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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2019

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**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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 Form10-K or any amendment to this Form10-K. ☒

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 28, 2019, was $ 487,988,477. This excludes 546,232 shares of the registrant's Common Stock held by executive officers, directors and stockholders affiliated with directors outstanding at June 28, 2019. 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 February 29, 2020, was 68,882,459.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2020 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, 2019, 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, 2019

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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 (PPARd), a nuclear receptor that regulates genes directly or indirectly involved in the synthesis of bile acids/sterols, metabolism of lipids and glucose, inflammation and fibrosis. We have been developing seladelpar for the treatment of liver diseases including:

- 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;
- 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; and
- primary sclerosing cholangitis (PSC), a rare, chronic cholestatic liver disease characterized by diffuse inflammation and fibrosis of the intrahepatic and extrahepatic bile ducts.

Key elements of our strategy have been to advance clinical development of seladelpar for patients with PBC, NASH and PSC, to strengthen our patent portfolio and other means of protecting exclusivity, and to evaluate other product candidates.

We reported net losses of approximately $102.8 million, $72.5 million and $27.6 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of December 31, 2019, we had cash equivalents and marketable securities totaling $190.9 million.

Recent Events

In November 2019, we announced the termination of our Phase 2b study of seladelpar in subjects with NASH and our recently initiated Phase 2 study of seladelpar in subjects with PSC. In addition, we placed on hold all studies of seladelpar in subjects with PBC. The decision to halt development of seladelpar was based on initial histological observations in the Phase 2b study of seladelpar in NASH that were observed in the first blinded tranche of liver biopsies in the trial. These observations were characterized by an interface hepatitis presentation, with or without biliary injury. Although these patients had stable or improving biochemical markers of liver disease, the decision to halt development was based on a need to understand the significance of the observations, and possible impact on patients, before dosing additional patients with seladelpar. The U.S. Food and Drug Administration (FDA) agreed with this decision and subsequently placed a formal clinical hold on seladelpar in December 2019. We have since terminated our Phase 3 and other NDA-enabling studies of seladelpar in subjects with PBC.

With the receipt of additional requests from the FDA, we have initiated a series of investigative actions to better understand the baseline characteristics of patients enrolled in our Phase 2b NASH study and the histological observations identified by our study pathologists at the end of treatment.

The investigation includes three activities intended to confirm and subsequently understand the significance of the observations. The first is a comprehensive collection and review of data including patient demographics, medical history, concomitant medications and additional biochemical markers. The second is a blinded, independent review of baseline and end of treatment biopsies by several, experienced liver pathologists. Finally, the third, is a formal pathology and clinical hepatology review panel meeting during which experts will review all information gathered to provide a consensus independent determination of the role of seladelpar in these findings. These activities are essential to our follow-up with the FDA and to determine if there may be a path forward for seladelpar. Following the announcement of the histological observations, we also commenced a process to evaluate all potential ways to maximize stockholder value. This includes a comprehensive evaluation of possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing agreements, dissolution and liquidation of our assets, and/or continuing development of our internal programs.

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 (terminated)	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 (terminated)	52-week study to evaluate safety, tolerability, and effect of seladelpar in patients with NASH (NCT03551522)†
Seladelpar	Primary Sclerosing Cholangitis (PSC)	Phase 2 (terminated)	A 24-week study to evaluate the safety, tolerability, and efficacy of Seladelpar in patients with PSC (NCT04024813)†
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 (discontinued) in type 2 diabetes supported safety and pharmacokinetic profile, currently being explored for other indication(s).

Seladelpar (MBX-8025)

Summary

Seladelpar is a selective agonist for the peroxisome proliferator-activated receptor delta (PPARd). The PPARd 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 (ALP) 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.

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 November 2019, we announced that we were terminating our Phase 2b study of seladelpar in subjects with NASH and our Phase 2 study of seladelpar in patients with PSC and putting ENHANCE, our Phase 3 study of seladelpar in subjects with PBC, on hold. The FDA agreed with this decision and subsequently placed a formal clinical hold on seladelpar in December 2019. We have since terminated our Phase 3 and other NDA-enabling studies of seladelpar in subjects with PBC. The decision to halt development of seladelpar was based on initial histological observations in the Phase 2b study of seladelpar in NASH that were observed in the first tranche of liver biopsies in the trial. These observations were characterized by an interface hepatitis presentation, with or without biliary injury. Although these patients had stable or improving biochemical markers of liver disease, the decision to halt development was based on a need to understand the significance of the observations, and possible impact on patients, before dosing additional patients with seladelpar. We have initiated a series of investigative actions that will involve consultation with independent, third-party experts to better understand the baseline characteristics of patients enrolled in our Phase 2b NASH study and the histological observations identified by our study pathologists at the end of treatment.

Overall, our seladelpar program remains on hold as we continue our investigation of the histological observations and continue our discussions with the FDA.

Target Indications for Seladelpar Clinical

We have been targeting PBC, NASH, and PSC as indications for seladelpar, although our programs for each of these indications are on hold. The following is a short description of each of these target indications.

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 alkaline phosphatase (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, or itching (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. TheFDA-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. Elafibranor (Genfit S.A.) is a mixed PPARa/d agonist in development for patients with PBC. In April 2019, Genfit announced elafibranor had been granted Breakthrough Therapy Designation by the U.S. FDA for the treatment of PBC. In December 2018, Genfit announced positive Phase 2 results from a Phase 2 study evaluating the efficacy and safety of elafibranor (80 mg and 120 mg once-daily) in adult patients with PBC who had an inadequate response to UDCA.

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 265 patients were randomized to receive placebo, 5 mg of seladelpar, or 10 mg of seladelpar. Patients on 5 mg were to 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 was 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 effective measure was to compare response rates of treatment groups to those of the placebo. Key secondary endpoints were to be AP normalization rate and changes in pruritus, as measured by the numerical rating scale, or NRS.

In December 2019, we announced that this trial was being terminated based on initial histological observations in our Phase 2b study of seladelpar in NASH. The FDA subsequently placed a formal clinical hold on development of seladelpar in all indications.

Safety Extension Study

Our long-term safety extension study of seladelpar was open to patients participating in current or future PBC studies in the PBC clinical development program. Patients completing the Phase 2 open label study discussed immediately below began transferring into the long-term safety extension study in December 2017. To date, 54 patients have received seladelpar between 12 and 24 months and 52 patients have received seladelpar between 24 and 36 months. The extension study was discontinued due to the histological observations in the Phase 2b NASH study.

Phase 2 Open Label Study

In December 2016, we initiated a second Phase 2 Low Dose study of seladelpar in patients with PBC. The study was an open label, randomized, dose-ranging study evaluating lower doses of seladelpar and the primary efficacy endpoint percent change in AP from baseline. Secondary outcomes were 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 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.

The study is complete and in the data cleaning phase. 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.

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. In September 2019, Intercept Pharmaceuticals filed a New Drug Application to the U.S. FDA for obeticholic acid in patients with fibrosis due to NASH. 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 Ocaliva®, an FXR-agonist (Intercept Pharmaceuticals), elafibranor (GFT505), a PPARa/d 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 were studied versus placebo in a 2:2:2:1 randomization. The primary efficacy outcome was 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). In June 2019, we announced results from the primary efficacy outcome, which were that treatment with seladelpar resulted in minimal reductions in liver fat that were not significant when compared to placebo. Treatment with seladelpar did, however, result in robust and clinically meaningful reductions in markers associated with liver injury. Alanine aminotransferase (ALT) declined up to 37.5% or 32 U/L in 12 weeks. These reductions in ALT are significantly greater than the 17 U/L threshold that has been correlated with histologic improvement in NASH. Gamma glutamyl transferase (GGT) also decreased significantly, suggesting a reduction in hepatocellular oxidative stress. Significant reductions in alkaline phosphatase (AP) at 12 weeks were observed, supportive of a decrease in hepatocellular bile acids. The marked changes in these liver enzymes collectively suggested the potential to impact ballooning and lobular inflammation, the two key components of NASH resolution. In November 2019, we announced that this trial was

terminated based on initial histological observations. Although these patients had stable or improving biochemical markers of liver disease, FDA placed a clinical hold on dosing additional patients with seladelpar due to the lack of understanding the significance of the observations, and possible impact on patients. We have initiated a series of investigative actions to better understand the histological observations.

In March 2020, we announced additional preliminary data from the terminated Phase 2b study of seladelpar in patients with NASH. For liver tests at 52 weeks, there were 19, 35, 41 and 40 evaluable patients in the placebo, 10, 20 and 50 mg groups, respectively. The corresponding percent changes from baseline at week 52 in ALT were +1.1%, -29.1%, -41.9% and -41.3%. Similarly for AST, relative changes at week 52 were -0.5%, -19.7%, -25.0%, and -16.6% percent for placebo, 10, 20 and 50 mg, respectively. Finally, corresponding changes in GGT were -0.6%, -29.0%, -46.1% and -35.0%. Out of 181 patients enrolled in the study, there were 152 with paired biopsies at entry and end-of-treatment. The number of patients with paired biopsies in the placebo, 10, 20 and 50 mg seladelpar groups were 25, 39, 42 and 46, respectively. The proportion of responders with resolution of NASH with no worsening in fibrosis were 8.0%, 10.3%, 19.0% and 26.1% in the placebo, 10, 20 and 50 mg seladelpar groups, respectively. The corresponding responder rates for at least a one stage improvement in fibrosis with no worsening in NASH were 20.0%, 23.1%, 23.8% and 37.0%. The proportion of patients meeting both endpoints were 8.0%, 5.1%, 11.9% and 19.6% for the placebo, 10, 20 and 50 mg seladelpar groups, respectively.

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.

