We receive payments from our customers based on billing schedules established in each contract. Up-front payments and fees are recorded as deferred revenue upon receipt or when due until we perform our obligations under these arrangements. Amounts are recorded as accounts receivable when our right to consideration is unconditional. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

As of the adoption date of ASC 606, we had only one contract with a customer, Kowa Pharmaceuticals America, Inc. (Kowa), that had not been completed. Based on our review, we concluded there was no significant change in applying ASC 606 to the contract with Kowa and no amounts have been recognized within "accumulated deficit" in the consolidated balance sheet related to the adoption of the new standard. On October 24, 2018, we received a notice from Kowa terminating the collaboration agreement for the development of arhalofenate. The termination will be effective as of January 22, 2019. See Note 5 in the notes to the consolidated financial statements for further discussion.

Research and Development Expenses and Related Prepayments and Accruals

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 unless there is an alternative future use in other research and development projects.

As part of the process of preparing our consolidated 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 consolidated financial statements based on facts and circumstances known to us at that time. Such payments are evaluated for current or noncurrent classification based on when they will be realized. 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 screening and 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, 2018, 2017, and 2016.

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 we ultimately expect 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 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.

Common Stock Warrant Liability

Historically, our outstanding common stock warrants issued in connection with certain equity and debt financings that occurred in 2013 through 2015 were classified as liabilities in the accompanying consolidated balance sheets because of certain contractual terms that preclude equity classification. All outstanding warrants related to these financings had been exercised or had expired by September 30, 2018. Upon expiration, the remaining fair value of the liability was extinguished and credited to other (expense) income, net in our consolidated statement of operations. Prior to expiration, we estimated the fair value of common stock warrants at each reporting period until the exercise of the warrants, at which time the liability was revalued and reclassified to stockholders' equity. The determination of fair value of these common stock warrants required management to make certain assumptions regarding subjective input variables such as timing, probability and valuation impact of certain potential strategic events, expected term, dividends, expected volatility and risk-free interest rates.

Results of Operations

General

To date, we have not generated any income from operations. As of December 31, 2018, we have an accumulated deficit of $523.1 million, primarily as a result of expenditures for research and development and general and administrative expenses from inception to that date. While we have generated revenue from our license arrangement with Kowa and may in the future generate revenue from a variety of other sources, including license fees and milestone payments in connection with any future strategic partnerships, seladelpar is at a mid-level stage of development and our other product candidates are at an 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 the years ended December 31, 2018, 2017 and 2016 are presented below (in thousands):

	Year Ended December 31,				
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Collaboration revenue	$ -	$ 10,000	$ -	-100 %	N/A
Operating expenses:					
Research and development	58,124	18,938	15,941	207 %	19 %
General and administrative	14,381	12,387	9,645	16 %	28 %
Total operating expenses	72,505	31,325	25,586	131 %	22 %
Loss from operations	(72,505)	(21,325)	(25,586)	240 %	-17 %
Other income (expense):					
Interest income (expense), net	3,652	(459)	(1,161)	896 %	60 %
Loss on extinguishment of debt	(407)	-	-	N/A	N/A
Other (expense) income, net	(3,288)	(5,773)	76	-43 %	7696 %
Net loss	$ (72,548)	$ (27,557)	$ (26,671)	163 %	3 %

Collaboration Revenue

To date, our revenues have been recognized through collaborative licensing agreements as presented in the table below (in thousands):

	Year Ended December 31,				
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Collaboration revenue	$ -	$ 10,000	$ -	-100 %	N/A

Comparison of Years Ended December 31, 2018 and 2017

There was no collaboration revenue for the year ended December 31, 2018, compared to revenue of $10.0 million in the prior year. Collaboration revenue was recognized in 2017 upon the fulfillment of certain obligations and deliverables under our collaboration agreement with Kowa.

Comparison of Years Ended December 31, 2017 and 2016

Collaboration revenue for the year ended December 31, 2017 and 2016 was $10.0 million and none, respectively. Collaboration revenue was recognized in 2017 upon the fulfillment of certain obligations and deliverables under our collaboration agreement with Kowa. Specifically, collaboration revenue of $4.8 million was recognized in the first quarter of 2017 primarily upon transfer of the license and related technical knowhow. Additional collaboration revenue of $5.2 million was recognized in the fourth quarter of 2017 primarily due to the achievement of a collaboration milestone upon Kowa's initiation of a study to evaluate the pharmacokinetics of arhalofenate in subjects with renal impairment and upon transfer of certain arhalofenate product to Kowa.

Operating Expenses

Operating expenses consist of research and development and general and administrative expenses as presented in the table below (in thousands):

	Year Ended December 31,				
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Operating expenses:					
Research and development	$ 58,124	$ 18,938	$ 15,941	207 %	19 %
General and administrative	14,381	12,387	9,645	16 %	28 %
Total operating expenses	$ 72,505	$ 31,325	$ 25,586	131 %	22 %

Research & Development Expenses

Conducting research and development is central to our business model. We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue product development for seladelpar. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our research and development expenses will increase in the future.

For the years ended December 31, 2018, 2017 and 2016, research and development expenses were $58.1 million, $18.9 million and $15.9 million, respectively, and are detailed in the table below (in thousands):

	Year Ended December 31,				
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Project costs:					
Seladelpar PBC clinical studies	$ 21,009	$ 6,919	$ 5,978	204 %	16 %
Seladelpar NASH clinical studies	15,614	-	-	N/A	N/A
Seladelpar drug manufacturing & development	5,759	5,008	3,100	15 %	62 %
Seladelpar other studies	1,181	452	55	161 %	722 %
Non-seladelpar studies	184	(375)	615	149 %	-161 %
Total project costs	43,747	12,004	9,748	264 %	23 %
Internal research and development costs	14,377	6,934	6,193	107 %	12 %
Total research and development	$ 58,124	$ 18,938	$ 15,941	207 %	19 %

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.

Comparison of Years Ended December 31, 2018 and 2017

Total project costs increased by $31.7 million to $43.7 million from $12.0 million for the years ended December 31, 2018, and 2017, respectively. Project costs for the year ended December 31, 2018 primarily consisted of seladelpar-related clinical trial expenses and increased due to the expansion and extension of our PBC Phase 2 clinical trial, start-up activities related to our PBC Phase 3 clinical trial, the enrollment of our NASH Phase 2b clinical trial, and the execution of other NDA-enabling studies. In addition, project costs increased due to manufacturing of seladelpar to support ongoing and planned clinical trials and other development activities.

Internal research and development costs increased by $7.5 million to $14.4 million from $6.9 million for the years ended December 31, 2018 and 2017, respectively, primarily due to higher employee compensation related expenses as we hired additional clinical, scientific and regulatory personnel to support our expanding clinical development activities.

Comparison of Years Ended December 31, 2017 and 2016

Total project costs increased by $2.3 million to $12.0 million from $9.7 million for the years ended December 31, 2017, and 2016, respectively. Project costs for the year ended December 31, 2017 and 2016 primarily consisted of PBC-related clinical trial and drug manufacturing expenses for seladelpar. Specifically, costs were higher due to increased manufacturing of seladelpar to support our ongoing lower dose Phase 2 PBC clinical study, our long-term safety extension PBC study, our planned Phase 3 PBC clinical study, and other seladelpar-related development activities.

Internal research and development cost increased by $0.7 million to $6.9 million from $6.2 million for the years ended December 31, 2017 and 2016 respectively, primarily due to higher employee compensation related expenses incurred to support our expanding clinical development activities.

General and Administrative Expenses

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

Comparison of Years Ended December 31, 2018 and 2017

General and administrative expenses increased by $2.0 million to $14.4 million, from $12.4 million, for the years ended December 31, 2018 and 2017, respectively, primarily due to higher compensation and consulting expenses, partially offset by decreases in severance.

Comparison of Years Ended December 31, 2017 and 2016

General and administrative expenses increased by $2.8 million, to $12.4 million from $9.6 million, for the years ended December 31, 2017 and 2016, respectively, primarily due to the recognition of $2.6 million in severance benefits expense associated with the retirement of our former chief executive officer in 2017. Total estimated severance expenses consisted of $0.8 million in cash severance payments to be paid out within 12 months of our former chief executive officer's separation date as well as $1.8 million in stock-based compensation to reflect the vesting acceleration and an extension of time to exercise certain of his stock options.

Other Income (Expense)

Interest income (expense), net consists of interest income from our investments net of expense related to our loan facility. Other (expense) income, net consists of gains and losses resulting from the remeasurement of our investor and lender warrant liabilities at fair value. Other income (expense) is detailed below (in thousands):

	Year Ended December 31,				
	2018	2017	2016	2018 vs. 2017	2017 vs. 2016
Other income (expense):					
Interest income (expense), net	$ 3,652	$ (459)	$ (1,161)	896%	60%
Loss on extinguishment of debt	(407)	-	-	N/A	N/A
Other (expense) income, net	(3,288)	(5,773)	76	-43%	7696%
Total other income (expense)	$ (43)	$ (6,232)	$ (1,085)	99%	-474%

Comparison of Years Ended December 31, 2018 and 2017

Interest income (expense), net increased to net income of $3.7 million from net expense of $0.5 million, for the years ended December 31, 2018 and 2017, respectively. The change of $4.2 million was primarily due to higher interest income earned on the marketable securities purchased with a portion of proceeds from our January 2018 public offering, as well as a decrease in interest expense resulting from the full repayment of our term loan in June 2018.

In connection with the payoff of our term loan facility in June 2018, we recognized a $0.4 million loss on the extinguishment of debt.

Other (expense) income, net decreased $2.5 million to $3.3 million from $5.8 million for the years ended December 31, 2018 and 2017, respectively. The loss in the year ended December 31, 2018 was driven by a loss on remeasurement of our warrant liabilities at fair value, partially offset by a gain on expiration of unexercised warrants and the resulting extinguishment of the associated warrant liability in September 2018.

Comparison of Years Ended December 31, 2017 and 2016

Interest income (expense), net increased by $0.7 million, to net expense of $0.5 million from net expense of $1.2 million, for the years ended December 31, 2017 and 2016, respectively, due to lower interest expense associated with our term loan and higher interest income earned from our investments in the second half of 2017. Interest income grew because we invested a significant portion of the $91.1 million in proceeds received from our July 2017 public offering in marketable securities.

Other (expense) income, net reflected a net expense of $5.8 million and an immaterial net gain for the years ended December 31, 2017 and 2016, respectively, in each case due to the remeasurement of our warrant liabilities at fair value. During the year ended December 31, 2017, the remeasurement loss recognized was primarily due to the increase in our stock price, which is a key input in the warrant liability revaluation process.

Income Taxes

As of December 31, 2018, we had federal net operating loss carryforwards of $332.7 million and state net operating loss carryforwards of $224.8 million to offset future taxable income, if any. In addition, we had federal research and development general tax credit carry forwards of $8.5 million, a federal research and development orphan drug tax credit carryforward of $11.2 million, and state research and development tax credit carryforwards of $4.5 million. If not utilized, the federal net operating loss and tax credits for tax years beginning before January 1, 2018 will expire beginning in 2024 through 2037 and the state net operating loss carryforwards will expire beginning in 2028 through 2038. The federal net operating losses for tax years beginning after January 1, 2018 will carry forward indefinitely. 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, 2018, we recorded a 100% valuation allowance against our deferred assets of approximately $118.4 million as our management believes it is more likely than not that they will not be fully realized.

On December 22, 2017, the U.S. federal government enacted the Tax Cuts and Jobs Act (Tax Act). The Tax Act contains, among other things, significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% for tax years beginning after December 31, 2017, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, implementing a territorial tax system, and requiring a mandatory one-time tax on U.S. owned undistributed foreign earnings and profits known as the transition tax. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118) to address the accounting implications of recently enacted U.S. federal tax reform. SAB 118 allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date to address ongoing guidance and tax interpretations that are expected over the next 12 months. In 2018, we concluded our assessment and no material adjustment was identified.

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, 2018, cash, cash equivalents and marketable securities totaled $178.7 million, compared to $97.2 million at December 31, 2017. Historical summaries of sales of our equity securities are noted below followed by overviews of sources of liquidity from our licensing and debt arrangements.

Equity Financings

During January 2017, we sold 124,100 shares of our common stock for net proceeds of $158,000 under our ATM facility with Cantor Fitzgerald & Co.

