
**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, 2020

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
(State or other jurisdiction of
incorporation or organization)

7575 Gateway Blvd, Suite 110
Newark, CA
(Address of principal executive offices)

94-3103561
(I.R.S. Employer
Identification No.)

94560
(Zip Code)

(510) 293-8800

(Registrant's telephone number, including area code)

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

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging Growth Company	<input type="checkbox"/>		

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on the Nasdaq Global Select Market on June 30, 2020, was \$238,474,701. This excludes 425,196 shares of the registrant's Common Stock held by executive officers, directors and stockholders affiliated with directors outstanding at June 30, 2020. 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 28, 2021, was 68,946,092.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2021 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, 2020, are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

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ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2020

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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.

RISK FACTOR SUMMARY

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

Risks Related to the COVID-19 Pandemic

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

Risks Related to Our Financial Condition and Capital Requirements

- We have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We may need to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development. In the event we do not successfully raise sufficient funds to finance our product development activities, we will curtail our product development activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether.
- Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully develop, obtain regulatory approval for, and commercialize product candidates, including most importantly, seladelpar.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Risks Related to Clinical Development and Regulatory Approval

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

Risks Related to Our Reliance on Third Parties

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

Commercialization Risks

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

Intellectual Property Risks

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

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

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

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.

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Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPAR δ), 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; and
- nonalcoholic steatohepatitis (NASH), a prevalent and serious chronic liver disease caused by excessive fat accumulation in the liver that results in inflammation and cellular injury that can progress to fibrosis and cirrhosis, and potentially liver failure and death.

We reported net losses of approximately \$51.0 million, \$102.8 million, and \$72.5 million for the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020, we had cash, cash equivalents and marketable securities totaling \$146.3 million, which we believe is sufficient to fund our current operating plan into mid-2022.

Strategy

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

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

Recent Events

We are currently in the process of commencing enrollment of a global, Phase 3 registration study (RESPONSE) to evaluate seladelpar in patients with PBC and recently enrolled our first subject in a global long-term safety study (ASSURE) to evaluate seladelpar in patients with PBC.

CymaBay Pipeline Overview

Our pipeline includes three clinical stage product candidates: seladelpar (a PPAR δ agonist), MBX-2982 (a GPR119 agonist) and CB-0406 (a PPAR γ non-agonist ligand). We also have one preclinical stage product candidate, CB-001 (a GPR120 agonist).

Product Candidates	Disease/condition	Status	Description
Seladelpar (PPAR δ agonist)	Primary Biliary Cholangitis (PBC)	Phase 3	Ongoing 52-week Phase 3 study to evaluate seladelpar in PBC patients with inadequate response or intolerance to ursodeoxycholic acid (UDCA) (RESPONSE)
Seladelpar (PPAR δ agonist)	Nonalcoholic Steatohepatitis (NASH)	Phase 2b	Completed 52-week Phase 2b study to evaluate safety, tolerability, and effect of seladelpar in patients with NASH
MBX-2982 (GPR119 agonist)	Hypoglycemia in Type 1 Diabetics	Phase 2a	Commencing proof-of-pharmacology Phase 2a study*
CB-0406 (PPAR γ non-agonist ligand)	Inflammation	Phase 1	Undisclosed indication(s)
CB-001 (GPR120 agonist)	Inflammation	Preclinical	Undisclosed indication(s)

* Being conducted and funded by third parties (see MBX-2982 section below)

Seladelpar (MBX-8025)

Summary

Seladelpar is a selective agonist for the peroxisome proliferator-activated receptor delta (PPAR δ). The PPAR δ 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 PBC and other conditions. These benefits include:

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

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, we have completed multiple Phase 1 clinical studies and three Phase 2 and one Phase 3 clinical study (ENHANCE) of seladelpar in PBC. In addition, we are in the process of commencing a second Phase 3 study (RESPONSE) with seladelpar. We believe that the data from the Phase 2 studies and the ENHANCE Phase 3 study established seladelpar's anti-cholestatic and anti-inflammatory effects and identified a dose that has the potential to offer patients improved efficacy and better tolerability over the only approved second-line treatment available today. Those studies showed reductions in markers of cholestasis including ALP and GGT, and showed that seladelpar also improved inflammatory and metabolic markers with patients experiencing decreases in levels of transaminases, hs-CRP, and LDL-C. Many PBC patients suffer from pruritus, or itching, which can significantly impact their quality of life. Based on data from our Phase 2 and Phase 3 studies, and unlike the only approved second-line treatment currently available, we believe that seladelpar may reduce the incidence of pruritus in PBC patients.

Target Indications for Seladelpar

We are actively pursuing PBC as our initial launch indication for seladelpar. Other indications, such as NASH, will be pursued opportunistically. Following is a review of PBC and NASH and our development progress in each indication.

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 their respective FDA and EMA orphan designation criteria. Diagnosis of PBC is confirmed by elevated serum alkaline phosphatase (ALP) 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 ALP and bilirubin are associated with worsened clinical outcomes including liver transplantation and death associated with PBC. These analyses supported the use of ALP and bilirubin as elements of a clinical surrogate reasonably likely to predict outcomes that was used for the approval of obeticholic acid as a second line therapy for PBC.

Competition/Industry

We face competition from pharmaceutical and biotechnology companies. The FDA-approved treatments for PBC are ursodeoxycholic acid (UDCA), also known as ursodiol, a generic drug, and obeticholic acid (Ocaliva[®], marketed by Intercept Pharmaceuticals, Inc). UDCA is a natural bile acid that decreases serum levels of ALP, 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 FDA for the treatment of PBC. In December 2018, Genfit announced Phase 2 results from a Phase 2 study of elafibranor in PBC and in September 2020, announced the commencement of a Phase 3 study of elafibranor in PBC. Saroglitazar (Zydus Cadila) is a dual PPARa/g agonist in development for patients with PBC. In November 2020, Zydus presented data from a Phase 2 study evaluating saroglitazar in patients with PBC at the annual meeting of the American Association for the Study of Liver Diseases and in December 2020, Zydus announced saroglitazar had received Fast Track Designation from the FDA for the treatment of PBC and in January 2021 it received Orphan Drug Designation for PBC from the FDA. Phase 2 study data in patients with PBC has been reported for the selective NOX inhibitor GKT137831 (Calliditas) along with the announced intention to conduct a Phase 2/3 study in the second half of 2021.

Studies of Seladelpar in PBC

RESPONSE (Phase 3)

We are currently in the process of commencing enrollment in a global, Phase 3 registration study (RESPONSE) to evaluate seladelpar in patients with PBC. The Phase 3 study is a 52-week, double blind, placebo-controlled, randomized, global, registration study evaluating the safety and efficacy of seladelpar in patients with PBC. The study is intended to enroll 180 patients, who have an inadequate response to, or intolerance to, ursodeoxycholic acid, in a 2:1 randomization to oral, once daily seladelpar 10 mg or placebo. The primary outcome measure will be the composite biochemical responder rate at 52 weeks. A responder is defined as a patient who achieves an ALP level less than 1.67 times the upper limit of normal with at least a 15%

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decrease from baseline and has a normal level of total bilirubin. Additional key outcomes of efficacy will compare the rate of normalization of ALP at 52 weeks and the change from baseline in level of pruritus at six months for patients with moderate to severe pruritus at baseline assessed by a numerical rating scale (NRS) recorded with an electronic diary.

ENHANCE (Phase 3)

In October 2018 we commenced a global, Phase 3 registration study (ENHANCE) to evaluate seladelpar in patients with PBC. The Phase 3 study was 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 UDCA.

Approximately 265 patients were randomized to receive placebo, 5 mg of seladelpar, or 10 mg of seladelpar. Patients on 5 mg could potentially increase their dose, in a double-blinded manner, to 10 mg after 6 months if they have not yet met the composite biochemical response criteria. The primary endpoint was a composite response defined as a patient achieving an ALP 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 efficacy analysis was to compare response rates of treatment groups to those of the placebo group. Key secondary endpoints were to be ALP normalization rate and changes from baseline in pruritus, as measured by the numerical rating scale, or NRS in patients with moderate to severe pruritus at baseline.

In December 2019 we terminated ENHANCE early based on initial histological observations obtained in our Phase 2b study of seladelpar in NASH. In May 2020, we announced completion of an independent expert panel review into the NASH findings that concluded the data, in aggregate, did not support liver injury related to seladelpar. In June 2020, we discussed the data, the panel's conclusions, and other matters with the FDA. In July 2020, the FDA lifted the clinical hold on the program and we made the decision to reinstate clinical development of seladelpar in PBC.

In August 2020 we announced positive results from ENHANCE, which we believe demonstrated seladelpar to be safe, well-tolerated, and efficacious in patients with PBC. Although the study was terminated prior to the completion of the 52-week treatment period, the statistical analysis plan was amended while the study remained blinded to adjust for evaluation of the primary and two key secondary endpoints at Week 12 rather than Week 52. Topline data for patients through 12 and to 26 weeks showed what we believe to be robust anti-cholestatic, anti-inflammatory and anti-pruritic activity of seladelpar. Specifically, 78.2% of patients on 10 mg of seladelpar compared with 12.5% on placebo achieved the primary composite outcome after 3 months ($p<0.0001$), and 27.3% of patients on 10 mg of seladelpar compared with 0% on placebo normalized ALP by 3 months ($p<0.0001$). In addition, the study revealed statistically significant improvement in change from baseline in pruritus at 3 months ($p<0.05$) for patients with moderate-to-severe itch treated with seladelpar 10 mg versus placebo.

Safety Studies

Prior to the decision to terminate in December 2019, we were conducting a long-term safety study of seladelpar, which was open to patients who had participated in other company-sponsored PBC studies. Patients completing the Phase 2 open label study discussed immediately below, as well as ENHANCE, were able to transfer into the long-term safety study. As of the time of termination, 106 patients had received seladelpar for at least 12 months and 51 patients had received seladelpar for at least 24 months. The safety study was discontinued due to the histological observations in the Phase 2b NASH study.

With the reinstatement of the clinical development of seladelpar we recently commenced a long-term safety study (ASSURE), which is open to patients who were eligible for the prior long-term extension study, including those from our Phase 2 open label study and our Phase 3 ENHANCE study, as well as patients completing treatment in RESPONSE.

Phase 2 Open Label Study

In December 2016, we initiated a Phase 2 study of seladelpar in patients with PBC. The study was an open label, randomized, dose-ranging study evaluating 2 mg, 5 mg and 10mg doses of seladelpar and the primary efficacy endpoint was percent change in ALP from baseline. The study had an initial twelve-week period in which starting doses were maintained, but after which doses could be increased to as high as 10 mg for those patients in which a greater biochemical response was deemed appropriate, these being described as titration groups. 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.

In November 2018 we announced data that we believe showed that seladelpar treatment led to sustained anti-cholestatic and anti-inflammatory effects with no worsening of pruritus through 52 weeks. Specifically, at 52 weeks the mean decreases in ALP were -47% and -46% in the 5/10 titration 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 ALP <1.67 x ULN, ³15% decrease in ALP, and total bilirubin £ULN. At 52 weeks 59% and 71% of patients met the composite endpoint in the 5/10 titration and 10 mg groups, respectively. The anti-cholestatic effect of seladelpar was further substantiated with normalization of ALP levels at 52 weeks in 24% and 29% of patients in the 5/10 titration 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 titration and 10 mg groups, respectively.

A 52-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. Patient self-reported experiences were collected using the pruritus visual analogue scale (VAS) in 101 PBC patients in the 5/10 titration or 10 mg groups. In patients with moderate to severe pruritus (VAS ³ 40), substantial improvement in pruritus (VAS³ 20-point decrease) was seen in 58% and 93% of patients in the 5/10 titration 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.

Of the 119 patients that received at least one dose of seladelpar (2, 5 or 10 mg), 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 with the FDA for obeticholic acid (Ocaliva®), an FXR-agonist, 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®, cenicriviroc, a CCR2/5 receptor antagonist (Abbvie), and Resmitron, a THR β agonist (Madrigal). Novo Nordisk is also planning to start a Phase 3 study in NASH in 2021 with semaglutide, a GLP-1 receptor agonist. In addition, 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 significant reductions in liver fat but that these changes were not significant when compared to placebo, which also had significant reductions. 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 (ALP) 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, we halted dosing of patients with seladelpar due to the lack of understanding the significance of the observations, and possible impact on patients.

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 (*thefoz/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

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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.

We have also 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.

NASH Histology Review

In November 2019, we announced the termination of our Phase 2b study of seladelpar in subjects with NASH. 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, and sometimes with the presence of numerous immune cells. 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. Thereafter, we terminated all our ongoing clinical studies of seladelpar pending further investigation of the histological observations.

With the receipt of additional requests from the FDA, we 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 included three activities intended to confirm and subsequently understand the significance of the observations. The first was a comprehensive collection and review of data including patient demographics, medical history, concomitant medications and additional biochemical markers. The second was a blinded, independent review of baseline and end of treatment biopsies by several experienced liver pathologists. Finally, the third, was a formal pathology and clinical hepatology review panel meeting during which experts reviewed all information gathered to provide a consensus independent determination of the role of seladelpar in these findings. These activities were essential to our follow-up with the FDA and to determine if there was a path forward for seladelpar.

In May 2020, we announced completion of an independent expert panel review into the findings from our NASH Phase 2b study. The eight-person panel included three hepatopathologists and five hepatologists with expertise in drug-induced liver injury, NASH and PBC. The expert panel found no clinical, biochemical or histological evidence of seladelpar-related liver injury in the study. The panel also unanimously supported lifting of the clinical hold and the re-initiation of clinical development. In June 2020, we discussed the data, the panel's conclusions, and other matters with the FDA and submitted a complete response letter to answer outstanding FDA questions and seek approval from the FDA to lift the clinical hold. In July 2020, we received a response from the FDA lifting the clinical hold, thereby permitting us to reinstate clinical development of seladelpar.

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MBX-2982

MBX-2982 targets G protein-coupled receptor 119 (GPR119), a receptor that interacts with bioactive lipids known to stimulate glucose-dependent insulin secretion. 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, we believe, safe and well tolerated.