Primary Sclerosing Cholangitis (PSC)

Summary

Primary Sclerosing Cholangitis (PSC) is a rare, chronic cholestatic liver disease that is characterized by diffuse inflammation and fibrosis of the bile ducts. The disease predominantly affects the medium to large-sized bile ducts inside and outside the liver and is manifested by ongoing ductal destruction leading to cholestasis, advanced fibrosis, and cirrhosis. Disease progression will eventually lead to liver failure with consequent complications such as portal hypertension and increased risk of malignancy, including hepatocellular carcinoma (HCC) and cholangiocarcinoma. Other clinical symptoms of PSC include fatigue and pruritus. Males are affected

twice as often as females and an estimated 70% of PSC patients have concomitant inflammatory bowel disease, particularly ulcerative colitis. There are currently no FDA-approved treatments for PSC. In other clinical studies, seladelpar has demonstrated anti-cholestatic and anti-inflammatory activity, suggesting the potential of seladelpar as a therapeutic option for the treatment of PSC.

Competition/Industry

There are currently no drugs approved in the U.S. or E.U. for the treatment of PSC. However, clinical studies have been completed or are underway with drug candidates that may affect disease outcomes in patients with PSC, including a Phase 2 study with Ocaliva®, an FXR-agonist (Intercept Pharmaceuticals), and other compounds which are in earlier stages of development in PSC.

Studies of Seladelpar in PSC

Phase 2 PSC Study

In June 2019, we initiated a Phase 2 randomized, placebo-controlled, dose-ranging study of seladelpar in patients with PSC that was designed to enroll approximately 100 patients at 60 sites globally. Seladelpar at doses of 5, 10, and 25 mg once daily would have been studied versus placebo in a 1:1:1:1 randomization. The primary efficacy outcome was the relative change in alkaline phosphatase (AP) from baseline at 24 weeks. The study was discontinued due to the histological observations in the Phase 2 NASH study. At the time of study termination, 1 subject, randomized to placebo was enrolled.

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 also have utility in various diseases impacting the gut, liver orgut-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 orgut-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 upfront 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 PPARd compounds (the PPARd Products) with the right to grant sublicenses to third parties to make, use and sell such PPARd Products. Under the terms of the agreement, we have full control and responsibility over the research, development and registration of any PPARd Products and are required to use diligent efforts to conduct all such activities. Janssen NV has the sole responsibility for the preparation, filing, prosecution, maintenance of, and defense of certain patents related to the PPARd Products. Janssen NV has a right of first negotiation under the agreement to license PPARd 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 PPARd Product. Under the terms of the agreement Janssen NV is entitled to receive up to an 8% royalty on net sales of PPARd Products. Under the terms of the agreement, if we do not expend more than a de minimis amount of effort and resources on the research and/or development of at least one PPARd Product, such action would constitute a default under the agreement. In addition, if we fail to use diligent efforts to promote, market and sell any PPARd Product under the agreement, such action would constitute a default under the agreement. In the event of such default, or upon our termination of the agreement, we 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 PPARd compound or PPARd Product and in all patents that are filed during the term of the agreement with a priority date after the effective date of the agreement and relate to a PPARd compound or PPARd Product.

In June 2010, we entered into two development and license agreements with Janssen Pharmaceuticals, Inc. (Janssen), 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 40 United States patents and 190 foreign patents, as well as approximately 10 United States patent applications and 40 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 1 United States patent application, 330 foreign patents and 20 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 PPARd 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 470 issued patents and 70 pending patent applications related to composition and method of use that we believe protect it through at least 2025-2038, 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 have been developing seladelpar for the treatment of patients with PBC, PSC and NASH; competition in these indications is discussed further below.

PBC Competition

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, methotrexate, 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.

Elafibranor (Genfit S.A.) is a mixed PPARa/d agonist in development for patients with PBC. In April 2019, Genfit announced elafibranor had been granted Breakthrough Therapy Designation by the U.S. FDA for the treatment of PBC. In December 2018, Genfit announced positive Phase 2 results from a Phase 2 study evaluating the efficacy and safety of elafibranor (80 mg and 120 mg once-daily) in adult patients with PBC who had an inadequate response to UDCA. 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 dual PPARa/g 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), an FGF-19 variant was also studied in PBC, but the clinical program has been re-focused towards the treatment of NASH.

NASH Competition

There are currently no drugs approved in the U.S. or E.U. for the treatment of NASH. In September 2019, Intercept Pharmaceuticals filed a New Drug Application to the U.S. FDA for obeticholic acid in patients with fibrosis due to NASH. 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 PPARa/d 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.

PSC Competition

There are currently no drugs approved in the U.S. or E.U. for the treatment of PSC. However, clinical studies have been completed or are underway with drug candidates that may affect disease outcomes in patients with PSC, including a Phase 2 study with Ocaliva®, an FXR-agonist (Intercept Pharmaceuticals), and other compounds which are in earlier stages of development in PSC.

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 (IND) application, 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 and it is unclear how these laws 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 December 31, 2019, and March 1, 2020, we had 36 and 24 full-time employees, respectively.

Information about our Executive Officers

As of March 1, 2020, our executive officers and key other officers were as follows:

Name	Age	Position Held With CymaBay
Executive Officers		
Sujal Shah	46	President & Chief Executive Officer
Charles A. McWherter, Ph.D.	64	Chief Scientific Officer
Klara Dickinson	52	Chief Regulatory and Compliance Officer
Daniel Menold	50	Vice President, Finance
Key Other Officers		
Robert L. Martin, Ph D	57	Senior Vice President, Manufacturing and Nonclinical Development
Patrick J. O'Mara	58	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 an MBA from Carnegie Mellon University — Tepper School of Business and M.S. and B.S. degrees in Biomedical Engineering from Northwestern University.

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.

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

Recent clinical setbacks may cause us to liquidate the company.

In November 2019, due to histologic observations in our NASH clinical trial, the NASH and PSC clinical trials and programs were terminated and the PBC program was placed on hold. In December 2019 the PBC clinical trials were terminated, pending further analysis of data from the NASH trial and further discussions with the FDA. This course of action terminated, or put on hold, substantially all of our active development programs. While we have several early stage development programs that are continuing, we are exploring various strategic alternatives, including liquidation, sale, merger, asset acquisitions and/or continuing development of our internal programs. If we are unable to restart clinical development of seladelpar, advance our earlier stage development programs, enter into a strategic transaction or acquire or in-license additional assets, or if we determine such alternatives will not be in the best interests of stockholders, we may choose to liquidate the company. Liquidation would take time and the proceeds of the liquidation are uncertain given the extent to which we may need to follow patients from our terminated clinical trials that may or may not have histologic observations.

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, 2019, we had cash, cash equivalents and marketable securities of approximately $190.9 million. If appropriate opportunities become available, or if we are unable to restart clinical development of seladelpar, advance our earlier stage development programs and/or are unable to enter into a strategic transaction and/or acquire or in-license additional assets, we may need 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.

In the event we do not successfully raise sufficient funds in financing our product development activities or do not have appropriate developmental assets, we will curtail our product development activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether. To the extent that any costs of the ongoing development exceed our current estimates and we are unable to raise sufficient additional capital to cover such additional costs, we will need to reduce operating expenses, sell assets, enter into another strategic transaction, 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.

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;
- the need for additional or expanded clinical studies;
- the rate of progress and cost of our Chemistry, Manufacturing and Control development, registration, validation and commercial programs;
- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining 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.

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 product candidates.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with collaborators, to successfully complete the development of, obtain the necessary regulatory approvals for, and commercialize, product candidates. We do not anticipate generating revenues from sales of our product candidates for the foreseeable future, if ever. Our ability to generate revenues from product sales depends heavily on our success in 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, including whether we will resume development of seladelpar, 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 may seek to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development.

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

If we raise additional funds through collaborations, strategic alliances, 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. 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.

Risks Related to Clinical Development and Regulatory Approval

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

We have not marketed, distributed or sold any products. The success of our business depends upon our ability to develop and commercialize our product candidates. Our lead product candidate, seladelpar, has been placed on clinical hold, pending further analysis of data from the NASH trial and further discussions with the FDA. It is uncertain if seladelpar will be taken off clinical hold or what requirements would need to be satisfied to lift the clinical hold. The success of any product candidate will depend on many factors, including the following:

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

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

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

Before obtaining regulatory approval for the sale of our product candidates, we must 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. For example, in November 2019, due

to histologic observations in our NASH clinical trial, the NASH and PSC clinical trials and programs were terminated and the PBC program was placed on hold. In December 2019, the PBC clinical trials were terminated, pending further analysis of data from the NASH trial and further discussions with the FDA. This course of action terminated, or put on hold, substantially all of our active programs. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

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

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

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

Negative or inconclusive results of our future clinical trials of product candidates could cause the FDA or other regulatory authorities to require that we repeat or conduct additional clinical studies. The histologic observations in our NASH clinical trial may cause the FDA or other regulatory authorities to require additional testing in order to lift the clinical hold on seladelpar. 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 terminated development of seladelpar for all indications. If seladelpar is not taken off clinical hold or does not demonstrate safety or efficacy, or if the benefits of treatment with seladelpar do not outweigh the risks, our ability to successfully develop and commercialize seladelpar will be stopped.

We commenced clinical trials of seladelpar for the indications for PBC, PSC and NASH. In November 2019, due to histologic observations in our NASH clinical trial, the NASH and PSC clinical trials and programs were terminated and the PBC program was placed on hold. In December 2019 the PBC clinical trials were terminated, pending further analysis of data from the NASH trial and further discussions with the FDA. This course of action terminated, or put on hold, substantially all of our active development programs. Seladelpar may not be demonstrated to be effective in these indications or other indications we may target. There is no guarantee that seladelpar will be taken off clinical hold or will prove to be safe or efficacious in the treatment of any disease, or that we will be able to obtain regulatory approval for any indication.