On February 7, 2017, pursuant to our 2014 shelf registration statement on Form S-3, we completed the issuance of 5,181,348 shares of our common stock at a public offering price of $1.93 per share in an underwritten public offering, which we refer to as the February 2017 public offering. Net proceeds to us in connection with the February 2017 public offering were approximately $9.2 million after deducting underwriting discounts, commissions and other offering expenses.

In March 2017, we terminated our ATM facility with Cantor Fitzgerald & Co. In June 2017, our new $100 million shelf registration statement on Form S-3 was declared effective, terminating our prior registration statement.

On July 24, 2017, pursuant to our $100 million shelf registration statement on Form S-3, we completed the issuance of 14,950,000 shares of our common stock at a public offering price of $6.50 per share in an underwritten public offering, which we refer to as the July 2017 public offering. Net proceeds to us in connection with the July 2017 public offering were approximately $91.1 million after deducting underwriting discounts, commissions and other offering expenses.

On December 29, 2017, we filed a new $200 million shelf registration statement on Form S-3 and we terminated our $100 million shelf registration statement.

On February 1, 2018, pursuant to our $200 million shelf registration statement on Form S-3, we completed the issuance of 13,340,000 shares of our common stock at a public offering price of $10.80 per share, which we refer to as our February 2018 public offering. Net proceeds to us in connection with the February 2018 public offering were approximately $135.5 million after deducting underwriting discounts, commissions and other offering expenses.

On December 28, 2018, we filed a new $200 million shelf registration statement on Form S-3 that was declared effective in February 2019. Our existing $200 million shelf registration statement was also terminated on the effective date.

Licensing & Collaboration Fees

In 2016, we entered into an exclusive licensing agreement granting Kowa Pharmaceuticals America, Inc. the rights to develop and commercialize arhalofenate in the U.S. (including all possessions and territories). Under the terms of the agreement with Kowa, we received an up-front payment of $5.0 million, and in January 2018 we received a $5.0 million milestone payment for the initiation of a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment.

On October 24, 2018, we received a notice from Kowa terminating the license agreement for the development of arhalofenate. The termination was effective as of January 22, 2019. As a result of the termination, the rights licensed to Kowa through the agreement reverted to us on the termination date and we are no longer eligible to receive additional milestone payments or royalties from Kowa. As of the time of the receipt of Kowa's notice to terminate, all remaining variable consideration under the license agreement had been fully constrained and all performance obligations had been satisfied.

Term Loan Facility

On August 7, 2015, we entered into a Loan and Security Agreement (the 2015 Term Loan Facility) pursuant to which we refinanced our then existing term loan facility for an aggregate amount of up to $15.0 million. The first $10.0 million tranche of this loan facility was made available to us immediately upon the closing and was used in part to retire all $4.1 million of our then existing debt outstanding under a prior term loan facility, and to settle accrued interest and closing costs with the lenders. The remaining $5.0 million, referred to as the second tranche, was made available to us until March 31, 2016, for draw down upon the achievement of a specified milestone.

The loan bore interest at 8.77%. We were 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 were payable.

At the closing, 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.

On June 4, 2018, we repaid in full the outstanding balance of the 2015 Term Loan Facility of $4.2 million plus a final fee of $0.7 million and a prepayment penalty of $0.1 million. In conjunction with this prepayment, we recorded a $0.4 million loss on early extinguishment of this debt. As of December 31, 2018, we had no further obligations under the 2015 Term Loan Facility and all warrants previously issued in connection with it had been exercised.

Cash Flows

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

	Year Ended December 31,		
	2018	2017	2016
Net cash used in operating activities	$ (54,936)	$ (19,632)	$ (23,353)
Net cash (used in) provided by investing activities	(54,111)	(67,528)	27,128
Net cash provided by (used in) financing activities	134,988	99,719	(986)
Net increase in cash and cash equivalents	$ 25,941	$ 12,559	$ 2,789

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2018 increased by $35.3 million to $54.9 million as compared to $19.6 million in the prior year. The increase in cash used was primarily due to a $44.9 million increase in our net loss resulting from our expanding drug development activities, offset in part by the collection in 2018 of a $5.0 million milestone payment receivable from Kowa, and to a lesser extent other changes in working capital.

Net cash used in operating activities for the year ended December 31, 2017, decreased by $3.8 million to $19.6 million as compared to $23.4 million in the prior year. Net loss was consistent year over year. The decrease in cash used was primarily due to increases in non-cash expense items such as a $5.8 million increase in expense related to the change in fair value of our common stock warrant liability, and a $2.4 million increase in stock-based compensation expense. The overall decrease in cash used was partially offset by the recognition of a $5.0 million receivable from Kowa and other changes in working capital.

Cash Flows from Investing Activities

Net cash used in investing activities was $54.1 million for the year ended December 31, 2018 compared to $67.5 million for the prior year. The overall decrease in cash used in 2018 was due to a decrease in net purchases of marketable securities as proceeds from our investments increased faster than our purchases.

Net cash used in investing activities was $67.5 million for the year ended December 31, 2017 compared to net cash provided of $27.1 million for the prior year. The overall increase in cash used in 2017 was due to an increase in net purchases of marketable securities, as we invested a portion of the proceeds from our 2017 equity financings.

Cash Flows from Financing Activities

Net cash provided by financing activities was $135.0 million for the year ended December 31, 2018 compared to $99.7 million in the prior year. The increase was primarily due to net proceeds of $135.5 million received from the February 2018 public equity offering compared to net proceeds of $100.4 million in prior year equity offerings.

Net cash provided by financing activities was $99.7 million for the year ended December 31, 2017 compared to net cash used of $1.0 million in the prior year. The increase was due to net proceeds of $100.4 million received from equity offerings in 2017, with no comparable activity in the prior year.

Capital Requirements

We have incurred operating losses since inception and had an accumulated deficit of $523.1 million at December 31, 2018. As of December 31, 2018, we had cash, cash equivalents and marketable securities of approximately $178.7 million, which we believe is sufficient to fund our current operating plan into 2021.

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

Off Balance Sheet Arrangements

As of December 31, 2018, 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 consolidated balance sheets.

Contractual Obligations

The following table summarizes our long-term contractual obligations as of December 31, 2018 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	Years 2-3	Years 4-5	More than 5 years
Operating lease obligations	$ 3,365	$ 628	$ 1,313	$ 1,394	$ 30
Total contractual obligations	$ 3,365	$ 628	$ 1,313	$ 1,394	$ 30

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,

2018, under the terms of our agreements with these organizations, we are obligated to make future payments as services are provided of approximately $51.0 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
Overview

We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates and foreign currency exchange rates. We do not hold or issue financial instruments for trading purposes.

Interest Rate Sensitivity

Our exposure to market risk for changes in interest rates relates primarily to our cash, cash equivalents, and investments. We had cash, cash equivalents, and investments of $178.7 million and $97.2 million as of December 31, 2018 and 2017, respectively. As of December 31, 2018 and 2017 we held our cash, cash equivalents, and investments in marketable securities in deposits, money market funds, corporate debt, commercial paper, asset-backed securities, and U.S. treasury securities. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of the interest rates. Therefore, a portion of our investments in marketable securities may be subject to interest rate risk and could fall in value if market interest rates increase. However, because our investments are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant and a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio as of December 31, 2018 or 2017. We actively monitor changes in interest rates. We do not hold investments for trading purposes.

Foreign Exchange

We conduct our operations primarily in the United States using the U.S. Dollar. However, we conduct limited operations in foreign countries, primarily for clinical and regulatory services, whereby settlement of our obligations are denominated in the local currency. Transactional exposure arises when transactions occur in currencies other than the U.S. Dollar. We record transactions denominated in foreign currencies at the exchange rate prevailing at the date of the transaction with the resulting liabilities being translated into the U.S. Dollar at exchange rates prevailing at the balance sheet date. The resulting gains and losses, which were insignificant for the years ended December 31, 2018, 2017 and 2016, are included in other expense in the consolidated statements of operations and comprehensive loss. We do not use currency forward exchange contracts to offset the related effect on the underlying transactions denominated in foreign currencies.

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 principal 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 principal financial officer have concluded that, as of the end of the period covered by this report, the design and operation of 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 President and Chief Executive Officer and our Vice President, Finance 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 President and Chief Executive Officer and Vice President, Finance, 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). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2018.

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, 2018, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Independent Registered Public Accounting Firm

Our independent registered public accounting firm, Ernst & Young LLP, has audited our Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K and have issued a report on our internal control over financial reporting as of December 31, 2018. Their report on the audit of internal control over financial reporting appears below.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited CymaBay Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, CymaBay Therapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 28, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting
A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting 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 the assets of the company; (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 receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Redwood City, California
February 28, 2019

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 the 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 2019 annual meeting of stockholders, or 2019 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 2019 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 2019 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 2019 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 2019 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 2019 Proxy Statement, which information is hereby incorporated by reference.

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

The information required by this item will be set forth in our 2019 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 2019 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 2019 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 2019 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

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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

The following exhibits are included herein or incorporated herein by reference:

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.
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 10.3 to our Registration Statement on Form 10, filed with the SEC on August 12, 2013, SEC File No. 000-55021.)
10.4*	Amended 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 7, 2018, SEC File No. 001-36500.)
10.5*	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.)
10.6*	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.)
10.7	Form of CymaBay Indemnity Agreement. (Filed with the SEC as Exhibit 10.7 to our Form 10-K, filed with the SEC on March 15, 2018, SEC File No 001-36500.)
10.8#	PPAR-δ 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 8-K, filed with the SEC on January 12, 2018, SEC File No. 001-36500.)

Exhibit No.	Description of Document
10.9	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.)
10.10	First Amendment to Lease, dated April 16, 2018, between CymaBay Therapeutics, Inc. and BMR-Pacific Research Center, LP. (Filed with the SEC as Exhibit 10.1 to our Form 10-Q, filed with the SEC on May 8, 2018, SEC File No. 001-36500.)
10.11*	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.)
10.12*	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.)
10.13*	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.)
10.14*	Offer Letter, dated August 2, 2017, between CymaBay Therapeutics, Inc. and Daniel Menold. (Filed with the SEC as Exhibit 10.4 to our Form 10-Q, filed with the SEC on August 10, 2017, SEC File No. 001-36500.)
10.15*	Offer Letter, dated September 4, 2018, between CymaBay Therapeutics, Inc. and Paul Quinlan. (Filed with the SEC as Exhibit 10.1 to our Form 10-Q, filed with the SEC on November 6, 2018, SEC File No. 001-36500.)
10.16*	Offer Letter, dated September 4, 2018, between CymaBay Therapeutics, Inc. and Klara Dickinson.
10.17*	Non-Employee Director Compensation Program.
10.18*	Compensation Arrangements with certain Executive Officers. (Filed with the SEC under Item 5.02 of our Form 8-K, filed with the SEC on May 3, 2017, SEC File No 001-36500.)
10.19*	Compensation Arrangements with certain Executive Officers. (Filed with the SEC under Item 5.02 of our Form 8-K, filed with the SEC on November 1, 2017, SEC File No 001-36500.)
10.20*	Compensation Arrangements with certain Executive Officers. (Filed with the SEC under Item 5.02 of our Form 8-K, filed with the SEC on February 4, 2019, SEC File No 001-36500.)
21.1	List of subsidiaries of the Registrant.
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 President and Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13-a-14(a) or Rule 15(d)-14(a) of the Exchange Act.
31.2	Certification of Vice President, Finance (Principal Financial Officer) pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act.
32.1	Certification of President and Chief Executive Officer (Principal Executive Officer) and Vice President, Finance (Principal Financial Officer) pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	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.

CymaBay Therapeutics, Inc.
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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CymaBay Therapeutics, Inc. ("the Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated February 28, 2019 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 1994.