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

In November 2020, we announced a study to evaluate the potential for MBX-2982 to stimulate the release of the hormone glucagon in response to hypoglycemia in patients with type 1 diabetes (T1D). Glucagon is a regulatory hormone that elevates blood sugar levels in response to below normal glucose levels (hypoglycemia). Insulin-induced hypoglycemia in diabetes is a significant limiting factor in achieving the desired glucose control and is the cause of significant morbidity. In recent preclinical studies, GPR119 agonists were shown to enhance glucagon secretion in response to low glucose levels and were able to prevent hypoglycemia in animal models. The Phase 2a proof-of-pharmacology study will assess whether MBX-2982 can enhance glucagon secretion during insulin-induced hypoglycemia in subjects with T1D. If successful, studies to evaluate MBX-2982 as a potential preventive therapy for hypoglycemia in patients with T1D may be warranted. The study is being led by the AdventHealth Translational Research Institute in Orlando, Florida and is fully funded by The Leona M. and Harry B. Helmsley Charitable Trust. CymaBay retains full commercial rights to MBX-2982.

CB-0406

In 2020, we began to evaluate CB-0406, the active metabolite of the pro-drug arhalofenate that had previously been studied for chronic metabolic diseases. We initiated a single and multiple ascending dose study of CB-0406 in healthy subjects to establish its pharmacokinetics, safety and maximum tolerated dose. CB-0406 is a PPAR γ non-agonist ligand that attenuates the expression of inflammatory genes. It has been shown to block innate immune responses to inflammatory triggers in macrophages, and to attenuate gouty inflammation when dosed as the pro-drug in mouse animal models and in a Phase 2 clinical study in gout patients. Based on pharmacokinetic studies in monkeys, we believe that CB-0406 may have greater exposure and potentially greater efficacy than does the pro-drug arhalofenate. Decisions on any future development are contingent on it achieving a favorable profile with respect to safety and exposure. The innate immune system plays a pivotal role in many diseases besides gout and thus we believe CB-0406 may have utility in various inflammatory diseases and are currently exploring potential opportunities to advance its development pending the results of the ongoing Phase 1 study.

CB-001 (GPR120)

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

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

Restructuring Plan

Following the announcement of the histological observations obtained in our NASH Phase 2 study in November 2019 and the subsequent termination of our ongoing seladelpar clinical trials in November and

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December 2019, we announced a restructuring plan to reduce our workforce by approximately 60% to control our operating costs, and we commenced a process to evaluate strategic alternatives to maximize stockholder value. Following the FDA's decision in July 2020 to lift the clinical hold on the seladelpar program, we subsequently concluded our formal review of strategic options, having made the determination to restart clinical development of seladelpar in PBC and to conduct other drug development activities. Specifically, we made the strategic decision to refocus our strategy primarily on clinical development of seladelpar in PBC and to explore the potential to partner seladelpar in NASH in a combination study with other complimentary agents. In addition, we intend to continue evaluating opportunities to develop other internal programs and possibly acquire or in-license new compounds or programs.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the global novel coronavirusdisease (COVID-19) outbreak a pandemic. Through the date of filing of this Annual Report, our operations, financial condition and liquidity have not been significantly impacted by the COVID-19 outbreak. As a result of the COVID-19 pandemic, we may experience future disruptions that could impact aspects of our business, including our progress towards the completion of our clinical studies, and other associated drug development activities. Possible disruptions are currently difficult to foresee. We continue to monitor areas of potential risk which include but are not limited to the following:

- *Remote workforce operations.* To date, our workforce has adapted to remotely working to maintain operations. Our reliance on personnel working from home could potentially negatively impact future productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, remote operations could increase our cyber-security and data privacy risks, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations, or delay necessary interactions with regulators, contract manufacturers, contract research organizations, clinical trial sites, and other important agencies and contractors, which may result in increased costs to us.
- *Clinical trial and drug manufacturing operations.* In collaboration with our clinical research organization partners, we sponsor clinical trials that take place at investigator sites in the United States and internationally. We also partner with contract manufacturing organizations to develop, manufacture, and distribute our product candidate drug supplies. To date, these collective research and development personnel and vendors are adapting to COVID-19 related travel restrictions and reduced access to work facilities through the use of remote working technologies and other measures as they continue to progress toward enrollment and completion of our existing clinical trials. However, in the future, as we look to enroll and complete the clinical development of seladelpar and initiate other programs, our research and development employees and contractors may not be able to sufficiently access their applicable work facilities as a result of continued facility closure orders and the possibility that governmental authorities might further modify such restrictions. Furthermore, patients we expect to enroll in our clinical trials may also be impacted by any ongoing travel and facility access restrictions. Although we and our contractors continue to plan for and develop pandemic-related risk mitigation strategies, it is uncertain whether these plans will continue to be sufficient to fully offset the potential impact that travel and facility access restrictions (or other unanticipated impediments) may have on our ability to execute our research and development activities in a timely and cost effective manner.
- *Drug regulator interactions.* The FDA, comparable foreign regulatory agencies, and ethics boards may experience operational interruptions or delays, which could impact timelines for regulatory meetings, submissions, trial initiations, and regulatory approvals.
- *Financial reporting and compliance.* To date, there has been no adverse impact on our ability to maintain our established financial reporting functions and internal controls over financial reporting. However, our ability to prepare our financial results timely and accurately is partially dependent upon

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the availability of third-party information systems and other cloud-based services. Any degradation in the quality or timeliness of critical third-party information or cloud-based services could adversely impact our financial reporting capabilities.

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

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.

DiaTex: On June 30, 1998, we entered into a License and Development Agreement with DiaTex, Inc. Under the agreement, DiaTex granted us an exclusive license to develop and commercialize therapeutic products containing halofenate, its enantiomers, derivatives, and analogs (the licensed products) for the treatment of diseases. CB-0406 is a derivative of halofenate.

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 CB-0406, as well as a 2% royalty payment on any net sales of products containing CB-0406. Under the terms of the agreement, if we fail to use diligent efforts to conduct preclinical and clinical testing of halofenate and its enantiomers to determine its efficacy for use in the treatment or prevention of human diseases or conditions, fail to make any payment called for under the agreement, or disclose non-exempt confidential information under the agreement, such action would constitute a material breach under the agreement. In addition, if we fail to execute all instruments and assignments or fail to take any action to effect joint ownership of any enantiomer patent with DiaTex, such action would constitute a material breach under the agreement. We may terminate the agreement at any time if we determine we are no longer interested in DiaTex's license grant, provided we provide sufficient written notice within a specified time period.

Research and Development

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 200 foreign patents, as well as approximately 20 United States patent applications and 50 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 PPAR α agonists (including seladelpar), their compositions and uses both alone and in combination with other drugs, CB-0406 methods of use and methods of manufacture, and certain GPR119 and GPR120 agonist compositions and uses.

The seladelpar portfolio consists of approximately 480 issued patents and 60 pending patent applications related to composition and method of use that expire between 2025 and 2038, before accounting for any potential patent term extension or orphan disease exclusivity. 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 also expect to use third party contract manufacturers to obtain our commercial supplies of 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 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 ALP, bilirubin, alanine aminotransferase, aspartate aminotransferase, cholesterol, and immunoglobulin M, all of which are elevated in patients with PBC and can serve as biochemical markers of the disease. In a study that combined data from three controlled trials with a total of 548 patients, ursodiol significantly reduced the likelihood of liver transplantation or death after

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four years. Ursodiol also delayed the progression of hepatic fibrosis in early-stage PBC, but was not effective in advanced disease. It is also known that up to 50% of PBC patients fail to respond adequately to ursodiol therapy. Ursodiol is available as a generic and is priced at a discount to typical branded therapies.

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

Although not approved for use in PBC, off-label use of fibrate drugs has been reported, though many fibrates are specifically contraindicated for use in PBC due to potential concerns over acute and long-term safety in this patient population. Nevertheless, off-label use of fibrates is mentioned in several published treatment guidelines. 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 PPAR α /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. In September 2020, Genfit announced the commencement of a Phase 3 study of elafibranor in patients with PBC who had an inadequate response or intolerance to UDCA. Another potential therapy in clinical development for PBC is the dual PPAR α /g agonist saroglitazar (Zydus Cadila). In November 2020, Phase 2 results were presented at the Liver Meeting hosted by the American Association for the Study of Liver Disease. In December 2020, Zydus announced saroglitazar had been granted Fast Track Designation for PBC and in January 2021 it received Orphan Drug Designation for PBC by the FDA. The selective NOX inhibitor GKT137831 (Calliditas) has also reported Phase 2 study data for PBC and announced its intention to conduct a Phase 2/3 study in PBC commencing in the second half of 2021. In cholestatic pruritus, GSK2330672 (GlaxoSmithKline) is an inhibitor of the Intestinal Bile Acid Transporter (IBAT), which is undergoing evaluation for decreasing symptoms of pruritus, including in PBC.

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), cenicriviroc, a CCR2/5 receptor antagonist (Abbvie), and Resmiltiron, a THR-beta agonist (Madrigal). Novo Nordisk is also planning to start a Phase 3 study in NASH in 2021 with semaglutide, a GLP-1 agonist. In addition, over two dozen other compounds are currently in Phase 2 development in NASH.

Government Regulation and Product Approval

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

United States Pharmaceutical Product Development Process

In the United States, the FDA regulates pharmaceutical products under the Federal Food, Drug and Cosmetic Act, and implements 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 candidate.

Clinical studies involve the administration of the drug 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, but not limited to, 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 drug candidate 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 drug candidate 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 drug 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 drug 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

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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. 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 HealthCare 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.

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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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its payments and other transfers of value during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives.

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 on covered entities, including certain healthcare providers, health plans, and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors 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". 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 significant penalties, including administrative, criminal and 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.

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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 executive, judicial and Congressional challenges to certain aspects of the PPACA. For example, President Trump signed several Executive Orders and other directives designed to

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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. The United States Supreme Court is currently reviewing the constitutionality of the PPACA, but it is unclear when a decision will be made. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the PPACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the PPACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the PPACA. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

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 2030 unless additional congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2021. 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, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals. The FDA also released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product

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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. Further, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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.

Environment, Health and Safety

Various laws and regulations have been implemented or are under consideration to mitigate the effects of climate change caused by greenhouse gas emissions. For example, the California Air Resources Board is in the process of drafting regulations to meet state emissions targets. Based on current information and subject to the finalization of the proposed regulations, we believe that our primary risk related to climate change is the risk of increased energy costs. However, because we are not an energy-intensive business, we do not anticipate being subject to a cap and trade system or any other mitigation measures that would likely be material to our capital expenditures, results of operations or competitive position.

We are also subject to other federal, state and local regulations regarding workplace safety and protection of the environment. We use hazardous materials, chemicals, and various compounds in our research and development activities and cannot eliminate the risk of accidental contamination or injury from these materials. Certain misuse or accidents involving these materials could lead to significant litigation, fines and penalties. We have implemented proactive programs to reduce and minimize the risk of hazardous materials incidents.

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, 2020, and February 28, 2021, we had 41 and 44 full-time employees, respectively.

Information about our Executive Officers

As of February 28, 2021, our executive officers were as follows:

Name	Age	Position Held With CymaBay
Sujal Shah	47	President & Chief Executive Officer
Charles A. McWherter, Ph.D.	66	Chief Scientific Officer
Klara Dickinson	54	Chief Regulatory and Quality Assurance Officer
Paul T. Quinlan	58	General Counsel and Chief Compliance Officer
Daniel Menold	51	Vice President, Finance

Biographical Information

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 Board of Directors of Tvardi Therapeutics, Inc. and the Executive Advisory Board of the Chemistry of Life Processes Institute at Northwestern University. Mr. Shah received an M.B.A. 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. From 2007 to 2013, he served as our Senior Vice President, Research and Preclinical Development. 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 Quality Assurance Officer since October 2020. Prior to that she was our Chief Regulatory and Compliance Officer since January 2019, and our Senior Vice President, Regulatory Affairs and Compliance since June 2017. Previously, she served as Senior Vice President, Chief Regulatory Officer of Anthera Pharmaceuticals, Inc., a biopharmaceutical company. From 2007 to 2014, she was Senior Vice President of Regulatory Affairs and Compliance at Hyperion Therapeutics Inc, where she was responsible for the general supervision of the company's regulatory affairs and quality assurance. 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 such as Scios, Inc. and DEY Laboratories (a subsidiary of Mylan, Inc.). Ms. Dickinson holds a B.S. in Biology from the College of Great Falls in Montana and is certified by the Regulatory Affairs Certification Board.

Paul T. Quinlan has served as our General Counsel, Chief Compliance Officer and Corporate Secretary since October 2020. He was also our General Counsel and Corporate Secretary from December 2017 to February 2020. Previously, Mr. Quinlan served as General Counsel and Secretary at TerraVia Holdings, Inc. (formerly Solazyme, Inc.), a biotechnology company, from 2010 until January 2018, where he was responsible for the general supervision of the company's legal affairs. From 2005 to 2010, Mr. Quinlan was General Counsel and Secretary at Metabolex, Inc., a biopharmaceutical company, and from 2000 to 2005, Mr. Quinlan held various positions in the legal department at Maxygen, Inc., a biopharmaceutical company, most recently that of Chief Corporate Securities Counsel. Prior to joining Maxygen, Mr. Quinlan was an associate at Cooley LLP and Cravath, Swaine & Moore LLP. Mr. Quinlan obtained a law degree from Columbia University Law School and a M.Sc. in Medical Biophysics from the University of Toronto.

Daniel Menold has served as our Vice President, Finance since April 2017, and previously served as 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, Inc. from 2005 to 2010. 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 LLP 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.

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 the COVID-19 Pandemic

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

On January 30, 2020, the World Health Organization declared the outbreak of the coronavirus causing the disease COVID-19 a “Public Health Emergency of International Concern,” and on March 11, 2020, the World Health Organization characterized the outbreak as a “pandemic”. While the COVID-19 pandemic did not materially adversely affect our business operations in 2020, economic and health conditions in the United States and across most of the globe have continued to change since the end of the year. As a result of the COVID-19 pandemic, we may experience disruptions that could impact aspects of our business, including our progress towards the completion of our clinical studies and other associated drug development activities. Possible disruptions are currently difficult to foresee and include, but are not limited to, potential risk areas as noted below:

- We are currently starting up clinical trials in geographies that are affected by the COVID-19 pandemic. While we have not experienced significant impacts to our clinical activities through December 31, 2020, we believe that the COVID-19 pandemic could potentially have an impact on various aspects of our clinical activities in the future. For example, pandemic related restrictions, including stay-at-home orders and curtailment of all but essential services, could reduce the rate of patient enrollment in our RESPONSE clinical trial and other clinical studies, and impair the ability to efficiently treat patients at investigator sites. Additionally, our employees, representatives from our clinical research organization partners, and study investigators may be unable to efficiently collaborate to conduct investigator site activities in-person at the sites (as per standard practice) and may be required to delay, or alter their approach to complete this work due to diversion of resources at clinical sites or continued government-imposed limitations on travel. Further, our employees and representatives from our contract manufacturing organizations may experience unanticipated challenges producing and distributing sufficient quantities of clinical drug supplies for use in our clinical trials.
- We have limited access to our corporate office and requested that most of our personnel, including all of our administrative employees, work remotely, and restricted on-site staff to only those personnel and contractors who must perform essential activities that must be completed on-site. The COVID-19 pandemic could disrupt our ability to secure supplies for our operations. The safety, health and well-being of our workforce is of primary concern and we may need to enact further precautionary measures to help minimize the risk of our employees being exposed to the novel coronavirus.