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

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

Events that may result in delays or unsuccessful completion of clinical trials 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-treatmentfollow-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 clinical trials we may undertake for our product candidates is delayed for any of the above reasons, our development costs may increase, the approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced

and our competitors may bring products to market before us. Any of these events could impair our ability to generate revenues from product sales 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 a High Dose Phase 2 clinical study of seladelpar in patients with PBC. During the course of this trial three cases of asymptomatic, reversible transaminase elevations occurred, and we made the decision to discontinue the study early after review of safety and efficacy data demonstrated a need for further dose reduction to optimize clinical safety and efficacy. In November 2019, due to histologic observations in our NASH clinical trial, the NASH and PSC clinical trials were terminated and programs and the PBC program was placed on hold. In December 2019 the PBC clinical trials were terminated, pending further analysis of data from the NASH trial and further discussions with the FDA. This course of action terminated, or put on hold, substantially all of our active development programs. The emergence of adverse events (AEs) and histological observations in a seladelpar clinical trial could prevent us from further developing seladelpar or could result in the denial of regulatory approval.

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

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

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

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 our 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;
- 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, and from time to time receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical study site or in the applicable study may be questioned or jeopardized.

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

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

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

We cannot commercialize our product candidates until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for our product candidates. Additional delays may result if a product candidate is brought before an FDA advisory committee, which could recommend restrictions on approval or recommend non-approval of the product candidate. In addition, we may

experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical studies and the review process. As a result, we cannot predict when, if at all, we will receive any future revenue from commercialization of any of our product candidates. The FDA and foreign regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons, including the following:

- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for any indication;
- regulatory authorities may not find the data from nonclinical studies and clinical studies sufficient or may differ in the interpretation of the data;
- regulatory authorities may require additional nonclinical or clinical studies;
- 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 caution by the FDA and other regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals.

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

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

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with

current Good Manufacturing Practices (cGMP), and adherence to commitments made in the NDA. If we, or a regulatory agency, discover previously unknown problems with a product, such as quality issues or AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

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

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

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our 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 our product candidates in the United States, we may never obtain approval for or commercialize our product candidates outside of the United States, which would limit our ability to realize their full market potential.

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

including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

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 federal Anti-Kickback Statute, the federal False Claims Act, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, the federal false statements statute, the federal transparency requirements under the PPACA, commonly referred to as the Physician Payments Sunshine Act, and analogous state laws and regulations, such as state anti-kickback and false claims laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, exclusion from government funded health care programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to 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. 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. 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 Although the full effect of the PPACA remains uncertain, it appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens

and operating costs. Further, other legislative changes have been adopted since the PPACA was enacted, such as the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012, which have resulted in reduced reimbursement under the Medicare program.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, there have been several recent congressional inquiries, 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. 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 or another regulatory authority may also require inspection and approval of such contract manufacturing facilities. We are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of finished pharmaceutical products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements of safety, purity and potency, we will not be able to secure and/or maintain FDA approval for our product candidates. In addition, we have no direct control over the ability of the contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our contract manufacturers cannot meet FDA standards, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our 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 may enter into commercial agreements with contract manufacturers and with one or more pharmaceutical product packagers/distributors to ensure proper supply chain management once we are authorized to make commercial sales of our product candidates. However, we may be unable to maintain agreements or negotiate commercial supply agreements on commercially reasonable terms with contract manufacturers and pharmaceutical product packagers/distributors, which could delay our ability to launch commercial sales and/or have a material adverse impact upon our business.

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

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

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

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

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

- the inability to meet our product specifications, including product formulation, and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues, including those related toscale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- a failure to comply with cGMP and similar quality standards;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for key materials, such that if we are unable to secure a sufficient supply of these key materials, we will be unable to manufacture and sell our 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 delays in any clinical study we may undertake, failure to obtain regulatory approval or impact our ability to successfully commercialize any product candidates. Some of these events could be the basis for FDA or other regulatory authorities' action, including injunction, recall, seizure, or total or partial suspension of production.

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

If any of our product candidates receive marketing approval, they may nonetheless be unable to gain sufficient market acceptance by physicians, patients, health care payors and others in the medical community. If

these products do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any of our product candidates 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 is approved but does not achieve an adequate level of acceptance by physicians, patients and health care payors, we may not generate sufficient revenue and we may not become or remain profitable.

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

We currently do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved 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.

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 the product, or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring the product to market or generate product revenue.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable.

We will be competing with companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

In addition, there are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product 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 outside the United States, we expect that we will be subject to additional risks related to international operations, including the following:

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

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

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

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

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

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

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

- decreased demand for our 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 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 proprietaryknow-how that is not patentable, processes for which patents are difficult to enforce and other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that such agreements provide adequate protection

and will not be breached, that our trade secrets and other confidential proprietary information will not otherwise be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party re-examination proceedings before the United States Patent and Trademark Office (U.S. PTO) and its foreign counterparts. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we 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 PPARd compounds (the PPARd Products). Under the exclusive license with Janssen NV we have full control and responsibility over the research, development and registration of any PPARd Products and are required to use diligent efforts to conduct all such activities. If we fail to comply with our obligations under our agreement with Janssen NV, including our obligations to expend more than a de minimis amount of effort and resources on the research and/or development of at least one PPARd product, to make any payment called for under the agreement, not to disclose anynon-exempt confidential information related to the agreement, or to use diligent efforts to promote, market and sell any PPARd Product under the agreement, such action would constitute a default under the agreement and Janssen NV may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, including in the case of the Janssen NV license, seladelpar, which would have a materially adverse effect on our business.

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

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

Our business could be negatively affected as a result of stockholder activism, which could cause us to incur significant expense, hinder execution of our business strategy, and impact the trading value of our securities. Stockholder activism, including potential proxy contests, requires significant time and attention by management and the Board, potentially interfering with our ability to execute our strategic plan. Stockholder activism, including a proxy contest, could give rise to perceived uncertainties as to our future direction, adversely affect our relationships with key executives and business partners, and make it more difficult to attract and retain qualified personnel. Also, we may be required to incur significant legal fees and other expenses related to activist stockholder matters. Any of these impacts could materially and adversely affect our business and operating results. Further, the market price of our common stock could be subject to significant fluctuation or otherwise be adversely affected by stockholder activism.

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

We are 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 recently reduced the size of our organization, and we may experience difficulties as a result of this downsizing.

In December 2019 we announced a reduction in workforce of approximately 60% and have proceeded with additional cost cutting measures. This has resulted in a decrease in our managerial, clinical, and operational resources resulting in significant additional responsibilities for our remaining management and employees. We may not be able to effectively manage our downsized operations with the remaining workforce, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of additional employees and reduced productivity among remaining employees. If our management is unable to effectively manage our downsized operations, 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 our downsized operations and 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 is to occur and cause interruptions in our operations or our vendors, it may result in a material disruption of our product development programs and our reputation could be materially damaged. We could also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

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

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. 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.

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

Significant additional capital may be needed in the future to continue our 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. 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 February 29, 2020 was 2,722,567 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. Our office lease for that facility terminates on January 15, 2024 and has 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 February 29, 2020, there were approximately 227 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".

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

Not applicable.

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

Forward-Looking Statements

Some of the statements under in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" are forward-looking statements. These forward-looking statements are based on management's beliefs and assumptions and on information currently available to our management and involve significant elements of subjective judgment and analysis. Words such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "potential," "seek," "target," "goal," "intend," variations of such words, and similar expressions are intended to identify forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed under the caption "Special Note Regarding Forward Looking Statements" and in "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this Annual Report.

Overview

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

Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPARd), a nuclear receptor that regulates genes directly or indirectly involved in the synthesis of bile acids/sterols, metabolism of lipids and glucose, inflammation and fibrosis. We have been 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
- 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
- primary sclerosing cholangitis (PSC), a rare, chronic cholestatic liver disease characterized by diffuse inflammation and fibrosis of the intrahepatic and extrahepatic bile ducts.

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 and completed enrollment in October 2019. 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 our first Phase 2 High Dose and our ongoing second 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)

In February 2019, we completed enrollment of a placebo-controlled Phase 2bproof-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 preclinical studies, 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.

Primary Sclerosing Cholangitis (PSC)

In June 2019, we initiated a Phase 2 randomized, placebo-controlled, dose-ranging study of seladelpar in patients with PSC to enroll approximately 100 patients at 60 sites globally. Seladelpar at doses of 5, 10, and 25 mg once daily will be studied versus placebo in a 1:1:1:1 randomization. The primary efficacy outcome will be the relative change in alkaline phosphatase (AP) from baseline at 24 weeks. At the time of study termination, 1 subject, randomized to placebo was enrolled.

Recent Developments in the Seladelpar Program

In November 2019, we announced that the termination of our Phase 2b study of seladelpar in subjects with NASH and our Phase 2 study of seladelpar in patients with PSC due to histological observations discovered during planned liver biopsies. In December 2019, we announced the termination of our ongoing studies of seladelpar in subjects with PBC. Our overall PBC program remains on hold as we continue our investigation of the histological observations and continue our discussions with the FDA.

We estimate our overall cash burn will be between $30 million and $50 million for the six months ending June 30, 2020. Of this total, we expect between $20 million to $35 million will be used to fund clinical study close-out, patient monitoring, and seladelpar investigation activities.

Strategic Options Review

Following the announcement of the histological observations in our NASH Phase 2 study in November 2019 and the subsequent termination of our ongoing seladelpar clinical trials in November and December 2019, we commenced a process to evaluate strategic alternatives to maximize stockholder value. This includes a comprehensive evaluation of possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing agreements, dissolution and liquidation of our assets, and/or continuing development of our internal programs.