Redwood City, California
February 28, 2019

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

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 48,995	$ 23,054
Marketable securities	129,669	74,156
Receivable from collaboration	-	5,000
Prepaid expenses	2,594	1,208
Other current assets	304	126
Total current assets	181,562	103,544
Property and equipment, net	2,905	69
Other assets	2,280	634
Total assets	$ 186,747	$ 104,247
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,973	$ 1,311
Accrued clinical expenses	8,588	2,929
Other accrued liabilities	3,854	2,828
Warrant liability	-	6,091
Facility loan	-	3,108
Accrued interest payable	-	43
Total current liabilities	14,415	16,310
Deferred rent, less current portion	1,914	-
Facility loan, less current portion	-	2,990
Total liabilities	16,329	19,300
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; 59,456,493 and 44,408,796 shares issued and outstanding as of December 31, 2018 and 2017, respectively	6	4
Additional paid-in capital	693,534	535,503
Accumulated other comprehensive loss	(58)	(44)
Accumulated deficit	(523,064)	(450,516)
Total stockholders' equity	170,418	84,947
Total liabilities and stockholders' equity	$ 186,747	$ 104,247

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,		
	2018	2017	2016
Collaboration revenue	$ -	$ 10,000	$ -
Operating expenses:			
Research and development	58,124	18,938	15,941
General and administrative	14,381	12,387	9,645
Total operating expenses	72,505	31,325	25,586
Loss from operations	(72,505)	(21,325)	(25,586)
Other income (expense):			
Interest income	3,988	621	176
Interest expense	(336)	(1,080)	(1,337)
Loss on extinguishment of debt	(407)	-	-
Other (expense) income, net	(3,288)	(5,773)	76
Total other income (expense)	(43)	(6,232)	(1,085)
Net loss	$ (72,548)	$ (27,557)	$ (26,671)
Other comprehensive (loss) income:			
Unrealized (loss) gain on marketable securities	(14)	(43)	20
Other comprehensive (loss) income	(14)	(43)	20
Comprehensive loss	$ (72,562)	$ (27,600)	$ (26,651)
Basic net loss per common share	$ (1.25)	$ (0.79)	$ (1.14)
Diluted net loss per common share	$ (1.26)	$ (0.79)	$ (1.14)
Weighted average common shares outstanding used to calculate basic net loss per common share	57,808,254	34,903,960	23,447,003
Weighted average common shares outstanding used to calculate diluted net loss per common share	57,838,299	34,903,960	23,447,003

See accompanying notes to the consolidated financial statements.

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances as of December 31, 2015	23,447,003	$ 2	$ 424,422	$ (21)	$ (396,288)	$ 28,115
Stock-based compensation 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
Issuance of common stock upon exercise of warrants	99,207	-	1,058	-	-	1,058
Issuance of common stock upon exercise of stock options and incentive awards	607,138	-	2,196	-	-	2,196
Stock-based compensation expense	-	-	4,920	-	-	4,920
Issuance of common stock, net of $7,047 issuance costs	20,255,448	2	100,434	-	-	100,436
Net loss	-	-	-	-	(27,557)	(27,557)
Net unrealized loss on marketable securities	-	-	-	(43)	-	(43)
Balances as of December 31, 2017	44,408,796	4	535,503	(44)	(450,516)	84,947
Issuance of common stock upon exercise of warrants	956,845	-	11,929	-	-	11,929
Issuance of common stock upon exercise of stock options	750,852	-	3,571	-	-	3,571
Stock-based compensation expense	-	-	7,013	-	-	7,013
Issuance of common stock, net of $8,553 issuance costs	13,340,000	2	135,518	-	-	135,520
Net loss	-	-	-	-	(72,548)	(72,548)
Net unrealized loss on marketable securities	-	-	-	(14)	-	(14)
Balances as of December 31, 2018	59,456,493	$ 6	$ 693,534	$ (58)	$ (523,064)	$ 170,418

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,		
	2018	2017	2016
Operating activities			
Net loss	$ (72,548)	$ (27,557)	$ (26,671)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	105	35	29
Stock-based compensation expense	7,013	4,920	2,473
Net accretion and amortization of investments in marketable securities	(1,945)	(199)	125
Non-cash interest associated with debt discount accretion	148	437	476
Loss on extinguishment of debt	407	-	-
Change in fair value of warrant liability	3,710	5,773	(75)
Gain on extinguishment of warrant liability	(422)	-	-
Accretion of tenant improvement allowance	(263)	-	-
Changes in assets and liabilities:			
Receivable from collaboration	5,000	(5,000)	-
Other current assets	(178)	(98)	165
Prepaid expenses	(1,386)	161	(761)
Other assets	(1,646)	120	(13)
Accounts payable	662	412	(109)
Accrued liabilities	6,450	1,387	1,015
Accrued interest payable	(43)	(23)	(7)
Net cash used in operating activities	(54,936)	(19,632)	(23,353)
Investing activities			
Purchases of property and equipment	(529)	(27)	(42)
Purchases of marketable securities	(276,382)	(98,385)	(22,906)
Proceeds from maturities of marketable securities	222,800	30,884	50,076
Net cash (used in) provided by investing activities	(54,111)	(67,528)	27,128
Financing activities			
Proceeds from issuance of common stock, net of issuance costs	135,520	100,436	-
Proceeds from issuance of common stock pursuant to equity award plans	3,571	2,189	-
Proceeds from issuance of common stock upon exercise of warrants	2,550	231	-
Repayment of facility loan principal	(6,527)	(3,137)	(986)
Payment of fees to extinguish facility loan	(126)	-	-
Net cash provided by (used in) financing activities	134,988	99,719	(986)
Net increase in cash and cash equivalents	25,941	12,559	2,789
Cash and cash equivalents at beginning of period	23,054	10,495	7,706
Cash and cash equivalents at end of period	$ 48,995	$ 23,054	$ 10,495
Supplemental disclosure			
Cash paid for interest	$ 231	$ 666	$ 866
Supplemental non-cash investing and financing activities			
Issuance of common stock upon warrant exercises	$ 9,379	$ 827	$ -
Lessor funded lease incentives included in property and equipment	2,256	-	-
Accrued property and equipment	156	-	-
Net change in accrued financing costs	-	(144)	144

See accompanying notes to the consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

CymaBay Therapeutics, Inc. (the Company or CymaBay) is a clinical-stage biopharmaceutical company focused on developing and providing access to innovative therapies for patients with liver and other chronic diseases with high unmet medical need. The Company's key clinical development candidate is seladelpar (MBX-8025). Seladelpar is currently being developed for the treatment of the liver diseases primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (NASH). The Company was incorporated in Delaware in October 1988 as Transtech Corporation. The Company's headquarters and operations are located in Newark, California and it operates in one segment.

Liquidity

The Company has incurred net operating losses and negative cash flows from operations since its inception. During the year ended December 31, 2018, the Company incurred a net loss of $72.5 million and used $54.9 million of cash in operations. At December 31, 2018, the Company had an accumulated deficit of $523.1 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, 2018, the Company had cash, cash equivalents and marketable securities totaling $178.7 million which the Company believes is sufficient to fund the Company's current operating plan into 2021. 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 ongoing Phase 2b clinical trial activities in NASH, and most significantly, the timing and conduct of additional PBC development activities, including an ongoing Phase 2 clinical trial, a Phase 3 clinical trial, and other new drug application (NDA)-enabling studies. The Company has obtained and expects to obtain additional funding to develop its products and fund future operating losses, as appropriate, 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 to the Company, it could have a material adverse effect on the Company's business, results of operations, and financial condition.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

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

These consolidated 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 consolidated financial statements and accompanying notes. Certain reclassifications have been made to the prior period amounts to conform to the current year presentation. "Accrued clinical trial expenses" and "Other accrued liabilities", which previously were reported as "Accrued liabilities" on the consolidated balance sheet, are now reported as separate line items.

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.

Fair Value of Financial Instruments

The Company's financial instruments during the periods reported consist of cash and cash equivalents, marketable securities, accounts receivable, 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, accounts receivable, 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 at December 31, 2017, considering level 2 inputs, approximated 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):

	As of December 31, 2018			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents:				
Money market funds	39,481	-	-	39,481
U.S. and foreign commercial paper	-	6,469	-	6,469
Total cash equivalents	39,481	6,469	-	45,950
Short-term investments:				
U.S. and foreign commercial paper	-	51,627	-	51,627
U.S. and foreign corporate debt securities	-	34,634	-	34,634
Asset-backed securities	-	25,472	-	25,472
U.S. treasury securities	-	17,936	-	17,936
Total short-term investments	-	129,669	-	129,669
Total assets measured at fair value	$ 39,481	$ 136,138	$ —	$ 175,619

	As of December 31, 2017			
	Level 1	Level 2	Level 3	Fair Value
Cash equivalents:				
Money market funds	12,822	-	-	12,822
U.S. commercial paper	-	6,035	-	6,035
Total cash equivalents	12,822	6,035	-	18,857
Short-term investments:				
U.S. and foreign commercial paper	-	35,886	-	35,886
U.S. and foreign corporate debt securities	-	19,760	-	19,760
Asset-backed securities	-	11,060	-	11,060
U.S. treasury securities	-	7,450	-	7,450
Total short-term investments	-	74,156	-	74,156
Total assets measured at fair value	12,822	80,191	-	93,013
Warrant liability	-	-	6,091	6,091
Total liabilities measured at fair value	-	-	6,091	6,091

The Company estimates the fair value of its corporate debt, asset backed securities, and U.S. treasury 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.

Historically, the Company held a Level 3 liability associated with common stock warrants that were issued in connection with the Company's financings completed in September and October 2013, January 2014, and August 2015. The warrants were accounted for as liabilities until either they were exercised or expired in September 2018.

The Company used a binomial option pricing model to value its warrant liabilities prior to September 2017. The inputs for the binomial model are similar to the Black-Scholes model but also incorporate other more complex inputs that, in the Company's case, included the expected timing, probability and valuation impact of certain potential strategic events.

In September 2017, the Company changed its valuation technique and began to value its warrant liability using a Black-Scholes option pricing model, the inputs for which include: exercise price of the warrants, market price of the underlying common shares, dividend yield, expected term, expected volatility, and a risk-free interest rate. Changes to any of these inputs can have a significant impact on the estimated fair value of the warrants.

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

	Year Ended December 31,	
	2018	2017
Balance, beginning of period	$ 6,091	$ 1,145
Change in fair value	3,710	5,773
Settlement of financial instruments	(9,379)	(827)
Extinguishment of financial instruments	(422)	—
Balance, end of period	$ -	$ 6,091

See Note 3 for further discussion regarding the carrying value of the Company's financial instruments.

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, demand money market accounts and commercial paper.

The Company invests excess cash in marketable securities with high credit ratings that are classified in Level 1 and Level 2 of the fair value hierarchy. These securities consist primarily of corporate debt, commercial paper, asset-backed securities, and U.S. treasury securities and are classified as "available-for-sale." The Company considers marketable securities as short-term investments if the maturity date is less than or equal to one year from the balance sheet date. The Company considers marketable securities as long-term investments if the maturity date is in excess of one year of the balance sheet date.

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

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. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and investments and issuers of investments to the extent recorded on the consolidated balance sheets.

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

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 consolidated 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 for the years ended December 31, 2018, 2017 or 2016.

Leases

The Company leases office space under a non-cancelable operating lease agreement and recognizes related rent expense on a straight-line basis over the term of the lease. Incentives granted under the Company's office lease, including allowances for leasehold improvements and rent holidays, are recognized as reductions to rental expense on a straight-line basis over the term of the lease. The Company does not assume renewals in its determination of the lease term unless they are deemed to be reasonably assured at the inception of the lease and begins recognizing rent expense on the date that it obtains the legal right to use and control the leased space. Deferred rent consists of the difference between cash payments and the rent expense recognized.

Revenue Recognition

At the inception of an arrangement, the Company evaluates if a counterparty to a contract is a customer, if the arrangement is within the scope of revenue from contracts with customers guidance, and the term of the contract. The Company recognizes revenue when its customer obtains control of promised goods or services in a contract for an amount that reflects the consideration the Company expects to receive in exchange for those goods or services. For contracts with customers, the Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. As part of the accounting for contracts with customers, the Company must develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. The Company then allocates the total transaction price to each performance obligation based on the estimated standalone selling prices of each performance obligation. The Company recognizes the amount of the transaction price as revenue that is allocated to the respective performance obligation when the performance obligation is satisfied or as it is satisfied. Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon delivery.

The Company enters into collaboration arrangements, under which it licenses certain rights to its intellectual property to third parties. The terms of these agreements may include payment to the Company of one or more of the following: nonrefundable, upfront license fees; development and commercial milestone payments; funding of research and/or development activities; and royalties on net sales of licensed products. Revenues that result from these payments are classified as collaborative revenues except for royalties on net sales of licensed products, which are classified as royalty revenues.