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- Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cyber-security and data privacy risks, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations, or delay necessary interactions with regulators, contract manufacturers, contract research organizations, clinical trial sites, and other important agencies and contractors, which could result in increased costs to us.
- Our employees and contractors involved in conducting our research and development activities may not be able to access their applicable work facilities for an extended period of time as a result of facility closure orders and the possibility that governmental authorities further modify such access restrictions.
- The United States Food and Drug Administration (FDA), comparable foreign regulatory agencies, and ethics boards may experience operational interruptions or delays, which could impact timelines for regulatory meetings, submissions, trial initiations, and regulatory approvals.

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

Risks Related to Our Financial Condition and Capital Requirements

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

We have incurred significant net losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability. As of December 31, 2020, we had cash, cash equivalents and marketable securities of approximately \$146.3 million. We may need to raise additional equity and/or debt capital to fund our continued operations, including clinical trials and other product development. We may also choose to raise additional equity and/or debt capital if appropriate opportunities become available. Our monthly spending levels vary based on new and ongoing development and corporate activities. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete.

In the event we do not successfully raise sufficient funds 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 strategic transactions, 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.

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;

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- the timing, economic and other terms of any licensing, collaboration or other similar arrangement into which we may enter;
- the costs and timing of seeking and obtaining FDA and other regulatory approvals;
- the extent of our other development activities;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the effect of competing products and market developments.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results, 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 in the near 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 FDA to perform studies or trials in addition to those that we currently anticipate. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of any increase in our anticipated development costs.

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

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

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

Risks Related to Clinical Development and Regulatory Approval

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

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

- successful enrollment and completion of clinical trials, including, in the case of RESPONSE, enrollment of sufficient subjects willing to obtain a liver biopsy;
- 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. 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

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trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

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

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- the clinical study protocol may require one or more amendments delaying study completion;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, we may have to compete with other clinical trials to enroll eligible subjects, or subjects may drop out of these clinical trials at a higher rate than we anticipate;
- the number of patients in our RESPONSE clinical trial that choose to have biopsies may be insufficient to satisfy regulatory requirements;
- 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. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates may be adversely impacted.

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

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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-treatment follow-up;
- delays caused by the need to enroll additional subjects willing to have biopsies in the RESPONSE trial;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- changes to treatment guidelines or the introduction of a new standard of care;
- delays caused by clinical sites dropping out of a trial;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials; and
- delays in importing clinical trial materials into foreign countries where our clinical trials are being conducted.

If initiation or completion of any clinical trials we may undertake for our product candidates is delayed for any of the above reasons, our development costs may increase, the approval process could be delayed, any periods during which we may have the exclusive right to commercialize our product candidates may be reduced and our competitors may bring products to market before us. Any of these events could impair our ability to generate revenues from product sales 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 of a High Dose Phase 2 clinical study of seladelpar in patients with PBC. During the course of this trial three cases of asymptomatic, reversible transaminase elevations occurred, and we made the decision to discontinue the study early after review of safety and efficacy data demonstrated a need for further dose reduction to optimize clinical safety and efficacy. In November and December 2019, due to histologic observations in our NASH clinical trial, all seladelpar clinical trials were terminated, pending further analysis of data from the NASH trial and further discussions with the FDA. Although in June 2020 we shared data and conclusions from an expert panel with the FDA, and in July 2020 the FDA lifted the clinical hold on our seladelpar program, this process substantially delayed the development of seladelpar. The emergence of adverse events (AEs) and histological observations in subsequent seladelpar clinical trials could prevent us from further developing seladelpar or could result in the denial of regulatory approval.

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

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

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

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

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

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

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

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

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

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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

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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

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markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

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

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

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

Health care professionals and third-party payors play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, third-party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as market, sell and distribute our products 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA, commonly referred to as the Physician Payments Sunshine Act, and analogous state laws and regulations, such as state anti-kickback and false claims laws.

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

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

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

For example, the PPACA was enacted to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Since its enactment there have been judicial and Congressional challenges to certain aspects of the PPACA as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. For example, President Trump signed several 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 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. The United States Supreme Court is currently reviewing the constitutionality of the PPACA, but it is unclear when a decision will be made. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the PPACA and our business. 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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

Risks Related to Our Reliance on Third Parties

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

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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;

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

Any of these events could lead to 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 Council for Harmonization Good Clinical Practice (ICH GCP), which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical development. The FDA enforces the ICH GCP through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CSPs fail to comply with the ICH GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. Our CSPs are not our employees, and we cannot control whether or not they devote sufficient time and resources to our ongoing clinical and nonclinical programs. These CSPs may also have relationships with other entities, including our competitors, for whom they may also be conducting clinical studies, or other drug development activities that

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

Risks Related to Commercialization of Our Product Candidates

The commercial success of any product 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.

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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.

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.

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

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

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

The life sciences industry is highly competitive, and we face significant competition from other pharmaceutical, biopharmaceutical and biotechnology companies and possibly from academic institutions, government agencies and private and public research institutions that are researching, developing and marketing

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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 proprietary know-how that is not patentable, processes for which patents are difficult to enforce and other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our

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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. We are currently engaged in legal proceedings with Genfit S.A. (Genfit), which alleges that we misappropriated some of their trade secrets. For additional information regarding the Genfit proceedings, see Item 3 – Legal Proceedings.

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 any non-exempt confidential information related to the agreement, or to use diligent efforts to promote, market and sell any PPARd Product under the agreement, such action would constitute a default under the agreement and Janssen NV may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, including in the case of the Janssen NV license, seladelpar, which would have a materially adverse effect on our business.

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

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

We are highly dependent on principal members of our executive team. While we have entered into employment offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. We do not maintain “key person” insurance for any of our executives or other employees. Recruiting and retaining other qualified employees for our business, including clinical, scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. We also experience competition from universities, competitors and research institutions for the hiring of scientific and clinical personnel. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology

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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 strategies. Our consultants and advisors may be engaged by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us, which could also adversely affect the progress of our research, development and commercialization objectives.

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

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

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

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business, particularly in view of the ongoing COVID-19 pandemic and remote work requirements. 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

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prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems and security vulnerabilities could be significant, and our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event is to occur and cause interruptions in our operations or our vendors, it may result in a material disruption of our product development programs and our reputation could be materially damaged. We could also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

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

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

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

Risks Relating to Owning Our Common Stock

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

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

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

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

- adverse 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 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 health care 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 or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

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- 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 current and future clinical trials, and operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If in the future we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. These sales may also result in new investors gaining rights superior to our existing stockholders. Pursuant to our equity incentive plans, 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 28, 2021 was 2,635,011 shares.

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

Provisions in our 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.

General Risks

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

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

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

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

Item 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

Genfit Litigation

On January 15, 2021, Genfit S.A. (Genfit) filed a complaint against us in the U.S. District Court for the Northern District of California, alleging misappropriation of trade secrets and related causes of action based on our receipt of a Genfit protocol synopsis for Genfit's Phase 3 clinical trial of its drug candidate elafibranor in patients with primary biliary cholangitis. The Complaint seeks damages in an unspecified amount as well as injunctive relief. We have stated in pleadings that we did not request or take any steps to obtain Genfit's protocol synopsis, we have taken diligent steps to remove and quarantine it, and we are not using any Genfit trade secrets in our own clinical trials. We intend to defend ourselves vigorously.

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 28, 2021, there were approximately 223 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. See "Cautionary Language Regarding Forward Looking Statements" at the beginning of this Annual Report for cautionary information regarding forward-looking statements.

Overview

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

Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPAR δ), 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; and
- nonalcoholic steatohepatitis (NASH), a prevalent and serious chronic liver disease caused by excessive fat accumulation in the liver that results in inflammation and cellular injury that can progress to fibrosis and cirrhosis, and potentially liver failure and death.

Seladelpar has received an orphan designation from the FDA and EMA. Seladelpar also received Breakthrough Therapy Designation from the FDA for early stage PBC and PRiority MEdicine status from the EMA.

In late 2019, we terminated our NASH Phase 2b study and our ongoing PBC studies. The decision to halt development of seladelpar was based on initial histological observations in the NASH Phase 2b study 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. Thereafter, in December 2019, we announced a restructuring plan to reduce our workforce by approximately 60% to control our operating costs, and we commenced a process to evaluate strategic alternatives to maximize stockholder value, pending further investigation of the histological observations. In May 2020, an independent expert panel completed a review of the findings and unanimously concluded that the data in aggregate did not support liver injury related to seladelpar. We subsequently discussed the data, the panel's conclusions, and other matters with the FDA and in July 2020, the FDA lifted the clinical hold, thereby permitting us to reinstate clinical development of seladelpar. Specifically, we made the strategic decision to refocus our strategy primarily on clinical development of seladelpar in PBC and to explore the potential to partner seladelpar in NASH in a combination study with other complimentary agents. In addition, we plan to evaluate opportunities to develop other internal programs and possibly acquire or in-license new compounds or programs.

Seladelpar

Primary Biliary Cholangitis (PBC)

Following the decision to reinstate clinical development of seladelpar, in late 2020, we commenced startup and site feasibility activities for RESPONSE, a new global Phase 3 registration study to evaluate seladelpar in patients with PBC. The Phase 3 study is a 52-week, placebo-controlled, randomized, global, registration study evaluating the safety and efficacy of seladelpar in patients with PBC. The study is intended to enroll 180 patients, who have an inadequate response to, or intolerance to, ursodeoxycholic acid, in a 2:1 randomization to oral, once daily seladelpar 10 mg or placebo. The primary outcome measure will be the responder rate at 52 weeks. A responder is defined as a patient who achieves an alkaline phosphatase level less than 1.67 times the upper limit of normal with at least a 15% decrease from baseline and has a normal level of total bilirubin. Additional key outcomes of efficacy will compare the rate of normalization of alkaline phosphatase at 52 weeks and the level of pruritus at six months for patients with moderate to severe pruritus at baseline assessed by a numerical rating scale recorded with an electronic diary.

In addition to RESPONSE we also commenced startup activities in late 2020 for ASSURE, a new long-term safety study, which is open to patients who were eligible for our previous long-term extension study that was terminated early in late 2019, including those patients from our previously completed Phase 2 open label study and our Phase 3 ENHANCE study, as well as patients who complete treatment in RESPONSE in the future.

Previously, in October 2018, we commenced enrollment of ENHANCE, a global Phase 3 registration study to evaluate seladelpar in patients with PBC and in October 2019, the trial was fully enrolled with 265 patients, but we terminated the trial early in December 2019 after the seladelpar program was placed on clinical hold. In August 2020, we shared data accumulated through trial termination for ENHANCE, which we believe demonstrated seladelpar to be safe, well-tolerated, and efficacious in patients with PBC.

Nonalcoholic Steatohepatitis (NASH)

In May 2018, we initiated a randomized, placebo-controlled Phase 2b proof-of-concept study to evaluate seladelpar at three doses in biopsy-proven NASH. The primary efficacy outcome is the change from baseline in liver fat content at 12 weeks measured by magnetic resonance imaging using the proton density fat fraction method (MRI-PDFF). The study also included 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 February 2019, we announced full enrollment of 181 patients with liver biopsy proven NASH at specialized U.S. investigational centers. In June 2019, we announced results from the primary efficacy outcome, which were that treatment with seladelpar resulted in significant reductions in liver fat but that these changes were not significant when compared to placebo, which also had significant reductions. Treatment with seladelpar did, however, result in robust and clinically meaningful reductions in markers associated with liver injury. In November 2019, we terminated this trial based on initial histological observations. Although these patients had stable or improving biochemical markers of liver disease, we halted dosing of patients with seladelpar due to the lack of understanding the significance of the observations, and possible impact on patients. Subsequent investigation indicated there was no seladelpar-induced liver injury in the Phase 2b study patients. As we continue to believe seladelpar may have therapeutic benefit in NASH patients, using the data accumulated to date from our Phase 2b study, we intend to explore the potential to partner seladelpar in NASH in a combination study with other complimentary agents.

MBX-2982

MBX-2982 targets G protein-coupled receptor 119 (GPR119), a receptor that interacts with bioactive lipids known to stimulate glucose-dependent insulin secretion. In November 2020, we announced a study to evaluate the potential for MBX-2982 to stimulate the release of the hormone glucagon in response to hypoglycemia in patients with type 1 diabetes (T1D). The Phase 2a proof-of-pharmacology study will assess whether MBX-2982

can enhance glucagon secretion during insulin-induced hypoglycemia in subjects with T1D. If successful, studies to evaluate MBX-2982 as a potential preventive therapy for hypoglycemia in patients with T1D may be warranted. The study is being led by the AdventHealth Translational Research Institute in Orlando, Florida and is fully funded by The Leona M. and Harry B. Helmsley Charitable Trust. CymaBay retains full commercial rights to MBX-2982. We believe MBX-2982 may also have utility in various inflammatory diseases and are currently exploring potential opportunities to advance development.

CB-0406

In 2020 we began to evaluate CB-0406, the active metabolite of arhalofenate, a pro-drug previously studied for chronic metabolic diseases, in a single and multiple ascending dose study in healthy subjects to establish its pharmacokinetics, safety and maximum tolerated dose. Decisions on any future development are contingent on it achieving a favorable profile with respect to safety and exposure. We believe CB-0406 may have utility in various inflammatory diseases and are currently exploring potential opportunities to advance development.