Arhalofenate

Arhalofenate is a dual-acting anti-inflammatory and uric acid lowering agent. 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) as a treatment for gout. Under the terms of the agreement with Kowa, we received an upfront 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.

Restructuring Charges

We recognize restructuring charges related to reorganization plans that have been committed to by us and when liabilities have been incurred. In connection with these activities, we record restructuring charges at fair value for, a) contractual employee termination benefits when obligations are associated to services already rendered, rights to such benefits have vested, and payment of benefits is probable and can be reasonably estimated, b) one-time employee termination benefits when we have committed to a plan of termination, the plan identifies the employees and their expected termination dates, the details of termination benefits are complete, it is unlikely changes to the plan will be made or the plan will be withdrawn and communication to such employees has occurred, and c) contract termination costs when a contract is terminated before the end of its term.

One-time employee termination benefits are recognized in their entirety when communication has occurred and future services are not required. If future services are required, the costs are recorded ratably over the remaining period of service. Contract termination costs to be incurred over the remaining contract term without economic benefit are recorded in their entirety when the contract is canceled.

The recognition of restructuring charges requires us to make certain judgments and estimates regarding the nature, timing and amount of costs associated with the planned reorganization plan. To the extent the actual results differ from its estimates and assumptions, we may be required to revise the estimates of future accrued restructuring liabilities, requiring the recognition of additional restructuring charges or the reduction of accrued restructuring liabilities previously recognized. Such changes to previously estimated amounts may be material to our consolidated financial statements. Changes in the estimates of the restructuring charges are recorded in the period in which the change is determined.

At the end of each reporting period, we evaluate the remaining accrued restructuring balances to ensure that no excess accruals are retained and the utilization of the provisions are for their intended purpose in accordance with developed restructuring plans.

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. Additionally, if expectations change such that we do not expect goods to be delivered or services to be rendered, such prepayments are charged to expense. 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, 2019 and 2018.

Stock-Based Compensation

We measure 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.

Results of Operations

General

To date, we have not generated any income from operations. As of December 31, 2019, we have an accumulated deficit of $625.9 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 a past license arrangement, we will not generate any future revenue from that license agreement. Further, we have terminated all of the clinical trials of seladelpar, and as a result all of our product candidates are at an early stage of development and will require additional work before they can be licensed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate sufficient revenue to achieve and sustain profitability. As stated above, following the announcement of the histological observations in our NASH Phase 2 study in November 2019, we commenced a process to evaluated strategic alternatives to maximize shareholder value. If we are unable to raise additional funds or pursue one or more strategic alternatives, we may continue to reduce our expenditures in order to preserve our cash. Further cost-cutting measures that we may make may not be sufficient to enable us to meet our cash requirements, and they may negatively affect our business and our ability to derive any value from our product candidates. Until we can generate a sufficient amount of product revenue, which we may never do, we will need to finance future cash needs through potential collaborative, partnering or other strategic arrangements, as well as through public or private equity offerings, debt financings or a combination of the foregoing.

The discussion below generally highlights year-to-year comparisons between 2019 and 2018. Discussions of year-to-year comparisons between 2018 and 2017 that are not included in this Annual Report on Form 10-K can be found in "Management's Discussion and Analysis" in Part II Item 7 of our Annual Report on Form 10-K for the fiscal year December 31, 2018, filed with the SEC on February 28, 2019.

Our results of operations for the years ended December 31, 2019 and 2018 are presented below (in thousands):

	Year Ended December 31,		Change
	2019	2018	2019 vs. 2018
Operating expenses:			
Research and development	$ 83,837	$ 58,124	25,713
General and administrative	19,238	14,381	4,857
Restructuring charges	5,075	—	5,075
Total operating expenses	108,150	72,505	35,645
Loss from operations	(108,150)	(72,505)	(35,645)
Other income (expense):			
Interest income, net	5,342	3,652	1,690
Loss on extinguishment of debt	—	(407)	407
Other expense, net	—	(3,288)	3,288
Net loss	$(102,808)	$(72,548)	(30,260)

Operating Expenses

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

	Year Ended December 31,		Change
	2019	2018	2019 vs. 2018
Operating expenses:			
Research and development	$ 83,837	$58,124	25,713
General and administrative	19,238	14,381	4,857
Restructuring charges	5,075	—	5,075
Total operating expenses	$108,150	$72,505	35,645

Research & Development Expenses

Conducting research and development is central to our business model. We expect that our research and development expenses for the year ending December 31, 2020 to be significantly less than prior years due to our decision to terminate all of our ongoing seladelpar-related clinical trials.

For the years ended December 31, 2019 and 2018, research and development expenses were $83.8 million and $58.1 million, respectively, and are detailed in the table below (in thousands):

	Year Ended December 31,		Change
	2019	2018	2019 vs. 2018
Project costs:			
Seladelpar PBC clinical studies	$37,907	$21,009	16,898
Seladelpar NASH clinical studies	10,445	15,614	(5,169)
Seladelpar PSC clinical studies	4,189	—	4,189
Seladelpar drug manufacturing & development	9,235	5,759	3,476
Seladelpar other studies	2,442	1,181	1,261
Non-seladelpar studies	361	184	177
Total project costs	64,579	43,747	20,832
Internal research and development costs	19,258	14,377	4,881
Total research and development	$83,837	$58,124	25,713

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, 2019 and 2018

Total project costs increased by $20.8 million to $64.5 million from $43.7 million for the years ended December 31, 2019 and 2018, respectively. Project costs for the year ended December 31, 2019 primarily consisted of seladelpar-related clinical trial expenses. These increases were driven by ongoing enrollment activities related to our PBC Phase 3 clinical trial, startup activities related to our PSC Phase 2 clinical trial, and other NDA-enabling studies. The increased number and size of our clinical trials and the preparation of registration batches also resulted in higher manufacturing costs to support these activities. The overall increase in project costs was partially offset by decreased costs on our fully enrolled NASH Phase 2b study.

Internal research and development costs increased by $4.9 million to $19.3 million from $14.4 million for the years ended December 31, 2019 and 2018, 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.

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. We expect our general and administrative expenses for the year ending December 31, 2020 to decrease significantly in comparison to prior years due to the reductions in headcount during the fourth quarter of 2019 and the first quarter of 2020.

Comparison of Years Ended December 31, 2019 and 2018

General and administrative expenses increased by $4.8 million to $19.2 million, from $14.4 million, for the years ended December 31, 2019 and 2018, respectively. The increase was driven primarily by higher employee compensation and other administrative expenses incurred to support our expanding operations during 2019.

Restructuring Charges

In December 2019, we announced a restructuring plan to reduce our workforce by approximately 60%. This reduction in workforce was primarily due to results from our Phase 2b clinical trials from our studies of seladelpar in NASH. For the year ended December 31, 2019, we have incurred in aggregate $5.1 million of restructuring charges.

Restructuring charges consist of personnel-related costs, including severance costs, employee-related benefits, supplementalone-time termination payments, and non-cash share-based compensation expense related to the acceleration of stock options. Restructuring charges also includes contract termination costs (including costs to terminate agreements with our contract manufacturers that we had previously contracted with for clinical supplies). In the fourth quarter of 2019, we completed a reduction in force and incurred $5.1 million in restructuring charges. Substantially all of the cash payments are expected to be paid out by the end of 2020.

We may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the workforce reduction. See Note 13 in the consolidated financial statements for more information.

Other Income (Expense)

Interest income, net consists primarily of interest income from our marketable securities offset in part by interest expense related to our loan facility. In connection with the early payoff of our term loan facility in June 2018, we recognized a $0.4 million loss on the extinguishment of debt. Other expense, net consists of gains and losses resulting from the remeasurement of our warrant liabilities at fair value. Other income (expense) is detailed below (in thousands):

	Year Ended December 31,		Change
	2019	2018	2019 vs. 2018
Other income (expense):			
Interest income, net	$5,342	$ 3,652	1,690
Loss on extinguishment of debt	—	(407)	407
Other expense, net	—	(3,288)	3,288
Total other income (expense)	$5,342	$ (43)	5,385

Comparison of Years Ended December 31, 2019 and 2018

Interest income, net increased to $5.3 million from $3.7 million, for the years ended December 31, 2019 and 2018, respectively. The change of $1.6 million was due to higher interest earned on our investments portfolio and the extinguishment of our term loan in the second quarter of 2018.

Other expense, net decreased $3.3 million to none from $3.3 million for the years ended December 31, 2019 and 2018, 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. We had no activity related to warrants in the year ended December 31, 2019.

Income Taxes

As of December 31, 2019, we had federal net operating loss carryforwards of $435.9 million and state net operating loss carryforwards of $224.5 million to offset future taxable income, if any. In addition, we had federal research and development tax credit carryforwards of $9.8 million, federal orphan drug tax credit carryforwards of $18.1 million, and state research and development tax credit carryforwards of $5.3 million. If not utilized, the federal net operating losses for the years beginning before January 1, 2018 of $255.7 million will expire beginning in 2024 through 2037, and the federal net operating losses for the tax years beginning after January 1, 2018 of $180.2 million will be carried forward indefinitely (subject to certain utilization limitations). The state net operating loss carryforwards will expire beginning in 2028 through 2039. The federal research and development and federal orphan drug tax credit carryforwards will expire beginning in 2020 through 2039, and the state tax credit will carry forward indefinitely. Interest and penalties for the years ended December 31, 2019 and 2018 were not material. 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, 2019, we recorded a 100% valuation allowance against our deferred tax assets of approximately $141.9 million, as our management believes it is more likely than not that they will not be fully realized.