For each collaboration agreement that results in revenues, the Company identifies all material promised goods and services, which may include one or more of the following: a license to intellectual property and know-how, research and development services, and other transition support services. Promised goods or services are considered to be separate performance obligations if they are distinct. To determine the transaction price to be allocated to each performance obligation, in addition to any upfront payment, the Company estimates the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. The Company constrains (reduces) the estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue, deferred revenue, or other amounts will not occur in future reporting periods. When determining if variable consideration should be constrained, management considers whether there are factors outside the Company’s control that increase the likelihood of a significant reversal of previously recognized revenue and revenue-related amounts in future reporting periods. These estimates are re-assessed each reporting period as necessary depending on the facts and circumstances of each contract.

Once the estimated transaction price is established, amounts are allocated to identified performance obligations. The transaction price is generally allocated to each separate performance obligation on a relative standalone selling price (SSP) basis. The Company must develop assumptions that require judgment to determine the SSP to account for these agreements. To determine the SSP the Company’s assumptions may include (i) assumptions regarding the probability of obtaining marketing approval for the drug candidate, (ii) estimates regarding the timing of and the expected costs to develop and commercialize the drug candidate, (iii) estimates of future cash flows from potential product sales with respect to the drug candidate and (iv) appropriate discount and tax rates. SSPs used to perform the initial allocation are not updated after contract inception. The Company does not include a financing component to its estimated transaction price at contract inception unless it estimates that certain performance obligations will not be satisfied within one year.

Upfront License Fees: If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, upfront license fees based on the relative value prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company applies an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Development and Regulatory Milestone Payments: Depending on facts and circumstances, the Company may conclude that it is appropriate to include the milestone in the estimated transaction price using the most likely amount method or that it is appropriate to fully constrain the milestone. A milestone payment is included in the transaction price in the reporting period that the Company concludes that it is probable that recording revenue in the period will not result in a significant reversal in amounts recognized in future periods. The Company may record revenues from certain milestones in a reporting period before the milestone is achieved if the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. The Company records a corresponding contract asset when this conclusion is reached. Until that determination is made, milestone payments that have not been included in the transaction price to date are fully constrained. The Company re-evaluates the probability of achievement of such development milestones and any related constraint each reporting period. The Company adjusts its estimate of the overall transaction price, including the amount of collaborative revenue that it has recorded, if necessary.

Sales-based Milestone and Royalty Payments: The Company's collaborators may be required to pay the Company sales-based milestone payments or royalties on future sales of commercial products. The Company recognizes revenues related to sales-based milestone and royalty payments upon the later to occur of (i) achievement of the collaborator's underlying sales or (ii) satisfaction of any performance obligation(s) related to these sales, in each case assuming the license to the Company's intellectual property is deemed to be the predominant item to which the sales-based milestones and/or royalties relate.

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 risk-free rate. 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

Historically, the Company's outstanding common stock warrants issued in connection with certain equity and debt financings that occurred in 2013 through 2015 were classified as liabilities in the accompanying consolidated balance sheets because of certain contractual terms that preclude equity classification. All outstanding warrants related to these financings had been exercised or had expired by September 30, 2018. Upon expiration, the remaining fair value of the liability was extinguished and credited to other (expense) income, net in the Company's consolidated statement of operations. Prior to expiration, the Company estimated the fair value of common stock warrants at each reporting period until the exercise of the warrants, at which time the liability was revalued and reclassified to stockholders' equity. The determination of fair value of these common stock warrants required management to make certain assumptions regarding subjective input variables such as timing, probability and valuation impact of certain potential strategic events, expected term, dividends, expected volatility and risk-free interest rates.

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 that could affect the amount of tax paid to these jurisdictions.

In December 2017, Securities and Exchange Commission (SEC) staff issued Staff Accounting Bulletin No. 118, *Income Tax Accounting Implications of the Tax Cuts and Jobs Act* (SAB 118) to address the accounting implications of recently enacted U.S. federal tax reform. SAB 118 allows companies to record provisional amounts during a measurement period not to extend beyond one year of the enactment date to address ongoing guidance and tax interpretations that are expected over the next 12 months. The Company has concluded the assessment and no material impacts were noted on its deferred tax assets.

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 consolidated statements of operations and comprehensive loss. There was no interest or penalties related to income tax reserves during the years ended December 31, 2018, 2017 and 2016.

Comprehensive Loss

Comprehensive loss includes net loss and net unrealized gains and losses on marketable securities, which are presented in a single continuous statement. Other comprehensive (loss) gain is also disclosed in the consolidated balance sheets and statements of stockholders' equity in accumulated other comprehensive loss, and is stated net of related tax effects, if any.

Net Loss Per Common Share

Basic net loss per share of common stock is based on the weighted average number of shares of common stock outstanding equivalents during the period. 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,		
	2018	2017	2016
Numerator:			
Net loss allocated to common stock—basic	$ (72,548)	$ (27,557)	$ (26,671)
Adjustment for revaluation and extinguishment of common stock warrants	(422)	-	-
Net loss allocated to common stock—diluted	$ (72,970)	$ (27,557)	$ (26,671)
Denominator:			
Weighted average number of common stock shares outstanding - basic	57,808,254	34,903,960	23,447,003
Dilutive securities:			
Common stock warrants	30,045	-	-
Weighted average number of common stock shares outstanding - diluted	57,838,299	34,903,960	23,447,003
Net loss per share—basic	$ (1.25)	$ (0.79)	$ (1.14)
Net loss per share—diluted	$ (1.26)	$ (0.79)	$ (1.14)

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,		
	2018	2017	2016
Common stock warrants	-	1,461	1,667
Common stock options	5,593	4,356	2,721
Incentive awards	130	130	239
Total	5,723	5,947	4,627

Recently Adopted Accounting Pronouncements

Accounting Standards Update 2014-09

On January 1, 2018, the Company adopted ASU No. 2014-09, *Revenue from Contracts with Customers* (Accounting Standards Codification Topic 606) (ASC 606) using the modified retrospective method applied to those contracts which were not completed as of January 1, 2018. The Company also elected to use the practical expedient that allows an entity to expense the incremental cost of obtaining a contract as an expense when incurred if the amortization period of the asset that an entity otherwise would have recognized is less than one year. Results for the year ended December 31, 2018 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with historic accounting under previous revenue recognition guidance. As of the adoption date, the Company had only one contract with a customer, Kowa Pharmaceuticals America, Inc. (Kowa), that had not been completed. Based on the Company's review, the Company concluded there was no significant change in applying ASC 606 to the contract with Kowa and no amounts have been recognized within "accumulated deficit" in the consolidated balance sheet related to the adoption of the new standard.

Accounting Standards Update 2017-09

In May 2017, the Financial Accounting Standards Board (FASB) issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718) - Scope of Modification Accounting* (ASU 2017- 09). The amendments included in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The amendments in this update will be applied prospectively to an award modified on or after the adoption date. The amendments in ASU 2017-09 became effective for the Company on January 1, 2018 and the adoption of this standard did not have a material impact on the Company's consolidated financial statements.

Accounting Standards Update 2016-15

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230: Classification of Certain Cash Receipts and Cash Payments)* (ASU 2016-15). This guidance addresses specific cash flow issues with the objective of reducing the diversity in practice for the treatment of these issues. The areas identified include: debt prepayment or debt extinguishment costs; settlement of zero-coupon debt instruments; contingent consideration payments made after a business combination; proceeds from the settlement of insurance claims; proceeds from the settlement of corporate-owned life insurance policies; distributions received from equity method investees; beneficial interests in securitization transactions; and application of the predominance principle with respect to separately identifiable cash flows. The Company adopted ASU 2016-15 effective January 1, 2018. The adoption of this accounting standards update did not have a material impact on the Company's consolidated financial statements.

SEC Securities Act Release No. 33-10532

In August 2018, the SEC adopted amendments to certain disclosure requirements in Securities Act Release No. 33-10532, *Disclosure Update and Simplification*. The amendments will become effective on November 5, 2018 and will impact the Company's consolidated financial statements through, among other things, the addition of a requirement for a statement of stockholders' equity for interim periods. The amendments are effective for all filings made on or after November 5, 2018, however a recent SEC staff interpretation allowed companies to file the first interim statement of stockholders' equity in the quarter that begins after the effective date of the amendment. As a result, the Company will present its first interim statement of stockholders' equity in its Form 10-Q for the quarter ending March 31, 2019. Additionally, the guidance also simplified certain non-material disclosures in its 10-K.

Recently Issued Accounting Pronouncements

Accounting Standards Update 2018-15

In August 2018, the FASB issued ASU No. 2018-15, Intangibles (Topic 350): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This new standard also requires customers to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. This ASU is effective for public companies for fiscal years beginning after December 15, 2019. This new standard can be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

Accounting Standards Update 2018-13

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement which modifies the disclosure requirements in Topic 820, Fair Value Measurement, by removing certain disclosure requirements related to the fair value hierarchy, modifying existing disclosure requirements related to measurement uncertainty and adding new disclosure requirements, such as disclosing the changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period and disclosing the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. This ASU is effective for public companies for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. Early adoption is permitted for any removed or modified disclosures. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

Accounting Standards Update 2018-08

In June 2018, the FASB issued ASU No. 2018-08, Not-For-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made, which is intended to clarify and improve the scope and the accounting guidance for contributions received and contributions made. The amendments in ASU No. 2018-08 should assist entities in (1) evaluating whether transactions should be accounted for as contributions (nonreciprocal transaction) within the scope of Topic 958, Not-for-Profit Entities, or as exchange (reciprocal) transactions subject to other guidance and (2) determining whether a contribution is conditional. This amendment applies to all entities that make or receive grants or contributions. This ASU is effective for public companies serving as resource providers for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The Company will adopt this standard on January 1, 2019 and does not expect it will have a material impact on the Company's consolidated financial statements.

Accounting Standards Update 2018-07

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation* (Topic 718). This update is intended to simplify the accounting for share-based payments to non-employees by aligning it with the accounting guidance for share-based payments for employees. The ASU expands the scope of Topic 718, Compensation – Stock Compensation, which currently only includes share-based payments issued to employees, to also include share-based payments issued to non-employees for goods and services. Consequently, the accounting for share-based payments to non-employees and employees will be substantially aligned. This standard will be effective for financial statements issued by public companies for the annual and interim periods beginning after December 15, 2018. Early adoption of the standard is permitted. The Company will adopt this standard on January 1, 2019 and does not expect it will have a material impact on the Company's consolidated financial statements.

Accounting Standards Update 2016-02 and 2018-11

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, the 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 the 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 and entities are required to use a modified retrospective approach for

leases that exist at or are entered into after the beginning of the earliest comparative period in the financial statements. In July 2018, the FASB issued ASU 2018-11, Leases (Topic 842) Targeted Improvements, which provides an additional transition method in which the new lease standard is applied at the adoption date and recognized as a cumulative adjustment to retained earnings without adjustment to comparative periods. The amendments have the same effective date and transition requirements as the new lease standard.

The Company will adopt this standard on January 1, 2019 using the modified retrospective approach with a cumulative effect adjustment to accumulated deficit at the beginning of the period of adoption. The Company will also adopt certain practical expedients provided by ASU 2018-11. The standard will have a material impact due to the recognition of right of use (ROU) assets and lease liabilities on the Company's consolidated balance sheets, but it is not expected to have a material impact on the Company's consolidated income statements. Adoption of the standard will result in the recognition of additional ROU assets and lease liabilities of $0.2 million and $2.5 million, respectively, and the derecognition of the deferred rent balance of $2.3 million as of January 1, 2019.

3. Marketable Securities

Marketable available-for-sale securities as of December 31, 2018 and 2017 consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2018:				
U.S. and foreign commercial paper	$ 51,627	$ -	$ -	$ 51,627
U.S. and foreign corporate debt securities	34,668	-	(34)	34,634
Asset-backed securities	25,494	-	(22)	25,472
U.S. treasury securities	17,938	-	(2)	17,936
	$ 129,727	$ -	$ (58)	$ 129,669

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2017:				
U.S. and foreign commercial paper	$ 35,886	$ -	$ -	$ 35,886
U.S. and foreign corporate debt securities	19,785	-	(25)	19,760
Asset-backed securities	11,070	-	(10)	11,060
U.S. treasury securities	7,459	-	(9)	7,450
	$ 74,200	$ -	$ (44)	$ 74,156

The Company's commercial paper and corporate debt securities consist of U.S. and foreign securities, from issuers in various sectors including finance and industry. The Company's asset-backed securities consist of credit card receivables with investment-grade ratings.