COVID-19 Pandemic

In March 2020, the World Health Organization declared the global novel coronavirus disease (COVID-19) outbreak a pandemic. To date, our operations, financial condition and liquidity have not been significantly impacted by the COVID-19 outbreak. However, economic and health conditions in the United States and across most of the globe have changed rapidly since the end of the first quarter of 2020. As a result of the COVID-19 pandemic, we may experience future disruptions that could impact aspects of our business, including our progress towards the initiation and completion of certain clinical studies, and other associated drug development activities. Possible disruptions are currently difficult to foresee. We continue to monitor areas of potential risk, which include but are not limited to the following:

- Remote workforce operations—To date, our workforce has adapted to remotely working to maintain operations. Our increased reliance on personnel working from home could potentially negatively impact future productivity, or disrupt, delay, or otherwise adversely impact our business. In addition, remote operations could increase our cyber-security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations, or delay necessary interactions with regulators, contract manufacturers, contract research organizations, clinical trial sites, and other important agencies and contractors, which may result in increased costs to us.
- Clinical trial and drug manufacturing operations—In collaboration with our clinical research organization partners, we sponsor clinical trials that take place at investigator sites in the United States and internationally. We also partner with contract manufacturing organizations to develop, manufacture, and distribute our product candidate drug supplies. To date, these collective research and development personnel and vendors are adapting to COVID-19 related travel restrictions and reduced access to work facilities through the use of remote working technologies and other measures as they continue to progress toward completion of our existing clinical trials. However, in the future, as we look to enroll and complete the clinical development of seladelpar and initiate other programs, our research and development employees and contractors may not be able to sufficiently access their applicable work facilities as a result of continued facility closure orders and the possibility that governmental authorities might further modify such restrictions. Furthermore, patients we expect to enroll in our future clinical trials may also be impacted by any ongoing travel and facility access restrictions. Although we and our contractors continue to plan for and develop pandemic-related risk mitigation strategies, it is uncertain whether these plans will continue to be sufficient to fully offset the potential impact that travel and facility access restrictions (or other unanticipated impediments) may have on our ability to execute our research and development activities in a timely and cost-effective manner.

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- Drug regulator interactions—The FDA and comparable foreign regulatory agencies may experience operational interruptions or delays, which could impact timelines for regulatory meetings, submissions, trial initiations, and regulatory approvals.
- Financial reporting and compliance—To date, there has been no adverse impact on our ability to maintain our established financial reporting functions and internal controls over financial reporting. However, our ability to prepare our financial results timely and accurately is partially dependent upon the availability of third-party information systems and other cloud-based services. Any degradation in the quality or timeliness of critical third-party information or cloud-based services could adversely impact our financial reporting capabilities.

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

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.

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

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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, 2020 and 2019.

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 the portion that we ultimately expect to vest as an expense over the related vesting periods, net of 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 and forfeitures are account for as they occur.

The Black-Scholes option-pricing model requires the input of certain 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. Prior to 2020, we estimated expected volatility based on our own historical volatility supplemented by a review of historical volatilities of industry peers. Beginning in 2020, we determined our historical stock price data was sufficient to exclusively estimate volatility for awards granted using a volatility measured solely based on our stock price thereafter. The change in estimate did not have a material impact on the Company's estimated fair value of its awards. Due to insufficient historical data of exercise behavior, we have used the "simplified method" to determine the expected life of stock options granted with a service condition. 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, 2020, we have an accumulated deficit of \$676.9 million, primarily as a result of expenditures for research and development and general and administrative expenses from inception to that date. All of our product candidates are at various

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stages of development and will require additional work and regulatory approval before they can be licensed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate sufficient revenue to achieve and sustain profitability. Until we can generate 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.

Operating Results

Our results of operations for the years ended December 31, 2020 and 2019 are presented below (in thousands):

	Year Ended December 31,		Change 2020 vs 2019
	2020	2019	
<i>(\$ in thousands)</i>			
Operating expenses:			
Research and development	\$ 35,882	\$ 83,837	\$ (47,955)
General and administrative	17,425	19,238	(1,813)
Restructuring (benefit) charges	(705)	5,075	(5,780)
Total operating expenses	52,602	108,150	(55,548)
Loss from operations	(52,602)	(108,150)	55,548
Other income:			
Interest income	1,616	5,342	(3,726)
Total other income	1,616	5,342	(3,726)
Net loss	<u>\$(50,986)</u>	<u>\$(102,808)</u>	\$ 51,822

Research & Development Expenses

Conducting research and development is central to our business model. Research and development expenses decreased \$48.0 million to \$35.9 million from \$83.8 million for the years ended December 31, 2020 and 2019, respectively. This decrease was largely due to the shutdown of our ongoing clinical trials after the seladelpar program was placed on clinical hold in late 2019 pending further investigation. This investigation was concluded in the second quarter of 2020, the clinical hold was subsequently lifted in July 2020, and we made the decision to restart development of seladelpar focusing primarily on our late-stage PBC program. We expect that our research and development expenses will increase in the future due to our decision to reinstate development of seladelpar.

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

	Year Ended December 31,		Change 2020 vs 2019
	2020	2019	
Project costs:			
Seladelpar PBC clinical studies	\$15,747	\$37,907	\$ (22,160)
Seladelpar NASH clinical studies	1,429	10,445	(9,016)
Seladelpar PSC clinical studies	196	4,189	(3,993)
Seladelpar drug manufacturing & development	1,332	9,235	(7,903)
Seladelpar other studies	815	2,442	(1,627)
Non-seladelpar studies	3,374	361	3,013
Total project costs	22,893	64,579	(41,686)
Internal research and development costs	12,989	19,258	(6,269)
Total research and development	<u>\$35,882</u>	<u>\$83,837</u>	\$ (47,955)

Our project costs consist primarily of:

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

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

Total project costs decreased by \$41.7 million to \$22.9 million from \$64.6 million for the years ended December 31, 2020 and 2019, respectively. Project costs for the year ended December 31, 2020 primarily consisted of seladelpar-related clinical trial expenses for PBC and NASH. These cost decreases were driven primarily by the decision in the fourth quarter of 2019 to shut down our seladelpar clinical trials and place the development program on clinical hold pending further investigation. Internal research and development costs decreased by \$6.3 million to \$13.0 million from \$19.3 million for the years ended December 31, 2020 and 2019, respectively, primarily due to lower employee compensation incurred in 2020 following the completion of a December 2019 reduction-in-force. As the clinical hold on the seladelpar program was lifted in July 2020 and we made the decision to restart development, we expect both total project and internal costs to increase in the future as we commence new clinical trials and hire additional research personnel.

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. General and administrative expenses decreased by \$1.8 million to \$17.4 million, from \$19.2 million, for the years ended December 31, 2020 and 2019, respectively. The decrease was driven primarily by lower compensation costs incurred following our December 2019 reduction-in-force and was partially offset by the hiring of additional general and administrative personnel in the second of half of 2020 after we made the decision to restart our development activities. We expect general and administrative expenses to increase in the future as we continue to add administrative personnel and expand our infrastructure in support of our drug development activities.

Restructuring (Benefit) Charges

In December 2019, we announced a restructuring plan to reduce our workforce by approximately 60% and took measures to reduce operating expenses following the decision to place the seladelpar program on clinical hold. As a result of these actions, we incurred restructuring charges of \$5.1 million for the year ended December 31, 2019. Restructuring charges incurred consisted of personnel-related costs, including severance costs, employee-related benefits, supplemental one-time termination payments, and non-cash share-based compensation expense related to the acceleration of stock options. Restructuring charges also included contract termination costs associated with contract manufacturing agreements to provide clinical supplies and other vendor arrangements.

For the year ended December 31, 2020 we recorded a restructuring benefit of \$0.7 million. Specifically, we reduced restructuring charges by \$0.5 million to reverse a portion of previously accrued restructuring liabilities associated with severance benefits that were forfeited by certain executives pursuant to the terms of their respective employment agreements. We also reduced restructuring charges by \$0.4 million as a result of contract termination costs that were forgiven as part of a subsequent agreement with a vendor. These expense reversals were offset in part by a \$0.2 million non-cash charge for stock-based compensation expense associated with the acceleration of stock options of a departed executive.

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Substantially all the cash payments we are obligated to make pursuant to our restructuring plan have been paid out through December 31, 2020.

Other Income

Interest income consists of interest income from our marketable securities. Interest income decreased to \$1.6 million from \$5.3 million for the years ended December 31, 2020 and 2019, respectively. The decrease of \$3.7 million was due to lower prevailing interest rates and more conservative positioning of our investment portfolio compared to the prior year. in response to the market volatility created by the COVID-19 pandemic.

Income Taxes

As of December 31, 2020, we had federal net operating loss carryforwards of \$490.4 million and state net operating loss carryforwards of \$288.6 million to offset future taxable income, if any. In addition, we had federal research and development tax credit carryforwards of \$10.1 million, federal orphan drug tax credit carryforwards of \$21.4 million, and state research and development tax credit carryforwards of \$5.8 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 \$234.7 million will be carried forward indefinitely (subject to certain utilization limitations). The state net operating loss carryforwards will expire beginning in 2028 through 2040. The federal research and development and federal orphan drug tax credit carryforwards expire 2021 through 2040, and the state tax credit will carry forward indefinitely. Interest and penalties for the years ended December 31, 2020 and 2019 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, 2020, we recorded a 100% valuation allowance against our deferred tax assets of approximately \$159.1 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, 2020, cash, cash equivalents and marketable securities totaled \$146.3 million, compared to \$190.9 million at December 31, 2019.

Equity Financing

On March 8, 2019, pursuant to a shelf registration statement on Form S-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.

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

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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,	
	2020	2019
Net cash used in operating activities	<u>\$(44,725)</u>	<u>\$(97,911)</u>
Net cash provided by (used in) investing activities	47,957	(34,347)
Cash provided by financing activities	<u>92</u>	<u>108,132</u>
Net increase (decrease) in cash and cash equivalents	<u>\$ 3,324</u>	<u>\$(24,126)</u>

Cash Flows from Operating Activities

Cash used in operating activities for the year ended December 31, 2020 decreased by \$53.2 million to \$44.7 million as compared to \$97.9 million in the prior year. The decrease in cash used was primarily due to a \$51.8 million decrease in our net loss to \$51.0 million from \$102.8 million in the prior year period as a result of our scaled-down operations following the temporary clinical hold placed on our seladelpar development program. This effect was also impacted to a lesser extent by changes in our working capital.

Cash Flows from Investing Activities

Cash provided by investing activities was \$48.0 million for the year ended December 31, 2020 compared to \$34.4 million of cash used in the prior year, primarily due to the timing of making our investments in marketable securities.

Cash Flows from Financing Activities

Cash provided by financing activities was \$0.1 million for the year ended December 31, 2020 compared to \$108.1 million in the prior year. The decrease was primarily due to net proceeds of \$107.7 million received from the March 2019 public offering.

Capital Requirements

We have incurred operating losses since inception and had an accumulated deficit of \$676.9 million at December 31, 2020. As of December 31, 2020, we had cash, cash equivalents and marketable securities of approximately \$146.3 million, which we believe is sufficient to fund our current operating plan into mid-2022.

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

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Off Balance Sheet Arrangements

As of December 31, 2020, we had no off-balance sheet arrangements (as defined in Item 303(a)(4)(ii) of Regulation S-K under the Exchange Act).

Contractual Obligations

Our long-term contractual obligations as of December 31, 2020 primarily include \$1.7 million for our corporate office facility lease, which includes monthly rental payments that are payable through January 2024, the lease termination date. We are also obligated to reimburse the lessor for a prorated portion of monthly facility operating expenses during the lease term.

In addition, we rely on contract research organizations and other research support providers to perform clinical and preclinical studies for us and we contract with firms to supply our drug compounds for use in our development activities. Under the terms of our agreements with these organizations, we are obligated to make future payments as services are provided. However, these agreements are terminable by us upon written notice and we are generally only liable for actual effort expended or cost incurred by the organizations through the termination notice period.

We also have certain potential in-license obligations that are contingently payable by us to licensors upon our achievement of certain development and commercialization milestones for our product candidates.

Finally, in the normal course of business, we enter into various firm purchase commitments and other contractual obligations, which are cancelable within ninety days or less.

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.

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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 consolidated 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, 2020.

On June 28, 2018, the SEC adopted amendments that raise the thresholds in the smaller reporting company, or SRC, definition, whereby we were determined to qualify as an SRC. We elected to reflect that determination and avail ourselves with most of the SRC scaled disclosure accommodations in our filings subsequent to the adoption. On March 12, 2020, the SEC amended its rules to allow SRCs that have less than \$100.0 million in annual revenue and a public float of less than \$700.0 million to qualify as a non-accelerated filer. As a non-accelerated filer, we are not required to obtain an opinion of our independent auditors with respect to our internal controls over financial reporting for the period ended December 31, 2020.

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, 2020, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item with respect to our executive officers is incorporated herein by reference to the information set forth under the caption “Information about our Executive Officers” in Part I of this Annual Report. The information required by this item with respect to our directors is incorporated herein by reference to the information set forth under the caption “Proposal I—Election of Directors” in our proxy statement for our 2021 annual meeting of stockholders, or the 2021 Proxy Statement. The information required by this item with respect to late Section 16 filings, if applicable, is incorporated by reference to the information set forth under the caption “Delinquent Section 16(a) Reports” in the 2021 Proxy Statement. The information required by this item with respect to the committees of our board of directors is incorporated by reference to the information set forth under the caption “Information Regarding the Board of Directors and Corporate Governance—Information Regarding Committees of the Board” in the 2021 Proxy Statement.

If the 2021 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 Form 10-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 Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the address and location specified above.

A copy of our Code of Business Conduct and Ethics can be found on our website, <http://ir.cymabay.com/governance-docs>. The contents of our website are not a part of this Annual Report on Form 10-K.

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

Item 11. Executive Compensation

Reference is made to the information to be included under the heading “Executive Compensation” in our 2021 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 2021 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 2021 Proxy Statement under the caption “Securities Authorized for Issuance under Equity Compensation Plans—Equity Compensation Plan Information” and is incorporated herein by reference.

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

The information required by this item will be set forth in our 2021 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 2021 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 and Financial Statement Schedules*

(a) Documents filed as part of this report

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2. Financial Statement Schedules

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

(b) List of Exhibits

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

<u>Exhibit No.</u>	<u>Description of Document</u>
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	Certificate of Amendment to Amended and Restated Certificate of Incorporation (Filed with the SEC as Exhibit 3.1 to our Current Report on Form 8-K, filed with the SEC on June 26, 2020, SEC File No. 001-36500).
3.3	Amended and Restated By-Laws. (Filed with the SEC as Exhibit 3.2 to our Amendment No. 2 to Registration Statement on Form 10, filed with the SEC on October 17, 2013, SEC File No. 000-55021.)
4.1	Reference is made to Exhibits 3.1 , 3.2 and 3.3 .