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, 2019, cash, cash equivalents and marketable securities totaled $190.9 million, compared to $178.7 million at December 31, 2018. 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

On February 1, 2018, pursuant to our $200.0 million shelf registration statement on FormS-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 $200.0 million shelf registration statement on FormS-3 that was declared effective in February 2019. Our existing $200.0 million shelf registration statement was also terminated on the effective date.

On March 8, 2019, pursuant to a shelf registration statement on FormS-3, we issued 8,000,000 shares of our common stock at $12.50 per share in an underwritten public offering, which we refer to as the March 2019 public offering. On March 11, 2019, the underwriters fully exercised their option to purchase additional shares resulting in the issuance of an additional 1,200,000 shares. Net proceeds from the March 2019 public offering were approximately $107.7 million after deducting underwriting discounts, commissions and other offering expenses.

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 upfront 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.

2015 Term Loan Facility

On August 7, 2015, we entered into a Loan and Security Agreement (the 2015 Term Loan Facility). 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,	
	2019	2018
Net cash used in operating activities	$(97,911)	$(54,936)
Net cash used in investing activities	(34,347)	(54,111)
Net cash provided by financing activities	108,132	134,988
Net (decrease) increase in cash and cash equivalents	$(24,126)	$ 25,941

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 increased by $43.0 million to $97.9 million as compared to $54.9 million in the prior year. The increase in cash used was primarily due to a $30.3 million increase in our net loss resulting from our expanding drug development activities, substantially higher prepayments made to our clinical research organization partners, and other changes in working capital.

Cash Flows from Investing Activities

Net cash used in investing activities was $34.3 million for the year ended December 31, 2019 compared to $54.1 million in the prior year. The overall decrease in cash used in 2019 was due to a decrease in net purchases of marketable securities, as proceeds from our investments increased faster than our purchases.

Cash Flows from Financing Activities

Net cash provided by financing activities was $108.1 million for the year ended December 31, 2019 compared to $135.0 million in the prior year. The decrease was primarily due to net proceeds of $107.7 million received from the March 2019 public equity offering compared to net proceeds of $135.5 million in the prior year equity offering.

Capital Requirements

We have incurred operating losses since inception and had an accumulated deficit of $625.9 million at December 31, 2019. As of December 31, 2019, we had cash, cash equivalents and marketable securities of approximately $190.9 million, which we believe is sufficient to fund our current operating plan into 2021.

As noted above, in November 2019, the Phase 2b study of seladelpar in subjects with NASH and our Phase 2 study of seladelpar in patients with PSC were terminated following the discovery of histological observations during planned liver biopsies. Furthermore, in December 2019, the ongoing studies of seladelpar in subjects with PBC were terminated. To conserve our cash resources, we substantially reduced our workforce in the fourth quarter of 2019. Our overall PBC program remains on hold as we continue our investigation of the histological observations and continue our discussions with the FDA. In addition, following the announcement of the histological observations, we commenced a review of strategic alternatives to maximize stockholder value. This includes a comprehensive evaluation of possible mergers and business combinations, a sale of part or all of our assets, collaboration and licensing agreements, dissolution and liquidation of our assets, and/or continuing development of our internal programs.

Off Balance Sheet Arrangements

As of December 31, 2019, 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.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

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

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

None.

Item 9A. *Controls and Procedures*

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and 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, 2019.

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, 2019, 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, 2019. 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, 2019, 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, 2019, 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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes and our report dated March 16, 2020 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
March 16, 2020

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

None.

PART III

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

The information required by this item is incorporated herein by reference to our proxy statement for our 2020 annual meeting of stockholders, or the 2020 Proxy Statement, provided that if the 2020 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form10-K filed not later than the end of such 120-day period.

Code of Business Conduct

Our Code of Business Conduct and Ethics applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. 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 Form8-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.

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 Form8-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 2020 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 2020 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 2020 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 2020 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 2020 Proxy Statement under the caption “Principal Accountant Fees and Services” in the proposal under the caption “Ratification of Selection of Independent Registered Public Accounting Firm” and is incorporated herein by reference.

PART IV

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

(a) Documents filed as part of this report

1. Financial Statements

2. Financial Statement Schedules

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

(b) List of Exhibits

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.
4.2	Description of Common Stock
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.)

Exhibit No.	Description of Document
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-d 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.)
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. (Filed with the SEC as Exhibit 10.16 to our Form 10-K, filed with the SEC on February 28, 2019, SEC File No. 001-36500.)
10.17*	Non-Employee Director Compensation Program. (Filed with the SEC as Exhibit 10.17 to our Form 10-K, filed with the SEC on February 28, 2019, SEC File No. 001-36500.)
10.18*	Offer letter, dated June 18, 2019, between CymaBay Therapeutics, Inc. and Janet Dorling. (Filed with the SEC as Exhibit 10.1 to our Form 10-Q, filed with the SEC on August 7, 2019, SEC File No. 001-36500.)
21.1	List of subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.

Exhibit No.	Description of Document
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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in exhibit 101)

* 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.
Index to Consolidated Financial Statements

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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, 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, 2019, 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 March 16, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. 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 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 consolidated 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 consolidated 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 consolidated 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 consolidated 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
March 16, 2020

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 24,869	$ 48,995
Marketable securities	166,076	129,669
Accrued interest receivable	687	304
Prepaid research and development expenses	9,910	1,670
Other prepaid expenses	1,381	924
Total current assets	202,923	181,562
Property and equipment, net	2,409	2,905
Operating lease right-of-use assets	235	—
Other assets	160	2,280
Total assets	$ 205,727	$ 186,747
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,503	$ 1,973
Accrued research and development expenses	9,218	8,588
Accrued restructuring	3,193	—
Other accrued liabilities	2,722	3,854
Total current liabilities	17,636	14,415
Long-term portion of operating lease liability	1,743	—
Other liabilities	—	1,914
Total liabilities	19,379	16,329
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value: 100,000,000 shares authorized; 68,882,459 and 59,456,493 shares issued and outstanding as of December 31, 2019 and 2018, respectively	7	6
Additional paid-in capital	812,133	693,534
Accumulated other comprehensive income (loss)	80	(58)
Accumulated deficit	(625,872)	(523,064)
Total stockholders' equity	186,348	170,418
Total liabilities and stockholders' equity	$ 205,727	$ 186,747

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,	
	2019	2018
Operating expenses:		
Research and development	$ 83,837	$ 58,124
General and administrative	19,238	14,381
Restructuring charges	5,075	—
Total operating expenses	108,150	72,505
Loss from operations	(108,150)	(72,505)
Other income (expense):		
Interest income	5,342	3,988
Interest expense	—	(336)
Loss on extinguishment of debt	—	(407)
Other expense, net	—	(3,288)
Total other income (expense)	5,342	(43)
Net loss	$ (102,808)	$ (72,548)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities	138	(14)
Other comprehensive income (loss)	138	(14)
Comprehensive loss	$ (102,670)	$ (72,562)
Basic net loss per common share	$ (1.53)	$ (1.25)
Diluted net loss per common share	$ (1.53)	$ (1.26)
Weighted average common shares outstanding used to calculate basic net loss per common share	67,033,046	57,808,254
Weighted average common shares outstanding used to calculate diluted net loss per common share	67,033,046	57,838,299

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 Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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
Issuance of common stock upon exercise of stock options	225,966	—	386	—	—	386
Stock-based compensation expense	—	—	10,468	—	—	10,468
Issuance of common stock, net of $7,254 issuance costs	9,200,000	1	107,745	—	—	107,746
Net loss	—	—	—	—	(102,808)	(102,808)
Net unrealized gain on marketable securities	—	—	—	138	—	138
Balances as of December 31, 2019	68,882,459	$ 7	$ 812,133	$ 80	$ (625,872)	$ 186,348

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2019	2018
Operating activities		
Net loss	$ (102,808)	$ (72,548)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	572	105
Stock-based compensation expense	9,558	7,013
Accelerated vesting of stock-based compensation expense due to restructuring	910	—
Net accretion and amortization of investments in marketable securities	(2,237)	(1,945)
Non-cash interest associated with debt discount accretion	—	148
Loss on extinguishment of debt	—	407
Change in fair value of warrant liability	—	3,710
Gain on extinguishment of warrant liability	—	(422)
Accretion of tenant improvement allowance	—	(263)
Changes in assets and liabilities:		
Receivable from collaboration	—	5,000
Interest receivable and other current assets	(383)	(178)
Prepaid research and development and other prepaid expenses	(8,697)	(1,386)
Other assets	2,120	(1,646)
Accounts payable	530	662
Accrued restructuring	3,193	—
Accrued liabilities	(669)	6,450
Accrued interest payable	—	(43)
Net cash used in operating activities	(97,911)	(54,936)
Investing activities		
Purchases of property and equipment	(315)	(529)
Purchases of marketable securities	(290,893)	(276,382)
Proceeds from maturities of marketable securities	252,881	222,800
Proceeds from sale of marketable securities	3,980	—
Net cash used in investing activities	(34,347)	(54,111)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	107,746	135,520
Proceeds from issuance of common stock pursuant to equity award plans	386	3,571
Proceeds from issuance of common stock upon exercise of warrants	—	2,550
Repayment of facility loan principal	—	(6,527)
Payment of fees to extinguish facility loan	—	(126)
Net cash provided by financing activities	108,132	134,988
Net (decrease) increase in cash and cash equivalents	(24,126)	25,941
Cash and cash equivalents at beginning of period	48,995	23,054
Cash and cash equivalents at end of period	$ 24,869	$ 48,995
Supplemental disclosures		
Cash paid for amounts included in the measurement of lease liabilities	$ 628	$ —
Cash paid for interest	—	231
Supplemental non-cash investing and financing activities		
Issuance of common stock upon warrant exercises	$ —	$ 9,379
Operating lease right-of-use assets obtained in exchange for lease liabilities	152	—
Lessor funded lease incentives included in property and equipment	—	2,256
Accrued property and equipment	—	156

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), primary sclerosing cholangitis (PSC) 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, 2019, the Company incurred a net loss of $102.8 million and used $97.9 million of cash in operations. At December 31, 2019, the Company had an accumulated deficit of $625.9 million.