As of December 31, 2018 and 2017, the remaining contractual maturities of the Company's commercial paper, corporate debt securities, asset-backed securities, and U.S. treasury securities were less than 1 year. There were no realized gains and losses for the years ended December 31, 2018, 2017 and 2016. None of these investments have been in a continuous unrealized loss position for more than 12 months as of December 31, 2018 and 2017.

See Note 2 for further information regarding the fair value of the Company's financial statements.

4. Certain Balance Sheet Items

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

	December 31,	
	2018	2017
Leasehold improvements	$ 2,417	$ 65
Office and computer equipment	214	177
Purchased software	44	83
Furniture and fixtures	360	65
Total	3,035	390
Less accumulated depreciation and amortization	(130)	(321)
Property and equipment, net	$ 2,905	$ 69

Other accrued liabilities consist of the following (in thousands):

	December 31,	
	2018	2017
Accrued compensation	$ 2,759	$ 2,416
Accrued professional fees and other	670	399
Deferred rent	425	13
Total other accrued liabilities	$ 3,854	$ 2,828

5. Collaboration and License Agreements

Kowa Pharmaceuticals America, Inc.

On December 30, 2016, the Company entered into a license agreement with 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 upfront payment of $5.0 million upon contract execution. Kowa also agreed to pay the Company $5.0 million upon initiation of a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment, which occurred during the quarter ended December 31, 2017 and payment was received in January 2018. An additional milestone payment of $5.0 million is due on initiation of a Phase 3 study of arhalofenate, and up to $190.0 million based upon the achievement of other specific development and sales milestones.

The Company concluded that Kowa is a customer, and the contract is not subject to accounting literature on collaborative arrangements. This is because the Company granted to Kowa a license to its intellectual property and provided drug product and research and pre-clinical development services, all of which are outputs of the Company's ongoing activities, in exchange for consideration. The Company identified the following three material promises under the license agreement: 1) the transfer of a license to intellectual property, inclusive of the related technology know-how conveyance and contract manufacturing rights and privileges ("license and know-how"); 2) the performance of specific ongoing research and non-clinical development services; and 3) the delivery of existing on hand arhalofenate clinical product. The Company's participation on the JAC is not a performance obligation as the Company's participation in the JAC is not required and is primarily for the Company's benefit to obtain updates on the progress of Kowa's activities. The Company provided to Kowa standard indemnification and protection of licensed intellectual property, which is part of assurance that the license meets the contract's specifications and is not an obligation to provide goods or services.

The Company concluded that the license and know-how, the research and development services, and delivery of arhalofenate product were separate performance obligations since each was identified as a material promise that was by itself distinct. The Company concluded that Kowa can benefit from the license and know-how on its own by developing and commercializing arhalofenate using its own resources, and has the ability to sublicense and manufacture arhalofenate. The research and non-clinical development services promised will not significantly change the intellectual property underlying the license. Further, the Company

believes that Kowa has research and development expertise with compounds similar to those licensed under the agreement. The research and development services and arhalofenate product are not integrated or dependent upon each other and are provided by the Company separately from each other. The licensed intellectual property was considered to be functional as it has significant standalone functionality, and grants Kowa the right to use the Company's intellectual property as it exists on the effective date of the license. Accordingly, license revenue was recognized upon the substantial completion of the license technology transfer during 2017. The research and non-clinical development services are transferred as the services are performed, with cost used as the measure of progress. The arhalofenate product was transferred when Kowa assumed title and control of the inventory stored at the Company's contract manufacturer upon entering into a direct contract with such manufacturer in the fourth quarter of 2017.

To allocate transaction price among the three performance obligations, the Company estimated its SSP. For the license and know-how, the SSP was estimated using the income approach based on assumptions regarding Kowa's future revenues from the licensed intellectual property, projected costs of research and development, manufacturing and commercialization expenses, as well as the discount rate, the development timeline, and probabilities of technical and regulatory success. To estimate SSP of research and non-clinical development services and arhalofenate product on hand, the Company used a cost-plus margin approach. The Company believes that a change in the assumptions used to determine its best estimate of selling price for the performance obligations would not have a significant effect on the allocation of consideration received to the performance obligations.

As of January 1, 2018, the transaction price was limited to $10.0 million, consisting of a $5.0 million upfront fee due upon contract initiation and a $5.0 million development milestone payment triggered when Kowa initiated a study evaluating the pharmacokinetics of arhalofenate in subjects with renal impairment. Of these amounts, the Company allocated $9.5 million to the license; $0.4 million to the arhalofenate product; and $0.1 million to the research and pre-clinical development services. As of January 1, 2018, all these performance obligations had been completed and the associated revenue had been recognized.

The Company expensed the incremental costs of obtaining the Kowa contract prior to December 31, 2017, as substantially all costs related to the performance obligations completed by that date.

Revenue recognized during the year ended December 31, 2017 was determined in accordance with the accounting rules applicable prior to the adoption of ASC 606 on January 1, 2018. There was no difference in the revenue recognized under ASC 606 or legacy GAAP for the year ended December 31, 2018.

There were no contract assets or deferred revenues (contract liabilities) recorded during the year ended December 31, 2018. Accounts receivable from the Kowa contract consisted of the following (in thousands):

	December 31,	
	2018	2017
Accounts Receivable	$ -	$ 5,000

On October 24, 2018, the Company received a notice of Kowa's intent to terminate the license agreement for the development of arhalofenate. The termination will be effective on January 22, 2019. As a result of the termination, the rights licensed to Kowa through the agreement revert to the Company on the termination date and the Company is no longer eligible to receive additional milestone payments or royalties from Kowa. As of the time of the receipt of Kowa's notice to terminate, all remaining variable consideration under the license agreement had been fully constrained and all performance obligations had been satisfied.

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 PPARδ compounds (the PPARδ Products) with Janssen Pharmaceutical NV (Janssen NV), with the right to grant sublicenses to third parties to make, use and sell such PPARδ Products. Under the terms of the agreement, the Company has full control and responsibility over the research, development and registration of any PPARδ Products and is required to use diligent efforts to conduct all such activities. Janssen NV has the sole responsibility for the preparation, filing, prosecution, maintenance of, and defense of the patents with respect to, the PPARδ Products. Janssen NV has a right of first negotiation under the agreement to license PPARδ Products from the Company in the event that the Company elects to seek a third party corporate partner for the research, development, promotion, and/or commercialization of such PPARδ Products. Under the terms of the agreement Janssen NV is entitled to receive up to an 8% royalty on net sales of PPARδ Products. No amounts were incurred or accrued for this agreement as of and for the years ended December 31, 2018, 2017 and 2016.

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 Type 2 diabetes 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. In December 2016, the agreement was amended by the parties to change the timing of a specified development milestone. No development payments were made or due as of and for the years ended December 31, 2018, 2017 and 2016 and no royalties have been paid to date.

6. Facility Loans

On August 7, 2015, the Company entered into a Loan and Security Agreement (the 2015 Term Loan Facility) pursuant to which it refinanced its existing term loan facility for an aggregate amount of up to $15.0 million. The first $10.0 million tranche of this new loan facility was made available to the Company immediately upon the closing and was used in part to retire all $4.1 million of the Company's existing debt outstanding under the prior term loan facility, and to settle accrued interest and closing costs with the lenders. The remaining $5.0 million, referred to as the second tranche, was made available to the Company until March 31, 2016, for draw down upon the achievement of a specified milestone but expired as the second draw milestone was not achieved.

The loan bore interest at 8.77%. The Company was 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 were 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 consolidated balance sheet, to be revalued at each balance sheet date until the warrants were exercised or expire.

On June 4, 2018, the Company repaid in full the outstanding balance of the 2015 Term Loan Facility of $4.2 million plus a final fee of $0.7 million and a prepayment penalty of $0.1 million. In conjunction with this prepayment, the Company recorded a $0.4 million loss on early of extinguishment of this debt. As of December 31, 2018, the Company had no further obligations under the 2015 Term Loan Facility and all warrants previously issued in connection with it had been exercised.

The term loan facility, debt discounts and final payment balances as of December 31, 2018 and 2017 are as follows (in thousands):

	December 31,	
	2018	2017
Principal payments due under the loan facility	$ -	$ 5,877
Less: unamortized debt discount	-	(296)
Plus: accreted value of final payment	-	517
Term loan facility, net	$ -	$ 6,098

7. Commitments and Contingencies

Operating Lease Commitments

Rent expense was $0.3 million for each of the years ended December 31, 2018, 2017 and 2016.

From January 2014 to November 2018, the Company leased 8,894 square feet of office space in Newark, California pursuant to a lease which commenced January 16, 2014 and was set to expire on January 15, 2019.

On April 16, 2018, the Company entered into an amended lease to extend the term of its original lease by five years to January 15, 2024 and relocate and expand its office space within the same office park in Newark, California to approximately 17,698 square feet. The lease agreement includes an escalation clause for increased rent and a renewal provision allowing the Company to extend this lease for an additional five years by giving the landlord written notice of the election to exercise the option prior to the amended expiration date of January 15, 2024. The lease agreement also requires the lessor to fund and complete the construction of certain tenant improvements. These improvements were placed into service on December 1, 2018 and are classified as property and equipment, net on the consolidated balance sheet. The Company estimated the value of these tenant improvements at $2.3 million and also recorded them as a lease incentive within deferred rent on the Company's consolidated balance sheet.

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

	Lease Payments
Year ending December 31:	
2019	$ 628
2020	647
2021	666
2022	687
2023	707
Thereafter	30
Total future minimum lease payments	$ 3,365

Indemnification

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

The Company has agreed to indemnify its 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, 2018 and 2017. 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, 2018 and 2017, respectively. The Company is authorized to issue 100,000,000 shares of common stock as of December 31, 2018 and 2017, respectively.

Common Stock Issuances

On February 7, 2017, pursuant to a shelf registration statement on Form S-3, the Company completed the issuance of 5,181,348 shares of its common stock at $1.93 per share which the Company refers to as the February 2017 public offering. Net proceeds to the Company in connection with the February 2017 public offering were approximately $9.2 million after deducting underwriting discounts, commissions and other offering expenses.

On July 24, 2017, pursuant to a shelf registration statement on Form S-3, the Company completed the issuance of 14,950,000 shares of its common stock at $6.50 per share, which the Company refers to as the July 2017 public offering. Net proceeds to the Company in connection with the July 2017 public offering were approximately $91.1 million after deducting underwriting discounts, commissions and other offering expenses.

On February 1, 2018, pursuant to a new $200 million shelf registration statement on Form S-3, the Company completed the issuance of 13,340,000 shares of its common stock at $10.80 per share, which the Company refers to as the February 2018 public offering. Net proceeds in connection with the February 2018 public offering were approximately $135.5 million after deducting underwriting discounts, commissions and other offering expenses.

On December 28, 2018, the Company filed a new $200 million shelf registration statement on Form S-3 that was declared effective in February 2019. The Company's existing $200 million shelf registration statement was also terminated on the effective date.

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 which precludes them from being indexed to the Company's common stock and also do not meet other criteria for equity classification. 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. Accordingly, the Company recorded the warrants at fair value upon issuance and remeasured them at fair value at each balance sheet date until they were exercised or expired.

As of December 31, 2018 and 2017, the Company's warrants were remeasured using Level 3 inputs involving a Black-Scholes option pricing model, the inputs for which include: the exercise price of the warrants; the market price of the underlying common shares; a risk-free interest rate based on the rates for U.S. treasury zero-coupon bonds with maturities similar to those of the remaining contractual term of the warrants; an assumed dividend yield of zero based on the Company's expectation that it will not pay dividends in the foreseeable future; an expected term based on the remaining contractual term of the warrants; and expected volatility based upon the Company's historical volatility. The significant unobservable input used in measuring the fair value of the common stock warrant liabilities is the expected volatility. Significant increases in volatility would result in a higher fair value measurement.

The resulting increases in warrant liability fair value of $3.7 million and $5.8 million for the years ended December 31, 2018 and 2017, respectively, were recorded as revaluation losses in other (expense) income, net in the Company's consolidated statement of operations and comprehensive loss.

During the year ended December 31, 2018, 443,505 warrants were exercised for cash proceeds of $2.6 million and 938,300 warrants were cashless exercised for 513,340 shares of the Company's common stock. During the year ended December 31, 2017, 40,250 warrants were exercised for cash proceeds of $0.2 million and 166,193 warrants were cashless exercised for 58,957 shares of the Company's common stock.

On September 30, 2018, 79,150 of remaining unexercised warrants expired, resulting in the recognition of a $0.4 million gain on extinguishment of the related warrant liability. As of December 31, 2018, no warrants were outstanding.