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<u>Exhibit No.</u>	<u>Description of Document</u>
4.2	<u>Description of Common Stock.</u>
10.1*	<u>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.)</u>
10.2*	<u>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.)</u>
10.3*	<u>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.)</u>
10.4*	<u>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.)</u>
10.5*	<u>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.)</u>
10.6*	<u>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.)</u>
10.7*	<u>2020 New Hire Plan.</u>
10.8*	<u>Form of Stock Option Grant Notice and Option Agreement under the 2020 New Hire Plan.</u>
10.9	<u>Form of CymaBay Indemnity Agreement. (Filed with the SEC as Exhibit 10.7 to our Form 10-K, filed with the SEC on March 17, 2018, SEC File No 001-36500.)</u>
10.10#	<u>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.)</u>
10.11#	<u>License and Development Agreement, dated June 30, 1998, by and between Metabolex, Inc. and DiaTex, Inc. (Filed with the SEC as Exhibit 10.16 to our Amendment No. 3 to Registration Statement on Form 10, filed with the SEC on November 8, 2013, SEC File No. 000-55021.)</u>
10.12	<u>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.)</u>
10.13	<u>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.)</u>
10.14*	<u>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.)</u>
10.15*	<u>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.)</u>
10.16*	<u>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.)</u>

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<u>Exhibit No.</u>	<u>Description of Document</u>
10.17*	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.)
10.18*	Offer Letter, dated August 27, 2020, between CymaBay Therapeutics, Inc. and Paul Quinlan.
10.19*	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.)
21.1	List of subsidiaries of the Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney. (Incorporated by reference to the signature page of this Annual Report on Form 10-K.)
31.1	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-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.

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Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CymaBay Therapeutics, Inc. (the Company) as of December 31, 2020 and 2019, 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, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. We determined that there are no critical audit matters.

/s/ Ernst & Young LLP

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

Redwood City, California
March 25, 2021

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 28,193	\$ 24,869
Marketable securities	118,130	166,076
Accrued interest receivable	277	687
Prepaid research and development expenses	2,221	9,910
Other prepaid expenses and current assets	2,764	1,381
Total current assets	151,585	202,923
Property and equipment, net	1,761	2,409
Operating lease right-of-use asset	272	235
Other assets	207	160
Total assets	<u>\$ 153,825</u>	<u>\$ 205,727</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 231	\$ 2,503
Accrued research and development expenses	4,698	9,218
Accrued restructuring	18	3,193
Other accrued liabilities	4,910	2,722
Total current liabilities	9,857	17,636
Long-term portion of operating lease liability	1,262	1,743
Total liabilities	11,119	19,379
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, \$0.0001 par value: 200,000,000 shares authorized; 68,946,092 and 68,882,459 shares issued and outstanding as of December 31, 2020 and December 31, 2019, respectively	7	7
Additional paid-in capital	819,549	812,133
Accumulated other comprehensive income	8	80
Accumulated deficit	(676,858)	(625,872)
Total stockholders' equity	142,706	186,348
Total liabilities and stockholders' equity	<u>\$ 153,825</u>	<u>\$ 205,727</u>

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2020	2019
Operating expenses:		
Research and development	\$ 35,882	\$ 83,837
General and administrative	17,425	19,238
Restructuring (benefit) charges	(705)	5,075
Total operating expenses	<u>52,602</u>	<u>108,150</u>
Loss from operations	(52,602)	(108,150)
Other income:		
Interest income	1,616	5,342
Total other income	<u>1,616</u>	<u>5,342</u>
Net loss	<u>\$ (50,986)</u>	<u>\$ (102,808)</u>
Other comprehensive (loss) income:		
Unrealized (loss) gain on marketable securities	(72)	138
Total other comprehensive (loss) income	<u>(72)</u>	<u>138</u>
Comprehensive loss	<u>\$ (51,058)</u>	<u>\$ (102,670)</u>
Basic and diluted net loss per common share	<u>\$ (0.74)</u>	<u>\$ (1.53)</u>
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	68,893,127	67,033,046

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, 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
Issuance of common stock upon exercise of stock options	63,633	—	92	—	—	92
Stock-based compensation expense	—	—	7,324	—	—	7,324
Net loss	—	—	—	—	(50,986)	(50,986)
Net unrealized loss on marketable securities	—	—	—	(72)	—	(72)
Balances as of December 31, 2020	68,946,092	\$ 7	\$ 819,549	\$ 8	\$ (676,858)	\$ 142,706

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2020	2019
Operating activities		
Net loss	\$ (50,986)	\$ (102,808)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	632	572
Stock-based compensation expense	7,135	9,558
Accelerated vesting of stock-based compensation due to restructuring	189	910
Net accretion and amortization of investments in marketable securities	(104)	(2,237)
Changes in assets and liabilities:		
Interest receivable and other current assets	(361)	(383)
Prepaid expenses	7,077	(8,697)
Other assets	(47)	2,120
Accounts payable	(2,272)	530
Accrued restructuring charges	(3,175)	3,193
Accrued liabilities	(2,813)	(669)
Net cash used in operating activities	(44,725)	(97,911)
Investing activities		
Purchases of property and equipment	(21)	(315)
Purchases of marketable securities	(176,300)	(290,893)
Proceeds from maturities of marketable securities	224,278	252,881
Proceeds from sale of marketable securities	—	3,980
Net cash provided by (used in) investing activities	47,957	(34,347)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	—	107,746
Proceeds from issuance of common stock pursuant to equity award plans	92	386
Cash provided by financing activities	92	108,132
Net increase (decrease) in cash and cash equivalents	3,324	(24,126)
Cash and cash equivalents at beginning of period	24,869	48,995
Cash and cash equivalents at end of period	\$ 28,193	\$ 24,869
Supplemental disclosures		
Cash paid for amounts included in the measurement of lease liabilities	\$ 647	\$ 628
Operating lease right-of-use assets obtained in exchange for lease liabilities	\$ —	\$ 152

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. Seladelpar has primarily been under development for the treatment of liver diseases including primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (NASH). The Company was incorporated in Delaware in October 1988 as Transtech Corporation. The Company's headquarters and operations are located in Newark, California and it operates in one segment.

Liquidity

The Company has incurred net operating losses and negative cash flows from operations since its inception. During the year ended December 31, 2020, the Company incurred a net loss of \$51.0 million and used \$44.7 million of cash in operations. At December 31, 2020, the Company had an accumulated deficit of \$676.9 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.

As of December 31, 2020, the Company had cash, cash equivalents and marketable securities totaling \$146.3 million. As the Company continues to advance its clinical studies of seladelpar, cash is considered sufficient to fund the Company's operating plan into mid-2022. The Company has historically obtained, and expects to obtain in the future, additional financing to fund its business strategy through: future equity offerings; debt financing; one or more possible licenses, collaborations or other similar arrangements with respect to development and/or commercialization rights of the Company's product candidates; or a combination of the above. It is unclear if or when any such transactions will occur, on satisfactory terms or at all. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, it could have a material adverse effect on the Company's business, results of operations, and financial condition. Market volatility resulting from the global novel coronavirus disease (COVID-19) pandemic or other factors could also adversely impact our ability to access capital when and as needed. Failure to raise sufficient capital when needed could require us to significantly delay, scale back or discontinue one or more of our product development programs or commercialization efforts or other aspects of our business plans, and our operating results and financial condition would be adversely affected.

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

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.

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. 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, accrued interest receivables, 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, receivables, prepaid expenses, other current assets, accounts payable, and accrued expenses 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.

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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, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	\$22,415	\$ —	\$ —	\$ 22,415
Total cash equivalents	22,415	—	—	22,415
Marketable securities:				
U.S. and foreign commercial paper	—	38,561	—	38,561
U.S. and foreign corporate debt securities	—	29,189	—	29,189
Asset-backed securities	—	7,885	—	7,885
U.S. agency securities	—	23,994	—	23,994
U.S. treasury securities	—	15,499	—	15,499
Supranational debt securities	—	3,002	—	3,002
Total marketable securities	—	118,130	—	118,130
Total assets measured at fair value	<u>\$22,415</u>	<u>\$118,130</u>	<u>\$ —</u>	<u>\$140,545</u>

	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
Marketable securities:				
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 marketable securities	—	166,076	—	166,076
Total assets measured at fair value	<u>\$18,597</u>	<u>\$166,076</u>	<u>\$ —</u>	<u>\$184,673</u>

The Company estimates the fair value of its money market funds, corporate debt, asset backed securities, commercial paper U.S. treasury and agency securities and supranational debt securities by taking into consideration valuations obtained from third-party pricing services. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities, issuer credit spreads; benchmark securities; prepayment/default projections based on historical data; and other observable inputs. See Note 3 for further discussion regarding the carrying value of the Company's financial instruments.

Cash, Cash Equivalents, and Marketable Securities

The Company considers all highly liquid investments with an 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, and money market funds.

The Company invests excess cash in marketable securities with high credit ratings that are classified in Level 1 or Level 2 of the fair value hierarchy. These securities consist primarily of corporate debt, commercial paper, asset-backed securities, U.S. treasury and agency securities and supranational debt securities and are

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classified as “available-for-sale.” The Company considers marketable securities as short-term investments if the maturity date is less than or equal to one year from the balance sheet date. The Company considers marketable securities as long-term investments if the maturity date is in excess of one year from the balance sheet date.

Realized gains and losses from the sale of marketable securities, if any, are calculated using the specific-identification method. Realized gains and losses and declines in value judged to be other-than-temporary are included in interest income or expense in the 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, which are 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, including right-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 office. 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 sheets at December 31, 2020 and 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. The Company does not record leases on our consolidated balance sheets when a lease has a term of one year or less.

Research and Development Expenses

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

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

Restructuring Charges

The Company recognizes restructuring charges related to reorganization plans that have been committed to by management and when 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

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

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.

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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.

In March 2020, the Families First Coronavirus Response Act (FFCR Act) and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) were each enacted in response to the COVID-19 pandemic. The FFCR Act and the CARES Act contain numerous income tax provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations and technical corrections to tax depreciation methods for qualified improvement property.

In June 2020, Assembly Bill 85 (A.B. 85) was signed into California law. A.B. 85 provides for a three-year suspension of the use of net operating losses for medium and large businesses and a three-year cap on the use of business incentive tax credits to offset no more than \$5.0 million of tax per year. A.B. 85 suspends the use of net operating losses for taxable years 2020, 2021 and 2022 for certain taxpayers with taxable income of \$1.0 million or more. The carryover period for any net operating losses that are suspended under this provision will be extended. A.B. 85 also requires that business incentive tax credits including carryovers may not reduce the applicable tax by more than \$5.0 million for taxable years 2020, 2021 and 2022.

In December 2020, the Consolidated Appropriations Act, 2021 (CAA) was signed into law. The CAA included additional funding through tax credits as part of its economic package for 2021.

The FFCR Act, CARES Act, A.B. 85 and CAA did not have a material impact on the Company's consolidated financial statements; however, the Company continues to examine the impacts the FFCR Act, CARES Act, A.B. 85 and CAA may have on its business, results of operations, financial condition and liquidity.

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, if dilutive. 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.

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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,	
	2020	2019
Numerator:		
Net loss	\$ (50,986)	\$ (102,808)
Denominator:		
Weighted average number of common stock shares outstanding	68,893,127	67,033,046
Net loss per share	\$ (0.74)	\$ (1.53)

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,	
	2020	2019
Common stock options	8,812	6,727
Incentive awards	101	101
Total	8,913	6,828

Recently Adopted Accounting Pronouncements

ASU 2018-18

In November 2018, the FASB issued ASU2018-18, 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 became effective for the Company on January 1, 2020. The adoption of this standard did not have a material impact on its consolidated financial statements.

ASU 2018-15

In August 2018, the FASB issued ASUNo. 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 became effective for the Company on January 1, 2020. The adoption of this standard did not have a material impact on its consolidated financial statements.

ASU 2018-13

In August 2018, the FASB issued ASU2018-13, 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 became effective for the Company on January 1, 2020. The adoption of this standard did not have a material impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements

ASU 2016-13

In June 2016, the FASB issued ASUNo. 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.

ASU 2019-12

In December 2019, the FASB issued ASU2019-12, Income Taxes (Topic 740): *Simplifying the Accounting for Income Taxes*, which removes certain exceptions to the general principles in Topic 740 related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The new guidance also simplifies aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The guidance is effective for the Company for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently assessing the impact of this standard but does not believe it will have a material effect on its consolidated financial statements and related disclosures.

3. Marketable Securities

Marketable available-for-sale securities consist of the following (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2020:				
Cash equivalents:				
Money market funds	\$ 22,415	\$ —	\$ —	\$ 22,415
Total cash equivalents	22,415	—	—	22,415
Short-term investments:				
U.S. and foreign commercial paper	38,561	—	—	38,561
U.S. and foreign corporate debt securities	29,186	7	(4)	29,189
Asset-backed securities	7,883	2	—	7,885
U.S. treasury securities	23,991	3	—	23,994
U.S. agency securities	15,498	1	—	15,499
Supranational debt securities	3,003	—	(1)	3,002
Total short-term investments	118,122	13	(5)	118,130
Total marketable securities	<u>140,537</u>	<u>13</u>	<u>(5)</u>	<u>140,545</u>

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	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
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	<u>184,593</u>	<u>80</u>	<u>—</u>	<u>184,673</u>

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. The Company's government securities are issued by the U.S. treasury and certain U.S. government-backed agencies. Supranational debt securities consist of securities issued with funding from various national governments, including the U.S.

As of December 31, 2020 and 2019, the remaining contractual maturities of the Company's commercial paper, corporate debt securities, asset-backed securities, U.S. treasury and agency securities and supranational debt securities were less than 1 year. There were no realized gains and losses for the years ended December 31, 2020 and 2019. None of these investments have been in a continuous unrealized loss position for more than 12 months as of December 31, 2020 and 2019.

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

4. Certain Balance Sheet Items

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

	December 31,	
	2020	2019
Leasehold improvements	\$ 2,430	\$2,430
Office and computer equipment	290	290
Purchased software	44	44
Furniture and fixtures	451	430
Total	3,215	3,194
Less: Accumulated depreciation and amortization	(1,454)	(785)
Property and equipment, net	<u>\$ 1,761</u>	<u>\$2,409</u>

Depreciation and amortization expense for the years ended December 31, 2020 and 2019 was approximately \$0.6 million and \$0.6 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. All of our property and equipment is located in the U.S.

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

	December 31,	
	2020	2019
Accrued compensation	\$3,769	\$2,013
Accrued professional fees and other	659	302
Current portion of operating lease liability	482	407
Total other accrued liabilities	<u>\$4,910</u>	<u>\$2,722</u>

5. License Agreements

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 8.0% 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, 2020 and 2019.