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

More recently, in the fourth quarter of 2019, the Company terminated its ongoing clinical trials in PBC, PSC, and NASH and placed the further development of seladelpar on clinical hold pending further investigation and review of certain histological observations seen in NASH patients and pending additional discussions with the FDA. In parallel with this review, the Company also commenced a process to evaluate all potential ways to maximize stockholder value including possible mergers and business combinations, a sale of part or all of the Company's assets, collaboration and licensing agreements, dissolution and liquidation of the Company's assets, and/or continuing development of internal programs.

As of December 31, 2019, the Company had cash, cash equivalents and marketable securities totaling $190.9 million. While the Company completes its clinical review and FDA discussions and evaluates additional ways to maximize shareholder value, cash is considered sufficient to fund the Company's currently scaled-back operating plan into 2021. Once the Company's future business strategy is confirmed, its future liquidity and capital resource needs could be impacted by numerous factors, including but not limited to, funding requirements associated with a merger, collaboration, or licensing arrangement and/or the incurrence of costs associated with the continued development of internal programs as well as costs to wind down current seladelpar clinical trials. The Company has historically obtained and, if needed, expects to obtain additional financing to fund its business strategy through future equity offerings; debt financing; one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights of the Company's product candidates; or a combination of the above. It is unclear if or when any such transactions will occur, on satisfactory terms or at all. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, it could have a material adverse effect on the Company's business, results of operations, and financial condition.

2. Summary of Significant Accounting Policies

Basis of Presentation and Use of Estimates

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

These 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. “Prepaid research and development expenses” and “Other prepaid expenses”, which previously were reported as “Prepaid expenses” 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 a higher level of judgment is involved in determining and in estimating the valuation of stock-based compensation, accrued clinical expenses, restructuring liabilities, 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, and accrued expenses. 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.

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, 2019			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$18,597	$ —	$ —	$ 18,597
Total cash equivalents	18,597	—	—	18,597
Short-term investments:				
U.S. and foreign commercial paper	—	51,102	—	51,102
U.S. and foreign corporate debt securities	—	56,729	—	56,729
Asset-backed securities	—	39,788	—	39,788
U.S. treasury securities	—	18,457	—	18,457
Total short-term investments	—	166,076	—	166,076
Total assets measured at fair value	$18,597	$166,076	$ —	$184,673

	As of December 31, 2018			
	Level 1	Level 2	Level 3	Total
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

The Company estimates the fair value of its money market funds, corporate debt, asset backed securities, commercial paper 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 fair value measurement levels for any 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 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,	
	2019	2018
Balance, beginning of period	$—	$ 6,091
Change in fair value	—	3,710
Settlement of financial instruments	—	(9,379)
Extinguishment of financial instruments	—	(422)
Balance, end of period	$—	$ —

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 withan original 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 toone 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 on the balance sheet. The Company invests cash that is not required for immediate operating needs primarily in highly liquid instruments that bear minimal risk. The Company has established guidelines relating to the quality, diversification, and maturities of securities to enable the Company to manage its credit risk. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash, cash equivalents and investments and issuers of investments to the extent recorded on the 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 an 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 are recorded at cost, less accumulated depreciation and amortization. Depreciation and amortization are calculated using the straight-line method, and the costs are 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.

Long-Lived Assets

The Company reviews the carrying value long-lived assets, includingright-of-use operating lease assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. If a change in circumstance occurs, the Company performs a test of recoverability by comparing the carrying value of the asset or asset group to its undiscounted expected future cash flows. If cash flows cannot be separately and independently identified for a single asset, the Company will determine whether impairment has occurred for the group of assets for which the Company can identify the projected cash flows. If the carrying values are in excess of undiscounted expected future cash flows, the Company measures any impairment by comparing the fair value of the asset or asset group to its carrying value. There were no indicators of impairment of long-lived assets for any periods presented.

Leases

The Company has one lease, a non-cancelable operating lease agreement for its corporate offices. Prior to January 1, 2019, the Company recognized related rent expense on a straight-line basis over the term of the lease. Incentives granted under the Company's facilities lease, including allowances for leasehold improvements and rent holidays, were recognized as reductions to rental expense on a straight-line basis over the term of the lease. Deferred rent consisted of the difference between cash payments and the rent expense recognized.

Subsequent to the adoption of the new leasing standard on January 1, 2019, the Company recognizes a lease asset for its right to use the underlying asset and a lease liability for the corresponding lease obligation. The Company determines whether an arrangement is or contains a lease at contract inception. Operating leases are included in operating lease right-of-use assets, other accrued liabilities, and long-term portion of operating lease liabilities in our consolidated balance sheet at December 31, 2019. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses its incremental borrowing rate based on the information available at the lease commencement date. The incremental borrowing rate represents the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease. The Company considers a lease term to be the noncancelable period that it has the right to use the underlying asset, including any periods where it is reasonably assured the Company will exercise the option to extend the contract. Periods covered by an option to extend are included in the lease term if the lessor controls the exercise of that option.

The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected to not separate lease and non-lease components for its leased assets and accounts for all lease and non-lease components of its agreements as a single lease component.

Research and Development Expenses

Research and development expenses consist of costs incurred in identifying, developing, and testing product candidates. These expenses consist primarily of costs for research and development personnel, including related stock-based compensation; contract research organizations (CRO) and other third parties that assist in managing,

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

The Company records expenses related to clinical studies and manufacturing development activities based on its estimates of the services received and efforts expended pursuant to contracts with multiple CROs and manufacturing vendors that conduct and manage these activities on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment 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.

Restructuring Charges

The Company recognizes restructuring charges related to reorganization plans that have been committed to by management andwhen liabilities have been incurred. In connection with these activities, the Company records restructuring charges at fair value for, a) contractual employee termination benefits when obligations are associated to services already rendered, rights to such benefits have vested, and payment of benefits is probable and can be reasonably estimated, b) one-time employee termination benefits when management has committed to a plan of termination, the plan identifies the employees and their expected termination dates, the details of termination benefits are complete, it is unlikely changes to the plan will be made or the plan will be withdrawn and communication to such employees has occurred, and c) contract termination costs when a contract is terminated before the end of its term.

One-time employee termination benefits are recognized in their entirety when communication has occurred and future services are not required. If

future services are required, the costs are recorded ratably over the remaining period of service. Contract termination costs to be incurred over the remaining contract term without economic benefit are recorded in their entirety when the contract is canceled.

The recognition of restructuring charges requires the Company to make certain judgments and estimates regarding the nature, timing and amount of costs associated with the planned reorganization plan. To the extent the Company's actual results differ from its estimates and assumptions, the Company may be required to revise the estimates of future accrued restructuring liabilities, requiring the recognition of additional restructuring charges or the reduction of accrued restructuring liabilities already recognized. Such changes to previously estimated amounts may be material to the consolidated financial statements. Changes in the estimates of the restructuring charges are recorded in the period the change is determined.

At the end of each reporting period, the Company evaluates the remaining accrued restructuring balances to ensure that no excess accruals are retained, and the utilization of the provisions are for their intended purpose in accordance with developed restructuring plans.

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 has historically been subject to remeasurement at each reporting date as the underlying equity instruments vest and was recognized as an expense over the period during which services are received. Upon the adoption of Accounting Standards Update ("ASU") 2018-07, *Compensation – Stock Compensation* on January 1, 2019, the valuation was fixed at the implementation date and will be recognized as an expense on a straight-line basis over the remaining service period.

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.

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, 2019 or 2018.

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 income (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,	
	2019	**2018**
Numerator:		
Net loss allocated to common stock—basic	$ (102,808)	$ (72,548)
Adjustment for revaluation and extinguishment of common stock warrants	—	(422)
Net loss allocated to common stock—diluted	$ (102,808)	$ (72,970)
Denominator:		
Weighted average number of common stock shares outstanding—basic	67,033,046	57,808,254
Dilutive securities:		
Common stock warrants	—	30,045
Weighted average number of common stock shares outstanding—diluted	67,033,046	57,838,299
Net loss per share—basic	$ (1.53)	$ (1.25)
Net loss per share—diluted	$ (1.53)	$ (1.26)

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,	
	2019	2018
Common stock options	6,727	5,593
Incentive awards	101	130
Total	6,828	5,723

Recently Adopted Accounting Pronouncements

ASU 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 lease liabilities and right-of-use (ROU) assets on the balance sheet arising from lease transactions at the lease commencement date and the disclosure of key information about leasing arrangements. 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-effect adjustment to retained earnings without adjustment to comparative periods. The amendment has the same effective date and transition requirements as the new lease standard.

The Company adopted this standard on January 1, 2019 using the modified retrospective approach and elected the package of practical expedients permitted under transition guidance, which allowed the Company to carry forward its historical assessments of: 1) whether contracts are or contain leases, 2) lease classification and 3) initial direct costs. The Company did not elect the practical expedient allowing the use-of-hindsight which would require the Company to reassess the lease term of its leases based on all facts and circumstances through the effective date and did not elect the practical expedient pertaining to land easements as this is not applicable to the current contract portfolio. The Company elected the post-transition practical expedient to not separate lease components from nonlease components for all existing lease classes. The Company also elected a policy of not recording leases on its condensed consolidated balance sheets when the leases have a term of 12 months or less and the Company is not reasonably certain to elect an option to purchase the leased asset.