Shares of Common Stock Authorized for Issuance

As of December 31, 2018 and 2017, the Company had reserved shares of authorized but unissued common stock as follows:

	December 31,	
	2018	2017
Common stock warrants	-	1,460,955
Equity incentive plan	6,991,570	4,021,983
Total reserved shares of common stock	6,991,570	5,482,938

9. Stock Plan and Stock-Based Compensation

Stock Plan

In September 2013, the Company's stockholders approved the 2013 Equity Incentive Plan (the 2013 Plan), under which shares of common stock are reserved for the granting of incentive stock options, nonqualified 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, 2018, there were 1,268,662 shares available for grant under the 2013 Plan. In accordance with the provisions of the 2013 Plan, the Board of Directors reduced the automatic increase in the share reserve to 2,378,259 shares, which were automatically available for issuance on January 1, 2019.

The following table summarizes activity in the Company's stock option grants, including performance options:

	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, 2017	4,356,441	$ 5.15		
Options granted	2,167,272	11.84		
Options exercised	(750,852)	4.76		
Options forfeited	(179,729)	8.81		
Outstanding as of December 31, 2018	5,593,132	$ 7.68	8.04	$ 11,096
Vested and expected to vest as of December 31, 2018	5,593,132	7.68	8.04	11,096
Exercisable as of December 31, 2018	2,627,819	$ 5.65	7.07	$ 7,799

The total intrinsic value of options exercised was $4.9 million and $2.5 million for the years ended December 31, 2018 and 2017, respectively. No options were exercised during the year ended December 31, 2016.

Vested and Unvested Awards

The total fair value of options vested including performance options, was $7.0 million, $3.9 million, and $2.2 million for the years ended December 31, 2018, 2017 and 2016, respectively.

As of December 31, 2018, unamortized employee and non-employee stock-based compensation expense of $16.6 million is expected to be recognized over a weighted average period of 2.8 years.

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 that must occur before December 31, 2016. In December 2016, the PSOs were modified by extending the term by one month to January 31, 2017.

Upon achievement of the clinical development and capital raising milestones, related expense of $0.2 million was recognized in each of the years ended December 31, 2017 and 2016, respectively. The modification to extend the term of the PSOs did not have a material impact on the Company's consolidated financial statements. There was no expense in 2018 associated with these awards.

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 the Company's stockholders 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 recognized the value of the incentive awards over the remaining four year vesting period which ended in the first quarter of 2018.

The Company recorded an insignificant amount of stock based compensation expense in the year ended December 31, 2018 and $0.3 million of stock based compensation expense in the years ended December 31, 2017 and 2016, respectively, pertaining to its incentive awards. Incentive awards outstanding totaled 129,776 as of December 31, 2018 and 2017, respectively.

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 forty-eight months. The Company granted to these advisors and consultants options to purchase 10,000 and 15,000 shares of common stock, in 2018 and 2017, respectively. As of December 31, 2018, options to purchase 22,793 shares of common stock remained unvested, and under current guidance 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, which was fully vested as of December 31, 2018. The Company recorded $0.1 million of expense in the years ended December 31, 2018 and 2017, respectively, and an insignificant amount in the year ended December 31, 2016, related to these options and awards.

Stock-Based Compensation Expense

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

	Year Ended December 31,		
	2018	2017	2016
Research and development	$ 2,760	$ 1,301	$ 995
General and administrative	4,253	3,619	1,478
Total stock-based compensation expense	$ 7,013	$ 4,920	$ 2,473

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 granted in each of the years presented along with the resulting estimated weighted-average grant date fair values per share:

	Year Ended December 31,		
	2018	2017	2016
Expected term			
Options	6.2 yrs	6.0 yrs	6.1 yrs
Performance options	—	—	5.1 yrs
Expected volatility			
Options	77%	84%	80%
Performance options	—	—	85%
Risk-free interest rate			
Options	2.62%	2.15%	1.57%
Performance options	—	—	1.56%
Expected dividend yield			
Options	—	—	—
Performance options	—	—	—
Weighted-average grant date fair value per share			
Options	$ 8.14	$ 3.36	$ 0.89
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, 2018, 2017 and 2016, 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.

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. As is permitted under the plan, in 2018 the Company elected to match employee contributions up to $750 and accordingly matching contributions totaling an insignificant amount were made in the year ended December 31, 2018. No matching contributions were made in the years ended December 31, 2017 and 2016.

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	
	2018	2017
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 85,571	$ 63,935
Capitalized research and development	10,466	9,455
Federal and state tax credit carryforwards	18,590	13,529
Stock based compensation	2,848	1,493
Other	1,499	438
Total deferred tax assets	118,974	88,850
Deferred tax liabilities:		
Fixed assets	(622)	-
Total deferred tax liabilities	(622)	-
Valuation allowance	(118,352)	(88,850)
Net deferred tax assets	$ -	$ -

On December 22, 2017, the U.S. federal government enacted the Tax Cuts and Jobs Act (Tax Act). The Tax Act contains, among other things, significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% for tax years beginning after December 31, 2017, limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, implementing a territorial tax system, and requiring a mandatory one-time tax on U.S. owned undistributed foreign earnings and profits known as the transition tax.

Pursuant to SAB 118, an entity may select between one of three scenarios to determine a reasonable estimate arising from the Tax Act. The scenarios are (i) a final estimate which effectively closes the measurement window; (ii) a reasonable estimate leaving the measurement window open for future revisions; and (iii) no estimate as the law is still being analyzed. The Company was able to provide a reasonable estimate for the revaluation of deferred taxes. As such, the Company recorded a $38.2 million reduction in deferred tax assets for the revaluation of deferred taxes in 2017 which was offset by a corresponding decrease to the Company's full valuation allowance. The ultimate impact of the Act did not differ materially from provision amounts recorded. Adjustments, if any, would not have impacted the consolidated statement of operations and comprehensive loss due to the full valuation allowance on the Company's 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 $29.5 million during the year ended December 31, 2018 and decreased by $32.7 million during the year ended December 31, 2017, respectively.

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

	December 31		
	2018	2017	2016
Income tax benefit at federal statutory tax rate	$ (15,235)	$ (9,369)	$ (9,068)
Change in valuation allowance	29,501	(32,709)	9,775
Effect of change in enacted tax rates	-	38,194	-
State income taxes, net of federal benefit	(10,112)	5,094	(458)
Permanent items	563	4,027	196
Research credits	(4,717)	(5,237)	(445)
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, 2018 have been adjusted to reflect Section 382 limitations resulting from that change. The Company has been in a net operating loss position since 2008. 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, 2018, the Company has federal net operating loss carryforwards of $332.7 million and state net operating loss carryforwards of $224.8 million to offset future taxable income, if any. In addition, the Company has federal research and development tax credit carryforwards of $8.5 million, federal research and development orphan drug tax credit carryforwards of $11.2 million, and state research and development tax credit carryforwards of $4.5 million. If not utilized, the federal net operating loss and tax credit carryforwards for years beginning before January 1, 2018 will expire beginning in 2024 through 2037 and the state net operating loss carryforwards will expire beginning in 2028 through 2038. Under the Act, federal net operating losses for tax years beginning after January 1, 2018 will be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain to what extent various states will conform to the Act with regard to net operating loss carry forwards. 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, 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
Increases related to prior year tax positions	-
Increases related to 2017 tax positions	1,009
Balances as of December 31, 2017	$ 3,295
Increases related to prior year tax positions	6
Increases related to 2018 tax positions	1,283
Balances as of December 31, 2018	$ 4,584

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 jurisdictions and is not currently under examination by federal, state, or local taxing authorities for any open tax years. Due to net operating loss carryforwards, all years remain open for income tax examination by tax authorities in the U.S. and states in which the Company files tax returns.

12. Selected Quarterly Financial Data (Unaudited)

The following tables present selected quarterly financial data for the years ended December 31, 2018 and 2017 (in thousands, except per share data). This information has been prepared on the same basis as the audited consolidated financial statements and includes all adjustments (consisting only of normal recurring adjustments) necessary to present fairly the unaudited quarterly results of operations set forth herein:

	Quarter Ended			
	March 31	June 30	September 30	December 31
2018				
Collaboration revenue	$ -	$ -	$ -	$ -
Total operating expenses	12,850	17,971	21,129	20,555
Net loss	(17,005)	(17,531)	(18,563)	(19,449)
Basic net loss per common share	(0.32)	(0.30)	(0.31)	(0.32)
Diluted net loss per common share	$ (0.32)	$ (0.30)	$ (0.34)	$ (0.32)

	Quarter Ended			
	March 31	June 30	September 30	December 31
2017				
Collaboration revenue	$ 4,793	$ -	$ -	$ 5,207
Total operating expenses	7,742	7,626	6,394	9,563
Net loss	(5,351)	(8,929)	(8,234)	(5,043)
Basic net loss per common share	(0.20)	(0.31)	(0.21)	(0.11)
Diluted net loss per common share	$ (0.20)	$ (0.31)	$ (0.21)	$ (0.11)

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or Section 15(d) 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

February 28, 2019
Date

/s/ Sujal Shah
Sujal Shah
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Sujal Shah and Daniel Menold, 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/ Sujal Shah Sujal Shah	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 28, 2019
/s/ Daniel Menold Daniel Menold	Vice President, Finance *(Principal Financial Officer)*	February 28, 2019
/s/ Robert J. Wills Robert J. Wills, Ph.D.	Director	February 28, 2019
/s/ Carl Goldfischer Carl Goldfischer, M.D.	Director	February 28, 2019
/s/ Robert Booth Robert Booth, Ph.D.	Director	February 28, 2019
/s/ Kurt von Emster Kurt von Emster, CFA	Director	February 28, 2019
/s/ Caroline Loewy Caroline Loewy	Director	February 28, 2019
/s/ Evan A. Stein Evan A. Stein, M.D., Ph D.	Director	February 28, 2019
/s/ Paul F. Truex Paul F. Truex	Director	February 28, 2019
/s/ Robert J. Weiland Robert J. Weiland	Director	February 28, 2019

September 4, 2018

Klara Dickinson
c/o CymaBay Therapeutics, Inc.
7999 Gateway Blvd., Suite 130
Newark, CA 94560

Dear Klara:

CymaBay Therapeutics, Inc. (the "Company") is pleased to continue your employment as Senior Vice President, Regulatory Affairs and Quality Assurance on the following terms:

1. Position, Duties and Responsibilities. Subject to the terms set forth herein, the Company agrees to employ you in the position of Senior Vice President, Regulatory Affairs and Quality Assurance and you hereby accept such employment effective immediately. You will report to the Company's Chief Executive Officer (the "CEO") and will perform such duties as are assigned to you by the CEO. You will devote your full business time and attention to the business affairs of the Company, except for reasonable vacations and periods of illness or incapacity permitted by the Company's general employment policies. The employment relationship between you and the Company shall also be governed by the general employment policies and practices of the Company, including those relating to protection of confidential information and assignment of inventions, except that when the terms of this letter agreement differ from, or are in conflict with, the Company's general employment policies or practices, this letter agreement shall control. Subject to the other terms of this letter agreement, the Company may change your position, duties, reporting relationship and work location from time to time in its discretion.

2. Compensation and Employee Benefits.

2.1 Base Salary. Your base salary will be three hundred forty thousand two hundred four dollars ($340,204) on an annualized basis, less payroll deductions and required withholdings, paid according to the Company's regular payroll schedule and procedures. Subject to the other terms of this letter agreement, your base salary may be modified by the Company in its sole discretion.

2.2 Discretionary Bonus. You will be eligible to participate in the Company's annual bonus program pursuant to the terms of that program and you will be eligible to receive a bonus of up to thirty-five percent (35%) of your annual base salary. Your actual bonus, if any, will be determined by the Company's Board of Directors (the "Board"), or the Compensation subcommittee thereof, in its sole discretion, based upon its evaluation of your performance, the Company's performance, and any other considerations it deems relevant. You

must be employed through the bonus payment date to be eligible for , and to earn, any such bonus. Bonuses are typically paid within sixty (60) days after the end of the calendar year. Any bonus payment will be subject to payroll deductions and required withholdings.