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, 2020 and 2019 and no royalties have been paid to date.

6. 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, 2020 and 2019. 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.

Genfit Litigation

On January 15, 2021, Genfit S.A. (Genfit) filed a complaint against the Company in the U.S. District Court for the Northern District of California, alleging misappropriation of trade secrets and related causes of action based on the Company's receipt of a Genfit protocol synopsis for Genfit's Phase 3 clinical trial of its drug candidate elafibranor in patients with PBC. The Complaint seeks damages in an unspecified amount as well as injunctive relief. The Company has stated in pleadings that it did not request or take any steps to obtain Genfit's protocol synopsis, has taken diligent steps to remove and quarantine it, and it is not using any Genfit trade secrets in the Company's own clinical trials. The Company intends to defend itself vigorously and does not believe that the ultimate outcome of this matter as a loss is probable nor that any amount is reasonably estimable.

7. 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, 2020 and December 31, 2019, the Company's lease portfolio had a weighted average remaining term of 3.1 years, and 4.1 years, respectively, 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.

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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, 2020 and December 31, 2019 was 12.6% and 12.6%, respectively.

For the years ended December 31, 2020 and 2019, the Company incurred \$0.5 million and \$0.5 million, respectively, of lease costs included in operating expenses in the consolidated statements of operations and comprehensive loss 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, 2020, and December 31, 2019, the Company's operating lease right-of-use asset totaled \$0.3 million and \$0.2 million, respectively, and the operating lease liability totaled \$1.7 million and \$2.1 million, respectively. The short-term portion of the operating lease liability was \$0.5 million and is contained within other accrued liabilities on the balance sheet, with the remaining \$1.2 million liability reported on the balance sheet as long-term portion of operating lease liability.

As of December 31, 2020, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year ending December 31,	
2021	667
2022	686
2023	707
2024	30
Total undiscounted future minimum lease payments	\$ 2,090
Less: imputed interest	346
Total operating lease liability	\$ 1,744
Less: current portion of operating lease liability	482
Long-term portion of lease liability	<u>\$ 1,262</u>

8. Stockholders' Equity

The Company is authorized to issue 10,000,000 shares of preferred stock as of December 31, 2020 and 2019, and 200,000,000 and 100,000,000 shares of common stock as of December 31, 2020 and 2019, respectively.

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

The Company had reserved shares of authorized but unissued common stock as follows:

	December 31,	
	2020	2019
2013 Plan	9,080,230	9,143,863
2020 Plan	750,000	—
Total reserved shares of common stock	<u>9,830,230</u>	<u>9,143,863</u>

Sale of Common Stock

On March 8, 2019, pursuant to a shelf registration statement on FormS-3, the Company issued 8,000,000 shares of its common stock at \$2.50 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.

9. Stock Plans and Stock-Based Compensation

Stock Plans

In September 2013, the Company's stockholders approved the 2013 Equity Incentive Plan (the 2013 Plan), under which shares of common stock are reserved for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance stock awards, performance cash awards and other stock awards by the Company. These awards may be granted to employees, members of the Board of Directors, and consultants. The 2013 Plan has a term of ten years and replaced the 2003 Equity Incentive Plan, which had similar terms. The 2013 Plan permits the Company to (i) grant incentive stock options to directors and employees at not less than 100% of the fair value of common stock on the date of grant; (ii) grant nonqualified options to employees, directors, and consultants at not less than 85% of fair value; (iii) award stock bonuses; and (iv) grant rights to acquire restricted stock at not less than 85% of fair value. Options generally vest over a four year period and have a term of ten years. Options granted to 10% stockholders have a maximum term of five years and require an exercise price equal to at least 110% of the fair value on the date of grant. The exercise price of all options granted to date has been at least equal to the fair value of common stock on the date of grant. Stock option exercises are settled with shares reserved under the 2013 Plan. The share reserve under the 2013 Plan will automatically increase on January 1st of each year, for a period of not more than ten years, in an amount equal to 5% of the total number of shares of capital stock outstanding on December 31st of the preceding calendar year, unless the Board determines otherwise prior to December 31st of such calendar year.

In October 2020, the Company's board of directors approved the 2020 New Hire Plan (the 2020 Plan), under which shares of common stock are reserved for the granting of 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 as an inducement to prospective new hire employees of the Company. The 2020 Plan has a term of ten years. The 2020 Plan permits the Company to (i) grant nonqualified options to new hire employees at not less than 85% of fair value; (ii) award stock bonuses; and (iii) grant rights to acquire restricted stock at not less than 85% of fair value. Options generally vest over a four year period and have a term of ten years. The share reserve under the 2020 may be increased at the discretion of and approval by the board of directors. No options have been granted to date.

Stock Plan Activity

As of December 31, 2020, there were 167,159 shares available for grant under the 2013 Plan and an additional 750,000 shares which are available for grant under the 2020 Plan, which was approved during the year ended December 31, 2020, for a total of 917,159 shares available for grant under both plans as of December 31, 2020.

In December 2020, the Board of Directors reduced the automatic share increase in the 2013 Plan share reserve that was to take place on January 1, 2021 from 5% to 4% of common shares outstanding as of December 31, 2020, thereby adding an additional 2,757,843 shares to 2013 Plan share reserve.

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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, 2019	6,726,695	\$ 7.88		
Options granted	3,611,593	4.84		
Options exercised	(63,633)	1.44		
Options forfeited	(492,931)	11.46		
Options expired	(970,094)	9.02		
Outstanding as of December 31, 2020	<u>8,811,630</u>	\$ 6.35	7.60	\$ 9,507
Vested and expected to vest as of December 31, 2020	<u>8,811,630</u>	6.35	7.60	\$ 9,507
Exercisable as of December 31, 2020	<u>4,789,242</u>	\$ 6.57	6.49	\$ 5,734

The total intrinsic value of options exercised was \$0.4 million and \$0.4 million for the years ended December 31, 2020 and 2019, respectively.

The total fair value of options vested was \$3.3 million and \$9.9 million for the years ended December 31, 2020 and 2019, respectively.

As of December 31, 2020, unamortized stock-based compensation expense of \$17.9 million is expected to be recognized over a weighted average period of 2.8 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 \$.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 years ended December 31, 2020 and 2019 pertaining to its incentive awards. Incentive awards outstanding totaled 101,441 as of December 31, 2020 and 2019, respectively.

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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,	
	2020	2019
Research and development	\$ 2,739	\$ 4,361
General and administrative	4,396	5,197
Restructuring charges	189	910
Total stock-based compensation expense	<u>\$ 7,324</u>	<u>\$ 10,468</u>

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,	
	2020	2019
Expected term (years)	6.1	6.2
Expected volatility	105%	76%
Risk-free interest rate	0.4%	2.1%
Expected dividend yield	—	—
Weighted-average grant date fair value per share	\$3.91	\$5.60

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, 2020 and 2019, the Company has elected 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 had limited trading history for its common stock, the expected stock price volatility for the Company's common stock was estimated historically by considering the volatility rates of similar publicly traded peer entities within the life sciences industry prior to 2020 in a blended volatility methodology which weighted our own historical volatility as well as the historical volatility of the peer entities over a period commensurate with the expected term of the awards granted during the year. In 2020, the Company determined its historical stock price data was sufficient to exclusively estimate volatility thereafter. The change in estimate did not have a material impact on the Company's estimated fair value of its awards.

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.

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Expected Dividend Yield

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

10. 401(k) Plan

The Company provides a qualified 401(k) savings plan for its employees. All employees are eligible to participate, provided they meet the requirements of the plan. As is permitted under the plan, 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, 2020 and 2019.

11. Income Taxes

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

	December 31,	
	2020	2019
Deferred tax assets:		
Federal and state net operating loss carryforwards	\$ 123,144	\$ 107,213
State and federal research and development tax credit carryforwards	28,861	25,661
Capitalized research and development	2,363	4,725
Stock-based compensation	3,822	3,562
Other	1,256	1,199
Total deferred tax assets	159,446	142,360
Deferred tax liabilities:		
Depreciation and amortization	(269)	(372)
Other	(57)	(49)
Total deferred tax liabilities	(326)	(421)
Valuation allowance	(159,120)	(141,939)
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 \$17.2 million and \$23.6 million due to the increase in the Company's taxable losses during the years ended December 31, 2020 and 2019, respectively.

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

	December 31,	
	2020	2019
Income tax benefit at federal statutory tax rate	\$(10,707)	\$(21,589)
Change in valuation allowance	17,181	23,587
State income taxes, net of federal benefit	(4,768)	3,810
Research credits	(2,911)	(6,555)
Cancelled options	982	315
Other	223	432
Income tax (benefit) expense	\$ —	\$ —

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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, 2020 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, 2020, the Company had federal net operating loss carryforwards of \$490.4 million and state net operating loss carryforwards of \$288.6 million to offset future taxable income, if any. In addition, the Company had federal research and development tax credit carryforwards of \$10.1 million, federal orphan drug tax credit carryforwards of \$21.4 million, and state research and development tax credit carryforwards of \$5.8 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 \$234.7 million will be carried forward indefinitely (subject to certain utilization limitations). The state net operating loss carryforwards will expire beginning in 2028 through 2040. The federal research and development and federal orphan drug tax credit carryforwards expire 2021 through 2040, and the state tax credit will carry forward indefinitely. Interest and penalties for the years ended December 31, 2020 and 2019 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, 2018	\$4,584
Increases related to prior year tax positions	83
Increases related to 2019 tax positions	<u>1,719</u>
Balances as of December 31, 2019	6,386
Decreases related to prior year tax positions	(58)
Increases related to 2020 tax positions	<u>877</u>
Balances as of December 31, 2020	<u>\$7,205</u>

The unrecognized tax benefits, if recognized, would not have an impact on the Company's effective tax rate assuming the Company continues to maintain a full valuation allowance position. Based on prior year's operations and experience, the Company does not expect a significant change to its unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may increase or change during the next year for unexpected or unusual items for items that arise in the ordinary course of business.

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

12. 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 2019 announcement that it had halted clinical development of seladelpar. The restructuring liability is included in current liabilities on the consolidated balance sheets. The Company incurred restructuring charges of \$5.1 million for the year ended December 31, 2019 and a restructuring benefit of \$0.7 million for the year ended December 31, 2020.

Restructuring charges incurred under this plan primarily consisted of employee termination benefits and contract termination costs 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.

The following table summarizes the accrued restructuring liabilities and utilization by cost type associated with the restructuring activities (in thousands):

	<u>Termination Benefits</u>	<u>Contract Termination Costs</u>	<u>Total</u>
Balances as of December 31, 2018	\$ —	\$ —	\$ —
Restructuring charges	2,912	413	3,325
Reductions for cash payments	(132)	—	(132)
Balances as of December 31, 2019	2,780	413	3,193
Change in estimates	(539)	(413)	(952)
Reductions for cash payments	(2,223)	—	(2,223)
Balances as of December 31, 2020	<u>\$ 18</u>	<u>\$ —</u>	<u>\$ 18</u>

In addition to the activity in the above table, during the year ended December 31, 2019, 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 to be delivered and \$0.9 million of accelerated vesting for stock-based compensation for executives subject to the reorganization plan.

During the year ended December 31, 2020, the activity in the table above reflects a \$0.5 million reversal of severance liabilities associated with severance benefits that were forfeited by certain executives pursuant to the terms of their respective employment agreements, and a reversal of \$0.4 million of contract termination costs resulting from a subsequent arrangement between the Company and the vendor to waive these costs. In addition to the activity in the above table, during the year ended December 31, 2020, the Company also recognized in restructuring charges \$0.2 million of non-cash, stock-based compensation associated with the acceleration of stock options of a departed executive.

Substantially all the cash payments the Company is obligated to make pursuant to its restructuring plan were paid during 2020.

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 25, 2021	<u>/s/ Sujal Shah</u>
Date	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:

<u>Name and Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Sujal Shah</u> Sujal Shah	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	March 25, 2021
<u>/s/ Daniel Menold</u> Daniel Menold	Vice President, Finance <i>(Principal Financial and Accounting Officer)</i>	March 25, 2021
<u>/s/ Robert J. Wills</u> Robert J. Wills, Ph.D.	Director	March 25, 2021
<u>/s/ Kurt von Emster</u> Kurt von Emster, CFA	Director	March 25, 2021
<u>/s/ Caroline Loewy</u> Caroline Loewy	Director	March 25, 2021
<u>/s/ Paul F. Truex</u> Paul F. Truex	Director	March 25, 2021

DESCRIPTION OF COMMON STOCK

Our authorized capital stock consists of 200,000,000 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 certificate of incorporation, including provisions relating to amending our 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 certificate of incorporation and 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 certificate of incorporation and 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 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 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 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 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;

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- 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.

CYMABAY THERAPEUTICS, INC.

2020 NEW HIRE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: OCTOBER 21, 2020

1. GENERAL.

(a) Eligible Award Recipients. The only persons eligible to receive grants of Awards under this Plan are individuals who satisfy the standards for grants under Nasdaq Listing Rule 5635(c)(4) or 5635(c)(3), if applicable, and the related guidance under Nasdaq IM 5635-1. A person who previously served as an Employee or Director will not be eligible to receive Awards under the Plan, other than following a *bona fide* period of non-employment. Persons eligible to receive grants of Awards under this Plan are referred to in this Plan as “*Eligible Employees*.” These Awards must be approved by either a majority of the Company’s “*Independent Directors*” (as such term is defined in Nasdaq Listing Rule 5605(a)(2)) or the Company’s compensation committee, provided such committee comprises solely Independent Directors (the “*Independent Compensation Committee*”) in order to comply with the exemption from the stockholder approval requirement for grants provided under Rule 5635(c)(4) of the Nasdaq Listing Rules. Nasdaq Listing Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1 (together with any analogous rules or guidance effective after the date hereof, the “*Nasdaq Award Rules*”).

(b) Available Awards. The Plan provides for the grant of the following Awards: (i) Options, (ii) Stock Appreciation Rights, (iii) Restricted Stock Awards, (iv) Restricted Stock Unit Awards, (v) Performance Stock Awards, and (vi) Other Stock Awards. All Options shall be Nonstatutory Stock Options.

(c) Purpose. The Plan, through the grant of Awards, is intended to (i) satisfy the requirements for certain individuals to enter into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules, (ii) incentivize such persons to exert maximum efforts for the success of the Company and any Affiliate and (iii) be a means by which Eligible Employees may be given an opportunity to benefit from increases in value of the Common Stock.