The adoption of this standard resulted in the recognition of a ROU asset 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. The adoption of the standard had no impact on the Company's condensed consolidated statements of operations and comprehensive loss or to its cash flows from or used in operating, financing, or investing activities on its condensed consolidated statements of cash flows. No cumulative-effect adjustment within accumulated deficit was required to be recorded as a result of adopting this standard.

ASU 2018-08

On January 1, 2019 the Company adopted ASU No. 2018-08, Not-For-Profit Entities (Topic 958): *Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made* (ASU No. 2018-08), 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 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. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

ASU 2018-07

On January 1, 2019, the Company adopted ASU 2018-07, *Compensation – Stock Compensation* (Topic 718). This update simplifies 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 is substantially aligned. The adoption of this standard did not have a material impact on the Company's condensed consolidated financial statements.

Recently Issued Accounting Pronouncements

ASU 2018-18

In November 2018, the FASB issued ASU 2018-18, Collaborative Arrangements (Topic 808): *Clarifying the Interaction between Topic 808 and Topic 606.* The guidance clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer. The amendment will be effective for the Company on January 1, 2020. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

ASU 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. The amendment will be effective for the Company on January 1, 2020. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

ASU 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. The amendment will be effective for the Company on January 1, 2020. The Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

ASU 2016-13

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326):*Measurement of Credit Losses on Financial Instruments*, an amendment which modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The amendment updates the guidance for measuring and recording credit losses on financial assets measured at amortized cost by replacing the "incurred loss" model with an "expected loss" model. Accordingly, these financial assets will be presented at the net amount expected to be collected. The amendment also requires that credit losses related to available-for-sale debt

securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. In November 2019, FASB issued ASU No. 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842)*, which deferred the adoption deadline for smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted and entities are required to use a modified retrospective approach, with certain exceptions. The Company intends to adopt the standard on January 1, 2023 and will assess potential effects of the guidance prior to the adoption date.

3. Marketable Securities

Marketable available-for-sale securities as of December 31, 2019 and 2018 consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2019:				
Cash equivalents:				
Money market funds	$ 18,597	$ —	$ —	$ 18,597
U.S. and foreign commercial paper	—	—	—	—
Total cash equivalents	18,597	—	—	18,597
Short-term investments:				
U.S. and foreign commercial paper	51,102	—	—	51,102
U.S. and foreign corporate debt securities	56,691	38	—	56,729
Asset-backed securities	39,756	33	—	39,789
U.S. treasury securities	18,447	9	—	18,456
Total short-term investments	165,996	80	—	166,076
Total marketable securities	$184,593	$ 80	$ —	$184,673

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2018:				
Cash equivalents:				
Money market funds	$ 39,481	$ —	$ —	$ 39,481
U.S. and foreign commercial paper	6,469	—	—	6,469
Total cash equivalents	45,950	—	—	45,950
Short-term investments:				
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
Total short-term investments	129,727	—	(58)	129,669
Total marketable securities	$179,677	$ —	$ (58)	$175,619

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 are collateralized by credit card receivables and have investment-grade ratings.

As of December 31, 2019 and 2018, 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, 2019 and 2018.None of these investments have been in a continuous unrealized loss position for more than 12 months as of December 31, 2019 and 2018.

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

4. Certain Balance Sheet Items

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

	December 31,	
	2019	2018
Leasehold improvements	$2,430	$2,417
Office and computer equipment	290	214
Purchased software	44	44
Furniture and fixtures	430	360
Total	3,194	3,035
Less accumulated depreciation and amortization	(785)	(130)
Property and equipment, net	$2,409	$2,905

Depreciation expense for the years ended December 31, 2019 and 2018 was approximately $0.8 million and $0.1 million, respectively, and was recorded in both research and development expense and general and administrative expense in the consolidated statements of operations and comprehensive loss.

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

	December 31,	
	2019	2018
Accrued compensation	$2,013	$2,759
Operating lease liability	407	—
Accrued professional fees and other	302	670
Deferred rent	—	425
Other accrued liabilities	$2,722	$3,854

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. 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. Additional payments of up to $195.0 million could have been earned based upon the achievement of other specific development and sales milestones.

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 was 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 PPARd compounds (the PPARd Products) with Janssen Pharmaceutical NV (Janssen NV), with the right to grant sublicenses to third parties to make, use and sell such PPARd Products. Under the terms of the agreement, the Company has full control and responsibility over the research, development and registration of any PPARd Products and is required to use diligent efforts to conduct all such activities. Janssen NV has the sole responsibility for the preparation, filing, prosecution, maintenance of, and defense of the patents with respect to, the PPARd Products. Janssen NV has a right of first negotiation under the agreement to license PPARd 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 PPARd Products. Under the terms of the agreement Janssen NV is entitled to receive up to an 8% royalty on net sales of PPARd Products. No amounts were incurred or accrued for this agreement as of and for the years ended December 31, 2019 and 2018.

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, 2019 and 2018 and no royalties have been paid to date.

6. Term Loan

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. 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.

7. Commitments and Contingencies

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, 2019 and 2018. 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. Leases

The Company has one operating lease pertaining to 17,698 square feet of corporate office space in Newark, California pursuant to a lease agreement that commenced January 16, 2014 and was amended on April 16, 2018. At December 31, 2019 the Company's lease portfolio had a weighted average remaining term of 4.1 years, with an option to extend for an additional 5 years. The lease requires monthly lease payments that are subject to annual increases throughout the lease term. The optional period has not been considered in the determination of the right-of-use assets or lease liabilities associated with this lease as the Company did not consider it reasonably certain it would exercise the option.

The Company cannot determine the implicit rate in its lease, and therefore the Company uses its incremental borrowing rate as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment. The Company used an incremental borrowing rate as of the date of adoption for leases that commenced prior to January 1, 2019. The weighted average discount rate for the Company's lease portfolio at December 31, 2019 was 12.6%.

For the years ended December 31, 2019 and 2018, the Company incurred $0.5 million and $0.4 million, respectively, of lease costs included in operating expenses in the condensed consolidated statements of income and comprehensive income in relation to its operating lease, a portion of which was variable rent expense and not included within the measurement of the Company's operating ROU assets and lease liabilities. The variable rent expense consists primarily of the Company's proportionate share of operating expenses, property taxes, and insurance and is classified as lease expense due to the Company's election to not separate lease and non-lease components. Short-term lease costs were not material. At December 31, 2019, the Company's operating lease right-of-use asset totaled $0.2 million, and the operating lease liability totaled $2.1 million. The short-term portion of the operating lease liability was $0.4 million and is contained within other accrued liabilities on the balance sheet, with the remaining $1.7 million liability reported on the balance sheet as long-term portion of operating lease liability.

As of December 31, 2019, the maturities of the Company's operating lease liabilities were as follows (in thousands):

	Operating Leases
Year ending December 31,	
2020	647
2021	667
2022	686
2023	707
2024	30
Total undiscounted future minimum lease payments	$ 2,737
Less: Imputed interest	587
Total operating lease liability	$ 2,150
Less: Current portion of operating lease liability (included in other accrued liabilities)	407
Long-term portion of operating lease liability	$ 1,743

9. Stockholders' Equity

The Company is authorized to issue 10,000,000 shares of preferred stock as of December 31, 2019 and 2018, respectively. The Company is authorized to issue 100,000,000 shares of common stock as of December 31, 2019 and 2018, respectively.

As of December 31, 2019 and 2018, the Company had reserved shares of authorized but unissued common stock as follows:

	December 31,	
	2019	2018
Equity incentive plan	9,143,863	6,991,570
Total reserved shares of common stock	9,143,863	6,991,570

Sale of Common Stock

On February 1, 2018, pursuant to a $200.0 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 $200.0 million shelf registration statement on Form S-3 that was declared effective in February 2019. The Company's existing $200.0 million shelf registration statement was also terminated on the effective date.

On March 8, 2019, pursuant to a shelf registration statement on Form S-3, the Company issued 8,000,000 shares of its common stock at $12.50 per share in an underwritten public offering (referred to as the March 2019 public offering). On March 11, 2019, the underwriters fully exercised their option to purchase additional shares resulting in the issuance of an additional 1,200,000 shares. Net proceeds to the Company from the March 2019 public offering were approximately $107.7 million after deducting underwriting discounts, commissions and other offering expenses.

Common Stock Warrants

In connection with a 2013 financing and the Company's private placement ofcommon 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. Finally, 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.

During the year ended December 31, 2018, 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 increase in warrant liability fair value of $3.7 million for the year ended December 31, 2018 was 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.

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, 2019 and 2018, no warrants were outstanding.

10. 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 afour 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, 2019, there were 2,315,727 shares available for grant under the 2013 Plan. In accordance with the provisions of the 2013 Plan, the Board of Directors reduced the automatic share increase in the share reserve on January 1, 2020 to zero shares.

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, 2018	5,593,132	$ 7.68		
Options granted	2,775,360	8.25		
Options exercised	(223,631)	1.67		
Options forfeited	(1,127,078)	8.63		
Options expired	(291,088)	9.42		
Outstanding as of December 31, 2019	6,726,695	$ 7.88	$ 7.39	$ 369
Vested and expected to vest as of December 31, 2019	6,726,695	7.88	7.39	$ 369
Exercisable as of December 31, 2019	3,769,835	$ 6.87	$ 6.47	$ 328

The total intrinsic value of options exercised was $0.4 million and $4.9 million, for the years ended December 31, 2019 and 2018, respectively.