2.3 Employee Benefits. You will be entitled to all employee benefits, including vacation accrual of twenty (20) days per year and health and disability benefits for which you are eligible under the terms and conditions of the standard Company benefit plans that may be in effect from time to time and provided by the Company to its senior executive-level employees generally. Currently, such benefits include thirteen (13) paid holiday days, as well as paid sick leave of up to ten (10) days per year. Notwithstanding the foregoing, the Company reserves the right to adopt, amend or discontinue any employee benefit plan or policy, including changes required by applicable law.

2.4 Equity Awards. Subject to the approval of the Board, or the Board's Compensation Committee, pursuant to the Company's equity incentive plan, you may from time to time be granted equity awards. Such equity awards will vest as provided by the applicable award agreements as long as you remain in continuous service with the Company and may vest on an accelerated basis pursuant to Articles 6 or 7. Except as provided herein, such equity awards will be subject to the provisions of the equity incentive plan of the Company under which the applicable equity award is granted and the applicable form of equity award agreement thereunder (the "Plan Documents").

3. Other Activities During Employment.

3.1 Activities. Except with the prior written consent of the CEO, you will not, during your employment with the Company, undertake or engage in any other employment, occupation or business enterprise, other than ones in which you are a passive investor. You may engage in civic and not-for-profit activities so long as such activities do not interfere with the performance of your job duties for the Company.

3.2 Investments and Interests. Except as permitted by the first sentence of Section 3.1 and by Section 3.3, during your employment you agree not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by you to be adverse or antagonistic to the Company, or its business or prospects, financial or otherwise.

3.3 Noncompetition. During the term of your employment by the Company, except on behalf of the Company, you will not directly or indirectly, whether as an officer, director, stockholder, partner, proprietor, associate, representative, consultant, or in any capacity whatsoever engage in, become financially interested in, be employed by or have any business connection with any other person, corporation, firm, partnership or other entity whatsoever that competes with the Company anywhere in the world, in any line of business engaged in (or planned to be engaged in) by the Company; *provided, however*, that anything above to the contrary notwithstanding, you may own, as a passive investor, securities of any entity, so long as your direct holdings in any one such corporation do not in the aggregate constitute more than one percent (1%) of the voting stock of such corporation.

4. Company Policies; Confidential Information and Inventions Agreement . You acknowledge your obligations under your Company Employee Agreement on Confidential Information and Inventions. You further acknowledge your obligation to abide by the Company's rules, policies and procedures.

5. Your Representations and Warranties.

5.1 No Breach of Contract . You represent and warrant that the execution and delivery of this letter agreement by you and the performance of your obligations hereunder will not conflict with or breach any agreement, order or decree to which you are a party or by which you are bound. You warrant that you are subject to no employment agreement or restrictive covenant preventing full performance of your duties under this letter agreement.

5.2 No Conflict of Interest . You warrant that you are not, to the best of your knowledge and belief, involved in any situation that might create, or appear to create, a conflict of interest with your loyalty to or duties for the Company.

5.3 Notification of Materials or Documents from Other Employers . You further warrant that you have not brought and will not bring to the Company or use in the performance of your responsibilities at the Company any materials or documents of a former employer that are not generally available to the public, unless you have obtained express written authorization from the former employer for their possession and use.

5.4 Notification of Other Post-Employment Obligations . You also understand that, as part of your employment with the Company, you are not to breach any obligation of confidentiality that you have to former employers, and you agree to honor all such obligations to former employers during your employment with the Company.

6. Termination of Employment.

6.1 At-Will Employment Relationship. Your employment with the Company shall be at-will. Either you or the Company may terminate the employment relationship at any time, with or without Cause, and with or without advance notice.

6.2 Termination for Cause.

(a) Subject to the terms of this Article 6 and to the terms of Article 7, if the Company terminates your employment at any time for Cause (as defined below), your salary shall cease on the date of termination and you shall not be entitled to severance pay, COBRA premium payments, pay in lieu of notice or any other such compensation other than payment of accrued salary and vacation and such other benefits as expressly required by applicable law or the terms of applicable benefit plans. Subject to the terms of this Article 6 and to the terms of Article 7, the continued vesting of any equity awards held by you shall cease on your employment termination date, and your right to exercise vested equity awards shall be governed by the Plan Documents.

(b) Definition of Cause. For purposes of this letter agreement, "Cause" means the occurrence of any one or more of the following: (i) your conviction of, or

plea of no contest, with respect to any felony or any crime involving fraud, dishonesty or moral turpitude; (ii) your participation in a fraud or act of dishonesty that results in material harm to the Company; (iii) your intentional material violation of any contract or agreement between you and the Company, including but not limited to this letter agreement or your Employee Agreement on Confidential Information and Inventions, or your violation of any statutory duty that you owe to the Company, but only if you do not correct any such violation within thirty (30) days after written notice thereof has been provided to you (if such notice is reasonably practicable) ; or (iv) your gross negligence or willful neglect of your job duties, as determined by the Board in good faith, but only if you do not correct such violation within thirty (30) days after written notice thereof has been provided to you (if such notice is reasonably practicable) .

6.3 Severance Benefits for Termination Without Cause or Resignation for Good Reason.

(a) If the Company terminates your employment without Cause and other than as a result of your death or disability, or if you resign your employment for Good Reason (defined below), and provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "Separation from Service"), you will be eligible to receive the severance benefits described in this Section 6.3.

(b) You will be eligible to receive, subject to payroll deductions and required withholdings and net of any amounts earned by you pursuant to any employment or consulting arrangements obtained by you following such termination (other than the activities described in the last sentence of Section 3.1), continuation for twelve (12) months of the greater of your base salary: (i) in effect as of such termination date; or (ii) as set forth in Section 2.1. In addition, you will be eligible to receive your annual discretionary bonus amount at the higher of that (a) in effect as of such termination date; or (b) as set forth in Section 2.2, in either case determined as if all performance targets have been satisfied, pro-rated for the number of months elapsed in the year in which your employment terminates, but in no event will you receive a bonus pro-rated for less than nine (9) months. You agree to notify the Company promptly of any amount earned by you from other employment or a consulting engagement while you are receiving severance payments under this letter agreement.

(c) If you timely elect and remain eligible for continued coverage of your group health insurance under COBRA, the Company will pay your premiums for COBRA coverage for up to twelve (12) months following your Separation from Service, provided that such payments shall cease if you obtain full-time employment, or cease to be eligible for COBRA, within such period. You agree to notify the Company promptly if you obtain full-time employment while the Company is paying your COBRA premiums under this letter agreement. On the 60th day following your Separation from Service, the Company will make the first payment under this clause equal to the aggregate amount of payments that the Company would have paid through such date had such payments commenced on the Separation from Service through such 60th day, with the balance of the payments paid thereafter on the schedule described above. If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the period provided in this clause, you must

immediately notify the Company of such event, and all payments and obligations under this clause will cease.

(d) You will receive acceleration of vesting of all of your then-outstanding and then-unvested equity award grants as of the date of termination as to the number of shares that would have vested in their vesting schedules as if you had been in service for an additional twelve (12) months as of your Separation from Service.

(e) Your receipt of any severance benefits under this Section 6.3 is contingent upon your signing and making effective within sixty (60) days after the termination date, a full, general release of all claims against the Company in a form acceptable to the Company containing the language set forth in the Release Agreement attached as Exhibit A on or after the termination date. The base salary and bonus severance will be paid in substantially equal installments over the twelve (12) month period following your Separation in Service according to the Company's payroll procedures; *provided, however*, that no payments will be made to you prior to the 60th day following your Separation from Service. On the first payroll pay day following the 60th day after your Separation from Service, the Company will pay you the cash severance amounts you would have received on or prior to such date in a lump sum in compliance with Code Section 409A and the effectiveness of the release, with the balance of the cash payments being made as originally scheduled.

(f) **Definition of Good Reason.** For purposes of this letter agreement, "Good Reason" shall mean any one of the following events that occurs without your consent: (i) the material reduction in your responsibilities, authorities or functions as an employee of the Company (but not merely a change in reporting relationships); (ii) a material reduction in your level of compensation (including base salary, fringe benefits and target bonus under any corporate-performance based bonus or incentive programs); (iii) a material change of your place of employment that results in an increase to your round trip commute of more than twenty (20) miles; or (iv) the Company's material breach of this letter agreement. Notwithstanding the foregoing, you must provide written notice to the General Counsel of the Company and the CEO within thirty (30) days after the date on which such event first occurs, and allow the Company thirty (30) days thereafter (the "Cure Period") during which the Company may attempt to rescind or correct the matter giving rise to Good Reason. If the Company does not rescind or correct the conduct giving rise to Good Reason to your reasonable satisfaction by the expiration of the Cure Period, your employment will then terminate with Good Reason as of such thirtieth day.

6.4 **Voluntary or Mutual Termination**. You may voluntarily terminate your employment with the Company at any time without Good Reason. If you terminate without Good Reason or if your employment terminates as a result of your death or disability, your salary shall cease on the date of termination and you shall not be entitled to severance, pay in lieu of notice or any other such compensation other than payment of accrued salary and vacation and such other benefits as expressly required in such event by applicable law or the terms of applicable benefit plans. The continued vesting of any compensatory equity awards held by you shall cease on the termination date, and your right to exercise vested awards (or be issued shares under such vested awards) shall be governed by the terms of the Company's applicable compensatory equity plans and the corresponding award agreements.

6.5 Application of Section 409A. If the Company (or, if applicable, the successor entity thereto) determines that the severance payments and benefits provided for in this letter agreement (the "Agreement Payments") constitute "deferred compensation" under Section 409A of the Internal Revenue Code (together, with any state law of similar effect, "Section 409A") and you are a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) (a "Specified Employee"), then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Agreement Payments shall be delayed as follows: on the earliest to occur of (i) the date that is six months and one day after the termination date or (ii) the date of your death (such earliest date, the "Delayed Initial Payment Date"), the Company (or the successor entity thereto, as applicable) shall (A) pay to you a lump sum amount equal to the sum of the Agreement Payments that you would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the Agreement Payments had not been delayed pursuant to this Section 6.5 and (B) commence paying the balance of the Agreement Payments in accordance with the applicable payment schedules set forth in this letter agreement. For the avoidance of doubt, it is intended that (1) each installment of the Agreement Payments provided in this letter agreement is a separate "payment" for purposes of Section 409A, (2) all Agreement Payments satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under of Treasury Regulation 1.409A-1(b)(4) and 1.409A-1(b)(9)(iii), and (3) the Agreement Payments consisting of COBRA premiums also satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulation 1.409A-1(b)(9)(v).

7. Change in Control.

7.1 Definitions.

(a) "Change in Control" shall mean an Ownership Change Event (as defined below) or a series of related Ownership Change Events (collectively, a "Transaction") wherein the stockholders of the Company immediately before the Transaction do not retain direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding securities of the Company or, in the case of a Transaction described in Section 7.1(b)(iii), the corporation or other business entity to which the assets of the Company were transferred (the "Transferee"), as the case may be. For purposes of the preceding sentence, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities that own the Company or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities.

(b) An "Ownership Change Event" shall be deemed to have occurred if any of the following occurs with respect to the Company: (i) the direct or indirect sale or exchange in a single or series of related transactions by the stockholders of the Company of more than fifty percent (50%) of the voting stock of the Company; (ii) a merger or consolidation in which the Company is a party; or (iii) the sale, exchange or transfer of all or substantially all of the assets of the Company.

7.2 **Severance**. On the consummation of any Change in Control any remaining unvested portion of your equity awards will be accelerated such that fifty percent (50%) of your outstanding and then-unvested equity awards become fully vested and exercisable as of the date of the Change in Control (the "Acceleration"). If on or within twelve (12) months following a Change in Control, the Company or a successor corporation terminates your employment without Cause and other than as a result of your death or disability, or you resign for Good Reason (a "Change in Control Termination"), and provided that such termination constitutes a Separation from Service, then subject to your obligations below, and in lieu of any severance benefits set forth in Section 6.3 herein, you will be entitled to receive (collectively, the "Change in Control Severance Benefits"):

(a) Subject to payroll deductions and required withholdings and net of any amounts earned by you pursuant to any employment or consulting arrangements obtained by you following such termination (other than the activities described in the last sentence of Section 3.1), continuation for twelve (12) months of the greater of your base salary: (i) in effect as of such termination date; or (ii) as set forth in Section 2.1; or (iii) in effect on the date prior to the Change in Control. In addition, you will be eligible to receive one hundred and twenty-five percent (125%) of your annual discretionary bonus amount at the higher of that (a) in effect as of such termination date; (b) as set forth in Section 2.2; or (c) in effect on the date prior to the Change in Control, in any case determined as if all performance targets have been satisfied.