2. ADMINISTRATION.

(a) Administration by Board. The Board will administer the Plan; *provided, however*, that Awards may only be granted by either (i) a majority of the Company’s Independent Directors or (ii) the Independent Compensation Committee. Subject to those constraints and the other constraints of the Nasdaq Award Rules, the Board may delegate some of its powers of administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) Powers of Board. The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan and the Nasdaq Award Rules:

(i) To determine: (A) who will be granted Awards; (B) when and how each Award will be granted; (C) what type of Award will be granted; (D) the provisions of each Award (which need not be identical), including when a person will be permitted to exercise or otherwise receive cash or Common Stock under the Award; (E) the number of shares of Common Stock subject to, or the cash value of, an Award; and (F) the Fair Market Value applicable to an Award; *provided, however*, that Awards may only be granted by either (i) a majority of the Company's Independent Directors or (ii) the Independent Compensation Committee.

(ii) To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for administration of the Plan and Awards. The Board, in the exercise of these powers, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it will deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards granted under it.

(iv) To accelerate, in whole or in part, the time at which an Award may be exercised or vest (or the time at which cash or shares of Common Stock may be issued in settlement thereof).

(v) To suspend or terminate the Plan at any time. Except as otherwise provided in the Plan or an Award Agreement, suspension or termination of the Plan will not materially impair a Participant's rights under the Participant's then-outstanding Award without the Participant's written consent, except as provided in subsection (viii) below.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, by adopting amendments relating to certain nonqualified deferred compensation under Section 409A of the Code and/or to ensure the Plan or Awards granted under the Plan are exempt from, or compliant with, the requirements for nonqualified deferred compensation under Section 409A of the Code, subject to the limitations, if any, of applicable law. Except as provided in Section 9(a) relating to Capitalization Adjustments, if required by applicable law or listing requirements, the Company shall seek stockholder approval for any amendment of the Plan. Except as otherwise provided in the Plan or an Award Agreement, no amendment of the Plan will materially impair a Participant's rights under an outstanding Award without the Participant's written consent.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided, however*, that a Participant's rights under any Award will not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, (1) a Participant's rights will not be deemed to have been impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant's rights, and (2) subject to the limitations of applicable law, if any, the Board may amend the terms of any one or more Awards without the affected Participant's consent (A) to clarify the manner of exemption from, or to bring the Award into compliance with, Section 409A of the Code; or (B) to comply with other applicable laws or listing requirements.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Eligible Employees who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement that are required for compliance with the laws of the relevant foreign jurisdiction).

(c) Delegation to Committee.

(i) **General.** Subject to the terms of Section 4(b), the Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee, as applicable). Any delegation of administrative powers will be reflected in resolutions, not inconsistent with the provisions of the Plan, adopted from time to time by the Board or Committee (as applicable). The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revert in the Board some or all of the powers previously delegated.

(ii) **Rule 16b-3 Compliance.** The Committee may consist solely of two or more Non-Employee Directors, in accordance with Rule 16b-3.

(d) **Effect of Board's Decision.** All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

(e) **Repricing; Cancellation and Re-Grant of Awards.** Neither the Board nor any Committee will have the authority to reduce the exercise, purchase or strike price of any outstanding Option or SAR, unless the stockholders of the Company have approved such an action within twelve (12) months prior to such an event.

3. SHARES SUBJECT TO THE PLAN.

(a) **Share Reserve.** Subject to Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Awards will not exceed 750,000 shares. Shares may be issued in connection with a merger or acquisition as permitted by Nasdaq Listing Rule 5635(c) or, if applicable NYSE Listed Company Manual Section 303A.08, AMEX Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

(b) Reversion of Shares to the Share Reserve. If a Stock Award or any portion thereof (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (*i.e.*, the Participant receives cash rather than stock), such expiration, termination or settlement will not reduce (or otherwise offset) the number of shares of Common Stock that may be available for issuance under the Plan. If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares that are forfeited or repurchased will revert to and again become available for issuance under the Plan. Any shares reacquired by the Company in satisfaction of tax withholding obligations on a Stock Award or as consideration for the exercise or purchase price of a Stock Award will again become available for issuance under the Plan.

(c) Source of Shares. The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

4. ELIGIBILITY.

(a) Eligibility for Specific Stock Awards. Stock Awards may only be granted to persons who are Eligible Employees described in Section 1(a) of the Plan, where the Stock Award is granted in connection with the individual's entering into employment with the Company or an Affiliate in a manner that fits within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules or is otherwise permitted pursuant to Rule 5635(c) of the Nasdaq Listing Rules, *provided, however*, that Stock Awards may not be granted to Eligible Employees who are providing Continuous Service only to any "parent" of the Company, as such term is defined in Rule 405 of the Securities Act, unless (i) the stock underlying such Stock Awards is treated as "service recipient stock" under Section 409A of the Code (for example, because the Stock Awards are granted pursuant to a corporate transaction such as a spin off transaction), (ii) the Company, in consultation with its legal counsel, has determined that such Stock Awards are otherwise exempt from Section 409A of the Code, or (iii) the Company, in consultation with its legal counsel, has determined that such Stock Awards comply with the distribution requirements of Section 409A of the Code.

(b) Approval Requirements. All Stock Awards must be granted either by a majority of the Company's independent directors or the Independent Compensation Committee.

5. PROVISIONS RELATING TO OPTIONS AND STOCK APPRECIATION RIGHTS.

Each Option or SAR will be in such form and will contain such terms and conditions as the Board deems appropriate. All Options will be Nonstatutory Stock Options at the time of grant. The provisions of separate Options or SARs need not be identical; *provided, however*, that each Award Agreement will conform to (through incorporation of provisions hereof by reference in the applicable Award Agreement or otherwise) the substance of each of the following provisions:

(a) Term. No Option or SAR will be exercisable after the expiration of ten years from the date of its grant or such shorter period specified in the Award Agreement.

(b) Exercise Price. The exercise or strike price of each Option or SAR will be not less than 100% of the Fair Market Value of the Common Stock subject to the Option or SAR on the date the Award is granted. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value of the Common Stock subject to the Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Section 409A of the Code. Each SAR will be denominated in shares of Common Stock equivalents.

(c) Purchase Price for Options. The purchase price of Common Stock acquired pursuant to the exercise of an Option may be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by any combination of the methods of payment set forth below. The Board will have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to use a particular method of payment. The permitted methods of payment are as follows:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company will accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued. Shares of Common Stock will no longer be subject to an Option and will not be exercisable thereafter to the extent that (A) shares issuable upon exercise are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board and specified in the applicable Award Agreement.

(d) Exercise and Payment of a SAR. To exercise any outstanding SAR, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such SAR. The appreciation distribution payable on the exercise of a SAR will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the SAR) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such SAR, and with respect to which the Participant is exercising the SAR on such date, over (B) the aggregate strike price of the number of Common Stock equivalents with respect to which the Participant is exercising the SAR on such date. The appreciation distribution may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Award Agreement evidencing such SAR.

(e) Transferability of Options and SARs. The Board may, in its sole discretion, impose such limitations on the transferability of Options and SARs as the Board will determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options and SARs will apply:

(i) Restrictions on Transfer. An Option or SAR will not be transferable except by will or by the laws of descent and distribution (or pursuant to subsections (ii) and (iii) below), and will be exercisable during the lifetime of the Participant only by the Participant. The Board may permit transfer of the Option or SAR in a manner that is not prohibited by applicable tax and securities laws. Except as explicitly provided in the Plan, neither an Option nor a SAR may be transferred for consideration.

(ii) Domestic Relations Orders. Subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument.

(iii) Beneficiary Designation. Subject to the approval of the Board or a duly authorized Officer, a Participant may, by delivering written notice to the Company, in a form approved by the Company (or the designated broker), designate a third party who, on the death of the Participant, will thereafter be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, upon the death of the Participant the executor or administrator of the Participant's estate will be entitled to exercise the Option or SAR and receive the Common Stock or other consideration resulting from such exercise. However, the Company may prohibit designation of a beneficiary at any time, including due to any conclusion by the Company that such designation would be inconsistent with the provisions of applicable laws.

(f) Vesting Generally. The total number of shares of Common Stock subject to an Option or SAR may vest and become exercisable in periodic installments that may or may not be equal. The Option or SAR may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options or SARs may vary. The provisions of this Section(f) are subject to any Option or SAR provisions governing the minimum number of shares of Common Stock as to which an Option or SAR may be exercised.

(g) Termination of Continuous Service. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates (other than for Cause and other than upon the Participant's death or Disability), the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Award as of the date of termination of Continuous Service) within the period of time ending on the earlier of (i) the date which occurs

three (3) months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the applicable Award Agreement), and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR (as applicable) within the applicable time frame, the Option or SAR will terminate.

(h) Extension of Termination Date. If the exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause and other than upon the Participant's death or Disability) would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option or SAR will terminate on the earlier of (i) the expiration of a total period of time (that need not be consecutive) equal to the applicable post termination exercise period after the termination of the Participant's Continuous Service during which the exercise of the Option or SAR would not be in violation of such registration requirements, and (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement. In addition, unless otherwise provided in a Participant's Award Agreement, if the sale of any Common Stock received on exercise of an Option or SAR following the termination of the Participant's Continuous Service (other than for Cause) would violate the Company's insider trading policy, then the Option or SAR will terminate on the earlier of (i) the expiration of the period of days or months (that need not be consecutive) equal to the applicable post-termination exercise period after the termination of the Participant's Continuous Service during which the sale of the Common Stock received upon exercise of the Option or SAR would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Option or SAR as set forth in the applicable Award Agreement.

(i) Disability of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if a Participant's Continuous Service terminates as a result of the Participant's Disability, the Participant may exercise his or her Option or SAR (to the extent that the Participant was entitled to exercise such Option or SAR as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date which occurs 12 months following such termination of Continuous Service (or such longer or shorter period specified in the Award Agreement) and (ii) the expiration of the term of the Option or SAR as set forth in the Award Agreement. If, after termination of Continuous Service, the Participant does not exercise his or her Option or SAR within the applicable time frame, the Option or SAR (as applicable) will terminate.

(j) Death of Participant. Except as otherwise provided in the applicable Award Agreement or other agreement between the Participant and the Company, if (i) a Participant's Continuous Service terminates as a result of the Participant's death, or (ii) the Participant dies within the period (if any) specified in the Award Agreement for exercisability after the termination of the Participant's Continuous Service for a reason other than death, then the Option or SAR may be exercised (to the extent the Participant was entitled to exercise such Option or SAR as of the date of death) by the Participant's estate, by a person who acquired the right to exercise the Option or SAR by bequest or inheritance or by a person designated to exercise the Option or SAR upon the Participant's death, but only within the period ending on the earlier of (i) the date which occurs 18 months following the date of death (or such longer or shorter period specified in the Award Agreement) and (ii) the expiration of the term of such Option or SAR as set forth in the Award Agreement. If, after the Participant's death, the Option or SAR is not exercised within the applicable time frame, the Option or SAR (as applicable) will terminate.

(k) Termination for Cause. Except as explicitly provided otherwise in a Participant's Award Agreement or other individual written agreement between the Company or any Affiliate and the Participant, if a Participant's Continuous Service is terminated for Cause, the Option or SAR will terminate immediately upon such Participant's termination of Continuous Service, and the Participant will be prohibited from exercising his or her Option or SAR from and after the date of such termination of Continuous Service.

(l) Non-Exempt Employees. If an Option or SAR is granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, the Option or SAR will not be first exercisable for any shares of Common Stock until at least six months following the date of grant of the Option or SAR (although the Award may vest prior to such date). Consistent with the provisions of the Worker Economic Opportunity Act, (i) if such non-exempt Employee dies or suffers a Disability, (ii) upon a Corporate Transaction in which such Option or SAR is not assumed, continued, or substituted, (iii) upon a Change in Control, or (iv) upon the Participant's retirement (as such term may be defined in the Participant's Award Agreement in another agreement between the Participant and the Company, or, if no such definition, in accordance with the Company's then current employment policies and guidelines), the vested portion of any Options and SARs may be exercised earlier than six months following the date of grant. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay. To the extent permitted and/or required for compliance with the Worker Economic Opportunity Act to ensure that any income derived by a non-exempt employee in connection with the exercise, vesting or issuance of any shares under any other Stock Award will be exempt from the employee's regular rate of pay, the provisions of this Section 5(l) will apply to all Stock Awards and are hereby incorporated by reference into such Stock Award Agreements.

6. PROVISIONS OF STOCK AWARDS OTHER THAN OPTIONS AND SARs.

(a) Restricted Stock Awards. Each Restricted Stock Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. To the extent consistent with the Company's bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (y) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical. Each Restricted Stock Award Agreement will conform to (through incorporation of the provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) cash, check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of legal consideration (including future services) that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. Shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant's Continuous Service. If a Participant's Continuous Service terminates, the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement will be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board will determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(v) Dividends. A Restricted Stock Award Agreement may provide that any dividends paid on Restricted Stock will be subject to the same vesting and forfeiture restrictions as apply to the shares subject to the Restricted Stock Award to which they relate.

(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement will be in such form and will contain such terms and conditions as the Board will deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical. Each Restricted Stock Unit Award Agreement will conform to (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board, in its sole discretion, and permissible under applicable law.

(ii) Vesting. At the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions on or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Dividend Equivalents. Dividend equivalents may be credited in respect of shares of Common Stock covered by a Restricted Stock Unit Award, as determined by the Board and contained in the Restricted Stock Unit Award Agreement. At the sole discretion of the Board, such dividend equivalents may be converted into additional shares of Common Stock covered by the Restricted Stock Unit Award in such manner as determined by the Board. Any additional shares covered by the Restricted Stock Unit Award credited by reason of such dividend equivalents will be subject to all of the same terms and conditions of the underlying Restricted Stock Unit Award Agreement to which they relate.

(vi) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(c) Performance Awards.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award that is payable (including that may be granted, may vest or may be exercised) contingent upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may, but need not, require the Participant's completion of a specified period of Continuous Service. The length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained will be conclusively determined by the Board, in its sole discretion. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board may determine that cash may be used in payment of Performance Stock Awards.

(ii) Discretion. A majority of the Company's Independent Directors or the Independent Compensation Committee retains the discretion to adjust or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for a Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement.

(d) Other Stock Awards. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value of the Common Stock at the time of grant) may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan, a majority of the Company's Independent Directors or the Independent Compensation Committee will have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. COVENANTS OF THE COMPANY.

(a) Availability of Shares. The Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy then-outstanding Awards.