Vested and Unvested Awards

The total fair value of options vested was $9.9 million and $7.0 million for the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, unamortized employee and non-employee stock-based compensation expense of $15.0 million is expected to be recognized over a weighted average period of 2.4 years.

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 no stock-based compensation expense in the year ended December 31, 2019 pertaining to its incentive awards and an insignificant amount in the year ended December 31, 2018. Incentive awards outstanding totaled 101,441 and 129,776 as of December 31, 2019 and 2018, 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. No options were granted to these advisors and consultants in 2019 and the Company granted options to purchase 10,000 shares of common stock in 2018. As of December 31, 2019, options to purchase 9,646 shares of common stock remained unvested. The Company recorded $0.1 million of expense in the years ended December 31, 2019 and 2018, respectively, 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,	
	2019	2018
Research and development	$ 4,361	$2,760
General and administrative	5,197	4,253
Restructuring charges	910	—
Total stock-based compensation expense	$10,468	$7,013

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

	Year Ended December 31,	
	2019	2018
Expected term (in years)	6.2	6.2
Expected volatility	76%	77%
Risk-free interest rate	2.13%	2.62%
Expected dividend yield	— %	— %
Weighted-average grant date fair value per share	$5.60	$8.14

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, 2019 and 2018, 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.

11. 401(k) Plan

The Company provides a qualified 401(k) savings plan for its employees. All employees are eligible to participate, provided they meet the requirements of the plan. As is permitted under the plan, the Company has elected to match employee contributions up to $750 and accordingly matching contributions totaling an insignificant amount were made in the years ended December 31, 2019 and 2018.

12. 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. basedSignificant components of the Company's deferred tax assets are as follows (in thousands):

	December 31	
	2019	2018
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 107,213	$ 85,571
Federal and state research and development tax credit carryforwards	25,661	18,590
Capitalized research and development	4,725	10,466
Stock based compensation	3,562	2,848
Other	1,199	1,499
Total deferred tax assets	142,360	118,974
Deferred tax liabilities:		
Depreciation and amortization	(372)	(622)
Other	(49)	—
Total deferred tax liabilities	(421)	(622)
Valuation allowance	(141,939)	(118,352)
Net deferred tax assets	$ —	$ —

Realization of the net deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which is uncertain. Based on the weight of available positive and negative objective evidence,

management believes it more likely than not that the Company's deferred tax assets are not realizable. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by $23.6 million and $29.5 million during the years ended December 31, 2019 and 2018, respectively.

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

	December 31	
	2019	2018
Income tax benefit at federal statutory tax rate	$(21,589)	$(15,235)
Change in valuation allowance	23,587	29,501
State income taxes, net of federal benefit	3,810	(10,112)
Research credits	(6,555)	(4,717)
Other	747	563
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 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, 2019 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, 2019, the Company had federal net operating loss carryforwards of $435.9 million and state net operating loss carryforwards of $224.5 million to offset future taxable income, if any. In addition, the Company had federal research and development tax credit carryforwards of $9.8 million, federal orphan drug tax credit carryforwards of $18.1 million, and state research and development tax credit carryforwards of $5.3 million. If not utilized, the federal net operating losses for the years beginning before January 1, 2018 of $255.7 million will expire beginning in 2024 through 2037, and the federal net operating losses for the tax years beginning after January 1, 2018 of $180.2 million will be carried forward indefinitely (subject to certain utilization limitations). The state net operating loss carryforwards will expire beginning in 2028 through 2039. The federal research and development and federal orphan drug tax credit carryforwards will expire beginning in 2020 through 2039, and the state tax credit will carry forward indefinitely. Interest and penalties for the years ended December 31, 2019 and 2018 were not material.

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

	Total
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
Increases related to prior year tax positions	83
Increases related to 2019 tax positions	1,719
Balances as of December 31, 2019	$6,386

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.

13. Restructuring

In December 2019, the Company commenced a reorganization plan to reduce its operating costs and better align its workforce with the needs of its business following the Company's November 25, 2019 announcement that it had halted clinical development of seladelpar. As of December 31, 2019, the restructuring liability is included in current liabilities on the consolidated balance sheet.

The Company incurred aggregate restructuring charges of approximately $5.1 million for the year ended December 31, 2019. Restructuring charges incurred under this plan primarily consisted of employee termination benefits and contract termination costs primarily associated with nonrefundable prepayments and exit fees relating to third-party manufacturers that the Company contracted with for clinical supplies. Employee termination benefits include severance costs, employee-related benefits, supplemental one-time termination payments, and non-cash share-based compensation expense related to the acceleration of stock options. Charges and other costs related to the workforce reduction and structure realignment are presented as restructuring charges in the consolidated statements of operations and comprehensive loss. Substantially all cash payments are expected to be paid out by the end of 2020. The Company may also incur additional costs not currently contemplated due to events that may occur as a result of, or that are associated with, the restructuring.

The following table summarizes the accrued restructuring liabilities and utilization by cost type associated with the restructuring activities during the year ended December 31, 2019 (in thousands):

	Termination Benefits	Contract Termination Costs	Total
Balances as of January 1, 2019	$ —	$ —	$ —
Restructuring charges	2,912	413	3,325
Reductions for cash payments	(132)	—	(132)
Balances as of December 31, 2019	$ 2,780	$ 413	$3,193

The Company also recognized $1.8 million in restructuring charges related to $0.9 million of nonrefundable prepaid research and development costs for clinical trial materials no longer expected be delivered and $0.9 million of accelerated vesting for stock-based compensation for executives subject to the reorganization plan.

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

March 16, 2020
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)*	March 16, 2020
/s/ Daniel Menold Daniel Menold	Vice President, Finance *(Principal Financial Officer)*	March 16, 2020
/s/ Robert J. Wills Robert J. Wills, Ph.D.	Director	March 16, 2020
/s/ Kurt von Emster Kurt von Emster, CFA	Director	March 16, 2020
/s/ Caroline Loewy Caroline Loewy	Director	March 16, 2020
/s/ Paul F. Truex Paul F. Truex	Director	March 16, 2020

Exhibit 4.2

DESCRIPTION OF COMMON STOCK

Our authorized capital stock consists of 100,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share. A description of material terms and provisions of our certificate of incorporation and bylaws affecting the rights of holders of our capital stock is set forth below. The description is intended as a summary, and is qualified in its entirety by reference to our certificate of incorporation and the bylaws.

Common stock

Voting Rights. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. The certificate of incorporation and by-laws do not provide for cumulative voting rights in connection with election of directors unless, at the time of such election, we are subject to Section 2115(b) of the California General Corporation Law. The affirmative vote of holders of 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, and removal of directors.

Dividends. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of outstanding shares of common stock may receive dividends, if any, as may be declared from time to time by the Board of Directors out of legally available funds. We have never issued a dividend on shares of its common stock and has no intention to do so in the future.

Liquidation. In the event we of liquidate, dissolve or wind up, the assets legally available for distribution shall be distributed ratably to the holders of shares of common stock and preferred stock, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences. Holders of common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable. All outstanding shares of common stock are fully paid and nonassessable.

Anti-takeover effects of provisions of our certificate of incorporation and bylaws and Delaware law

Certificate of incorporation and bylaws. Our amended and restated certificate of incorporation and amended and restated bylaws, include a number of provisions that may deter or impede hostile takeovers or changes of control or management. These provisions include:

Issuance of undesignated preferred stock. Our Board of Directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our Board of Directors. The existence of authorized but unissued shares of preferred stock enables our Board of Directors to make it more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

Board of Directors vacancies. Our amended and restated certificate of incorporation and amended and restated bylaws authorize only our Board of Directors to fill vacant directorships. In addition, the number of directors constituting our Board of Directors may be set only by resolution adopted by a majority vote of our entire Board of Directors. These provisions prevent a stockholder from increasing the size of our Board of Directors and gaining control of our Board of Directors by filling the resulting vacancies with its own nominees.

Stockholder action; special meetings of stockholders. Our amended and restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. Stockholders will not be permitted to cumulate their votes for the election of directors unless required by applicable law. Our amended and restated bylaws provide that only the chairman of our Board of Directors, chief executive officer or a majority of our Board of Directors may call special meetings of our stockholders.

Advance notice requirements for stockholder proposals and director nominations. Our amended and restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders. Our amended and restated bylaws also specify certain requirements as to the form and content of a stockholder's notice. These provisions may make it more difficult for our stockholders to bring matters before our annual meeting of stockholders or to nominate directors at annual meetings of stockholders.

We designed these provisions to enhance the likelihood of continued stability in the composition of our Board of Directors and its policies, to discourage certain types of transactions that may involve an actual or threatened acquisition of us, and to reduce our vulnerability to an unsolicited acquisition proposal. We also designed these provisions to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they may also reduce fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in a business combination with any interested stockholder for a period of three years following the date the person became an interested stockholder, with the following exceptions:

- before such date, the Board of Directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (a) by persons who are directors and also officers and (b) pursuant to employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and
- on or after such date, the business combination is approved by the Board of Directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 of the DGCL defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

Section 203 of the DGCL defines an "interested stockholder" as an entity or person who, together with the entity's or person's affiliates and associates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation. A Delaware corporation may "opt out" of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Exhibit 21.1

List of Subsidiaries

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

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, 333-226741, and 333-229953) pertaining to the Metabolex, Inc. 2003 Equity Incentive Plan, and the CymaBay Therapeutics, Inc. 2013 Equity Incentive Plan;

of our reports dated March 16, 2020, 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, 2019.

/s/ Ernst & Young LLP

Redwood City, California
March 16, 2020

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: March 16, 2020

/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: March 16, 2020

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

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), 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, 2019, 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 16th day of March, 2020.

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

/s/ Daniel Menold
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.