(b) You will receive acceleration of vesting of all of your then-outstanding and then-unvested equity awards as of the date of termination such that the remaining fifty percent (50%) of your unvested equity awards following the Acceleration become fully vested and exercisable.

(c) If you timely elect and remain eligible for continued coverage of your group health insurance under COBRA, the Company will pay your premiums for COBRA coverage for up to fifteen (15) months following your Separation from Service, provided that such payments shall cease if you obtain full-time employment, or cease to be eligible for COBRA, within such period. You agree to notify the Company promptly if you obtain full-time employment while the Company is paying your COBRA premiums under this letter agreement. On the 60th day following your Separation from Service, the Company will make the first payment under this clause equal to the aggregate amount of payments that the Company would have paid through such date had such payments commenced on the Separation from Service through such 60th day, with the balance of the payments paid thereafter on the schedule described above. If you become eligible for coverage under another employer's group health plan or otherwise cease to be eligible for COBRA during the period provided in this clause, you must immediately notify the Company of such event, and all payments and obligations under this clause will cease.

(d) As a precondition of receiving the Change in Control Severance Benefits, you must first sign and make effective on or after the termination date a full, general release of claims against the Company in a form acceptable to the Company containing the language set forth in the Release Agreement attached as Exhibit A.

7.3 **Parachute Payments**.

(a) If any payment or distribution in the nature of compensation (within the meaning of Section 280G(b)(2) of the Code) to you or for your benefit, whether under this letter agreement or otherwise (a "Payment"), would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code of 1986, as amended (the "Code") (together with any interest or penalties imposed with respect to such excise tax, the "Excise Tax"), then you will be entitled to receive from the Company an additional payment (the "Gross-Up Payment") in an amount equal to (i) all Excise Taxes (including any interest or penalties imposed with respect to such taxes) on the Payment (the "First Reimbursement Payment"), (ii) all federal, state and local income taxes and employment taxes on the First Reimbursement Payment, and (iii) all Excise Taxes (including any interest or penalties imposed with respect to such taxes) on the First Reimbursement Payment.

(b) All determinations required to be made under this Section 7.3 including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by the nationally recognized certified public tax accounting firm used by the Company or, if such firm declines to serve, such other nationally recognized certified public tax accounting firm as you may designate (the "Accounting Firm"). The Accounting Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good-faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Accounting Firm shall provide its calculations, together with detailed supporting documentation, to the Company and you within thirty (30) calendar days after the date on which your right to a Payment is triggered (if requested at that time by the Company or you) and/or at such other times as requested by the Company or you. If the Accounting Firm determines that no Excise Tax is payable with respect to a Payment, it shall furnish the Company and you with an opinion reasonably acceptable to you that no Excise Tax will be imposed with respect to such Payment. If the Accounting Firm determines that an Excise Tax is payable with respect to a Payment, it shall furnish to the Company and you an opinion reasonably acceptable to you of the amount of Excise Tax payable with respect to the Payments and the amount of Gross-Up Payment due to you. The Company will pay the Gross-Up Payment to you within thirty (30) days of the date the Company receives the Accounting Firm's opinion, but in no event later than the end of your tax year following your tax year in which you pay the Excise Tax. The Company shall bear all reasonable expenses with respect to the determinations by the Accounting Firm required to be made hereunder. Any determination by the Accounting Firm shall be binding upon the Company and you.

8. General Provisions.

8.1 Dispute Resolution. To aid in the rapid and economical resolution of any disputes that may arise under this letter agreement, the parties agree that any and all claims, disputes or controversies of any nature whatsoever arising from or regarding the interpretation, performance, negotiation, execution, enforcement or breach of this letter agreement, or your relationship with the Company, including statutory claims, shall be resolved by confidential, final and binding arbitration conducted before a single arbitrator with Judicial Arbitration and Mediation Services, Inc. ("JAMS") in San Francisco, California, in accordance with JAMS' then-applicable employment arbitration rules (which may be reviewed at www.jamsadr.com/rules-employment-arbitration/). **The parties acknowledge that by agreeing**

to this arbitration procedure, they waive the right to resolve any such dispute through a trial by jury, judge or administrative proceeding. The parties will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; and (ii) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The Company shall bear all JAMS' arbitration fees and administrative costs in excess of the amount of administrative fees (e.g., filing fees) that you would otherwise be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement shall prevent any party from obtaining injunctive or other provisional relief in court to prevent irreparable harm pending the conclusion of any arbitration proceeding.

8.2 **Severability**. Whenever possible, each provision of this letter agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this letter agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but such invalid, illegal or unenforceable provision will be reformed, construed and enforced in such jurisdiction so as to render it valid, legal, and enforceable consistent with the intent of the parties insofar as possible.

8.3 **Notices**. Any notices provided hereunder must be in writing and shall be deemed effective upon the earlier of personal delivery (including personal delivery by fax) or the next day after sending by overnight courier, to the Company at its primary office location and to you at your address as listed on the Company payroll.

8.4 **Waiver**. If either party should waive any breach of any provisions of this letter agreement, you or the Company shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this letter agreement.

8.5 **Entire Agreement**. This letter agreement, together with its exhibits, constitutes the entire and exclusive agreement between you and the Company, and it supersedes any prior agreement, promise, representation, or statement, written or otherwise, between you and the Company with regard to this subject matter. It is entered into without reliance on any promise, representation, statement or agreement other than those expressly contained or incorporated herein, and it cannot be modified or amended except in a writing signed by you and a duly authorized officer of the Company. This letter supersedes and replaces all of your prior employment offer letter agreements and employment continuation letter agreements with the Company, (including, without limitation, the offer letter agreement dated June 5, 2017) and all amendments thereto, all of which shall have no further force or effect.

8.6 **Counterparts**. This letter agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same agreement.

8.7 **Headings**. The headings of the articles and sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

8.8 **Successors and Assigns**. This letter agreement is intended to bind and inure to the benefit of and be enforceable by you, the Company and your and its respective successors, assigns, heirs, executors and administrators, except that you may not assign any of your duties hereunder and you may not assign any of your rights hereunder without the written consent of the Company.

8.9 **Governing Law**. All questions concerning the construction, validity and interpretation of this letter agreement will be governed by the law of the State of California as applied to contracts made and to be performed entirely within California.

8.10 **Attorneys' Fees**. If either party hereto brings any action to enforce your or its rights hereunder, the prevailing party in such action shall be entitled to be paid by the other party such prevailing party's reasonable attorneys' fees and costs incurred in such action.

To indicate your acceptance of the terms of this letter agreement, please sign this letter agreement in the space provided below and return it to me. If you have any questions regarding this letter agreement, feel free to contact me.

Sincerely,

CymaBay Therapeutics, Inc.

By: /s/ Sujal Shah
Sujal Shah
President and Chief Executive Officer

Accepted and agreed:

/s/ Klara Dickinson
Klara Dickinson

Exhibit A - Release Agreement

Exhibit A

Release Agreement

(To be signed on or after the Separation Date)

I understand that my employment with CymaBay Therapeutics, Inc. (the "Company") terminated effective _____, ____ (the "Separation Date"). The Company has agreed that if I choose to sign this Release Agreement ("Release"), the Company will provide certain severance benefits (minus the required withholdings and deductions) pursuant to the terms of the employment agreement dated _____ (as amended, the "Letter Agreement"). I understand that I am not entitled to such severance benefits unless I sign this Release, and it becomes fully effective.

I understand that this Release, together with the Letter Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company that is not expressly stated therein.

I hereby confirm my obligations under my Employee Agreement on Confidential Information and Inventions with the Company.

I hereby represent that I have been paid all compensation owed and for all hours worked, have received all the leave and leave benefits and protections for which I am eligible, pursuant to the Family and Medical Leave Act or otherwise, and have not suffered any on-the-job injury for which I have not already filed a claim.

In exchange for the consideration provided to me by this Release that I am not otherwise entitled to receive, I hereby generally and completely release Company and its current and former directors, officers, employees, stockholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to my signing this Release. This general release includes, but is not limited to: (a) all claims arising out of or in any way related to my employment with the Company or the termination of that employment; (b) all claims related to my compensation or benefits from the Company, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership interests in the Company; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990, the federal Age Discrimination in Employment Act of 1967 (as amended) ("***ADEA***"), and the California Fair Employment and Housing Act (as amended).

11.

Nothing in this Release shall prevent me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, or the California Department of Fair Employment and Housing, except that I hereby acknowledge and agree that I shall not recover any monetary benefits in connection with any such proceeding.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA ("***ADEA Waiver***"). I also acknowledge that the consideration given for the ADEA Waiver is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) my ADEA Waiver does not apply to any rights or claims that arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release; (c) I have twenty-one (21) days to consider this Release (although I may choose to voluntarily sign it sooner); (d) I have seven (7) days following the date I sign this Release to revoke the ADEA Waiver; and (e) the ADEA Waiver will not be effective until the date upon which the revocation period has expired unexercised, which will be the eighth day after I sign this Release.

I acknowledge that I have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims which the creditor does not know or suspect to exist in his or her favor at the time of executing the release, which if known by him or her must have materially affected his or her settlement with the debtor."** I hereby expressly waive and relinquish all rights and benefits under that section and any law of any jurisdiction of similar effect with respect to my release of any claims hereunder.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than twenty-one (21) days following the date it is provided to me.

I accept and agree to the terms and conditions stated above:

Date Klara Dickinson

Exhibit 10.17

CymaBay Therapeutics, Inc.

Non-Employee Directors Compensation Program

Our Non-Employee Director Compensation Program is 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 $40,000 for such service. The chairperson of our board of directors ("Board") (provided he or she is not an employee) will receive an additional annual base cash retainer of $30,000 for this service. In addition, we intend to compensate the members of our Board for service on our committees as follows:

- The chairperson of our audit committee will receive an annual cash retainer of $20,000 for this service, and each of the other members of the audit committee will receive an annual cash retainer of $10,000.

- The chairperson of our compensation committee will receive an annual cash retainer of $15,000 for such service, and each of the other members of the compensation committee will receive an annual cash retainer of $7,500.

- The chairperson of our nominating and corporate governance committee will receive an annual cash retainer of $10,000 for this service, and each of the other members of the nominating and corporate governance committee will receive an annual cash retainer of $5,000.

Cash payments described above are paid quarterly.

Further, concurrently with the grants under our annual grant program for employees, each non-employee director is expected to be granted an annual equity award valued at approximately $150,000. If a new board member joins our board of directors, the director is expected to be granted an initial equity award valued at approximately $300,000. Annual equity awards and equity awards to new board members will be subject to vesting as determined by our Board or the compensation committee on the date of grant, generally vesting over 12 months for annual grants, and vesting over 36 months for initial grants.

Exhibit 21.1

List of Subsidiaries

Name of Subsidiary	State or Jurisdiction in Which Incorporated or Organized
CymaBay UK, Ltd.	United Kingdom
CymaBay Ireland, Limited	Ireland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

(1) Registration Statement (Form S-3 No. 333-229082) of CymaBay Therapeutics, Inc., and

(2) Registration Statements (Form S-8 Nos. 333-195211, 333-198289, 333-202941, 333-210453, 333-216905, 333-223687, and 333-226741) pertaining to the Metabolex, Inc. 2003 Equity Incentive Plan, and the CymaBay Therapeutics, Inc. 2013 Equity Incentive Plan,

of our reports dated February 28, 2019, with respect to the consolidated financial statements of CymaBay Therapeutics, Inc. and the effectiveness of internal control over financial reporting of CymaBay Therapeutics, inc., included in this Annual Report (Form 10-K) of CymaBay Therapeutics, Inc. for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Redwood City, California
February 28, 2019

Exhibit 31.1

CERTIFICATIONS

I, Sujal Shah, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 28, 2019

/s/ Sujal Shah

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

Exhibit 31.2

CERTIFICATIONS

I, Daniel Menold, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: February 28, 2019

/s/ Daniel Menold

Daniel Menold
Vice President, Finance
(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), Sujal Shah., President and Chief Executive Officer and Daniel Menold, Vice President, Finance of CymaBay Therapeutics, Inc. (the "Company"), hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2018, 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 28th day of February, 2019.

/s/ Sujal Shah	/s/ Daniel Menold
Sujal Shah President and Chief Executive Officer (Principal Executive Officer)	Daniel Menold Vice President, Finance (Principal 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.