(b) Securities Law Compliance. The Company will seek to obtain from each regulatory commission or agency having jurisdiction over the Plan, such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided, however,* that this undertaking will not require the Company to register under the Securities Act, the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained. A Participant will not be eligible for the grant of an Award or the subsequent issuance of cash or Common Stock pursuant to the Award if such grant or issuance would be in violation of any applicable securities law.

(c) No Obligation to Notify or Minimize Taxes. The Company will have no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company will have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award.

8. MISCELLANEOUS.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Awards will constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Awards. Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action constituting the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the papering of the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

(c) Stockholder Rights. No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to an Award unless and until (i) such Participant has satisfied all requirements for exercise of, or the issuance of shares of Common Stock under, the Award pursuant to its terms, and (ii) the issuance of the Common Stock subject to such Award has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or will affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(e) Change in Time Commitment. In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board has the right in its sole discretion to (x) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (y) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

(f) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that such Participant is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, will be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(g) Withholding Obligations. Unless prohibited by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; *provided, however*, that no shares of Common Stock are withheld with a value exceeding the minimum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; or (v) by such other method as may be set forth in the Award Agreement.

(h) Electronic Delivery. Any reference herein to a “written” agreement or document will include any agreement or document delivered electronically, filed publicly at www.sec.gov (or any successor website thereto) or posted on the Company’s intranet (or other shared electronic medium controlled by the Company to which the Participant has access).

(i) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee or otherwise providing services to the Company. The Board is authorized to make deferrals of Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant’s termination of Continuous Service, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(j) Compliance with Section 409A of the Code. Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A of the Code, and, to the extent not so exempt, in compliance with Section 409A of the Code. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to Section 409A of the Code, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes “deferred compensation” under Section 409A of the Code is a “specified employee” for purposes of Section 409A of the Code, no distribution or payment of any amount that is due because of a “separation from service” (as defined in Section 409A of the Code without regard to alternative definitions thereunder) will be issued or paid before the date that is six months following the date of such Participant’s “separation from service” (as defined in Section 409A of the Code without regard to alternative definitions thereunder) or, if earlier, the date of the Participant’s death, unless such distribution or payment can be made in a manner that complies with Section 409A of the Code, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

(k) Clawback/Recovery. All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other applicable law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of an event constituting Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a right to resign for "good reason" or "constructive termination" (or similar term) under any agreement with the Company.

9. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a); and (ii) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board will make such adjustments, and its determination will be final, binding and conclusive.

(b) Dissolution or Liquidation. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service; *provided, however*, that the Board may, in its sole discretion, cause some or all Stock Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Stock Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

(c) Corporate Transaction. The following provisions will apply to Stock Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Stock Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board at the time of grant of a Stock Award. In the event of a Corporate Transaction, then, notwithstanding any other provision of the Plan, the Board will take one or more of the following actions with respect to Stock Awards, contingent upon the closing or completion of the Corporate Transaction:

(i) arrange for the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) to assume or continue the Stock Award or to substitute a similar stock award for the Stock Award (including, but not limited to, an award to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction);

(ii) arrange for the assignment of any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to the Stock Award to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company);

(iii) accelerate the vesting, in whole or in part, of the Stock Award (and, if applicable, the time at which the Stock Award may be exercised) to a date prior to the effective time of such Corporate Transaction as the Board determines (or, if the Board does not determine such a date, to the date that is five days prior to the effective date of the Corporate Transaction), with such Stock Award terminating if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction;

(iv) arrange for the lapse, in whole or in part, of any reacquisition or repurchase rights held by the Company with respect to the Stock Award;

(v) cancel or arrange for the cancellation of the Stock Award, to the extent not vested or not exercised prior to the effective time of the Corporate Transaction, in exchange for such cash consideration, if any, as the Board, in its sole discretion, may consider appropriate; and

(vi) make a payment, in such form as may be determined by the Board equal to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of the Stock Award immediately prior to the effective time of the Corporate Transaction, over (B) any exercise price payable by such holder in connection with such exercise. For clarity, this payment may be \$0 if the value of the property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of the Company's Common Stock in connection with the Transaction is delayed as a result of escrows, earn outs, holdbacks or other contingencies.

The Board need not take the same action or actions with respect to all Stock Awards or portions thereof or with respect to all Participants. The Board may take different actions with respect to the vested and unvested portions of a Stock Award.

(d) Change in Control. A Stock Award may be subject to additional acceleration of vesting and exercisability upon or after a Change in Control as may be provided in the Stock Award Agreement for such Stock Award or as may be provided in any other written agreement between the Company or any Affiliate and the Participant, but in the absence of such provision, no such acceleration will occur.

10. TERMINATION OR SUSPENSION OF THE PLAN.

The Board may suspend or terminate the Plan at any time. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

11. EFFECTIVE DATE OF THE PLAN.

The Plan will come into existence on the Effective Date.

12. CHOICE OF LAW.

The laws of the State of Delaware will govern all questions concerning the construction, validity and interpretation of this Plan, without regard to that state's conflict of laws rules.

13. DEFINITIONS. As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "*Affiliate*" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Securities Act. The Board will have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "*Award*" or "*Stock Award*" means any right to receive Common Stock granted under the Plan, including a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award, or any Other Stock Award.

(c) "*Award Agreement*" or "*Stock Award Agreement*" means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement will be subject to the terms and conditions of the Plan.

(d) "*Board*" means the Board of Directors of the Company.

(e) "*Capitalization Adjustment*" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(f) "*Cause*" will have the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant's intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or

(v) such Participant's gross misconduct. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause will be made by the Company, in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(g) "**Change in Control**" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities; or (C) solely because the level of Ownership held by any Exchange Act Person (the "**Subject Person**") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction; *provided, however*, that a merger, consolidation or similar transaction will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing more than 50% of the combined voting power of the surviving Entity or its parent are owned by the IPO Entities;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately

prior to such sale, lease, license or other disposition; *provided, however*, that a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries will not constitute a Change in Control under this prong of the definition if the outstanding voting securities representing more than 50% of the combined voting power of the acquiring Entity or its parent are owned by the IPO Entities; or

(iv) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the “*Incumbent Board*”) cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing definition or any other provision of the Plan, the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company and the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant will supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition will apply.

(h) “*Code*” means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(i) “*Committee*” means a committee of one or more Independent Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(j) “*Common Stock*” means, as of the Effective Date, the common stock of the Company, having one vote per share.

(k) “*Company*” means CymaBay Therapeutics, Inc., a Delaware corporation.

(l) “*Consultant*” means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a “Consultant” for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company’s securities to such person.

(m) “*Continuous Service*” means that the Participant’s service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant’s service with the Company or an Affiliate, will not terminate a Participant’s Continuous Service; *provided, however*, that if the Entity for which a Participant is rendering services ceases to qualify as an

Affiliate, as determined by the Board, in its sole discretion, such Participant's Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(n) "**Corporate Transaction**" means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board, in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of more than 50% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(o) "**Director**" means a member of the Board. Directors are not eligible to receive Awards under the Plan with respect to their service in such capacity.

(p) "**Disability**" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment that can be expected to result in death or that has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Sections 22(e)(3) and 409A(a)(2)(c)(i) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(q) "**Effective Date**" means October 21, 2020.

(r) "**Employee**" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an "Employee" for purposes of the Plan.

(s) "**Entity**" means a corporation, partnership, limited liability company or other entity.

(t) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(u) “**Exchange Act Person**” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company’s then outstanding securities.

(v) “**Fair Market Value**” means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be, unless otherwise determined by the Board, the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

(ii) Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

(iii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Section 409A of the Code.

(w) “**Non-Employee Director**” means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act (“**Regulation S-K**”)), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a “non-employee director” for purposes of Rule 16b-3.

(x) “**Nonstatutory Stock Option**” means any option granted pursuant to Section 5 of the Plan that does not qualify as an “incentive stock option” within the meaning of Section 422 of the Code.

(y) “**Officer**” means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

(z) “**Option**” means a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(aa) “**Option Agreement**” means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement will be subject to the terms and conditions of the Plan.

(bb) “**Optionholder**” means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(cc) “**Other Stock Award**” means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(d).

(dd) “**Other Stock Award Agreement**” means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement will be subject to the terms and conditions of the Plan.

(ee) “**Own,**” “**Owned,**” “**Owner,**” “**Ownership**” means a person or Entity will be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(ff) “**Participant**” means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(gg) “**Performance Criteria**” means the one or more criteria that a majority of the Company’s Independent Directors or the Independent Compensation Committee will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any one of, or combination of, the following as determined by a majority of the Company’s Independent Directors or the Independent Compensation Committee: (i) earnings (including earnings per share and net earnings); (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) earnings before interest, taxes, depreciation, amortization and legal settlements; (v) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (vi) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (vii) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (viii) total stockholder return; (ix) return on equity or average stockholder’s equity; (x) return on assets, investment, or capital employed; (xi) stock price; (xii) margin (including gross margin); (xiii) income (before or after taxes); (xiv) operating income; (xv) operating income after taxes; (xvi) pre-tax profit; (xvii) operating cash flow; (xviii) sales or revenue targets; (xix) increases in revenue or product revenue; (xx) expenses and cost reduction goals; (xxi) improvement in or attainment of working capital

levels; (xxii) economic value added (or an equivalent metric); (xxiii) market share; (xxiv) cash flow; (xxv) cash flow per share; (xxvi) share price performance; (xxvii) debt reduction; (xxviii) implementation or completion of projects or processes; (xxix) user satisfaction; (xxx) stockholders' equity; (xxxi) capital expenditures; (xxxii) debt levels; (xxxiii) operating profit or net operating profit; (xxxiv) workforce diversity; (xxxv) growth of net income or operating income; (xxxvi) billings; (xxxvii) bookings; (xxxviii) the number of users, including but not limited to unique users; (xxxix) employee retention; and (xxxx) other measures of performance selected by the Company's Independent Directors or the Independent Compensation Committee.

(a) "**Performance Goals**" means, for a Performance Period, the one or more goals established by a majority of the Company's Independent Directors or the Independent Compensation Committee for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Company's Independent Directors or the Independent Compensation Committee (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Company's Independent Directors or the Independent Compensation Committee will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the Company's bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (12) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item. In addition, the Company's Independent Directors or the Independent Compensation Committee retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for such Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement.

(b) "**Performance Period**" means the period of time selected by a majority of the Company's Independent Directors or the Independent Compensation Committee over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to and the payment of a Stock Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of a majority of the Company's Independent Directors or the Independent Compensation Committee.

(c) “**Performance Stock Award**” means a Stock Award granted under the terms and conditions of Section 6(c)(i).

(d) “**Plan**” means this CymaBay Therapeutics, Inc. 2020 New Hire Plan, as it may be amended.

(e) “**Restricted Stock Award**” means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(f) “**Restricted Stock Award Agreement**” means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

(g) “**Restricted Stock Unit Award**” means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(h) “**Restricted Stock Unit Award Agreement**” means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement will be subject to the terms and conditions of the Plan.

(i) “**Rule 16b-3**” means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(j) “**Securities Act**” means the Securities Act of 1933, as amended.

(k) “**Stock Appreciation Right**” or “**SAR**” means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 5.

(l) “**Stock Appreciation Right Agreement**” means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement will be subject to the terms and conditions of the Plan.

(m) “**Subsidiary**” means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

CYMABAY THERAPEUTICS, INC.

STOCK OPTION GRANT NOTICE
(2020 NEW HIRE PLAN)

CymaBay Therapeutics, Inc. (the "*Company*"), pursuant to its 2020 New Hire Plan (the "*Plan*"), hereby grants to Optionholder an option to purchase the number of shares of the Company's Common Stock set forth below. This option is subject to all of the terms and conditions as set forth in this Stock Option Grant Notice, in the Option Agreement, the Plan and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Option Agreement will have the same definitions as in the Plan or the Option Agreement. If there is any conflict between the terms in this Stock Option Grant Notice and the Plan, the terms of the Plan will control.

Optionholder:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Shares Subject to Option:	_____
Exercise Price (Per Share):	_____
Total Exercise Price:	_____
Expiration Date:	_____

Type of Grant: Nonstatutory Stock Option

Exercise Schedule: Same as Vesting Schedule

Vesting Schedule: _____, subject to Optionholder's Continuous Service as of each such date

Payment: By one or a combination of the following items (described in the Option Agreement):

- By cash, check, bank draft or money order payable to the Company
- Pursuant to a Regulation T Program if the shares are publicly traded
- By delivery of already-owned shares if the shares are publicly traded
- Subject to the Company's consent at the time of exercise, by a "net exercise" arrangement

Additional Terms/Acknowledgements: Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder acknowledges and agrees that this Stock Option Grant Notice and the Option Agreement may not be modified, amended or revised except as provided in the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding this option award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) options previously granted and delivered to Optionholder, (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (iii) any written employment or severance arrangement that would provide for vesting acceleration of this option upon the terms and conditions set forth therein.

By accepting this option, Optionholder consents to receive such documents by electronic delivery and to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

CYMABAY THERAPEUTICS, INC.

OPTIONHOLDER:

By: _____
Signature
Title: _____
Date: _____

Signature
Date: _____

ATTACHMENTS: Option Agreement, 2020 New Hire Plan and Notice of Exercise

ATTACHMENT I

CYMABAY THERAPEUTICS, INC.
OPTION AGREEMENT
(2020 NEW HIRE PLAN)

(NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice (“*Grant Notice*”) and this Option Agreement, CymaBay Therapeutics, Inc. (the “*Company*”) has granted you an option under its 2020 New Hire Plan (the “*Plan*”) to purchase the number of shares of the Company’s Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the “*Date of Grant*”). The option is granted in compliance with Nasdaq Listing Rule 5635(c)(4) in connection with your entering into employment with the Company. If there is any conflict between the terms in this Option Agreement and the Plan, the terms of the Plan will control. Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

1. VESTING. Subject to the provisions contained herein, your option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments.

3. EXERCISE RESTRICTION FOR NON-EXEMPT EMPLOYEES. If you are an Employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (that is, a “*Non-Exempt Employee*”), and except as otherwise provided in the Plan, you may not exercise your option until you have completed at least six (6) months of Continuous Service measured from the Date of Grant, even if you have already been an employee for more than six (6) months. Consistent with the provisions of the Worker Economic Opportunity Act, you may exercise your option as to any vested portion prior to such six (6) month anniversary in the case of (i) your death or disability, (ii) a Corporate Transaction in which your option is not assumed, continued or substituted, (iii) a Change in Control or (iv) your termination of Continuous Service on your “retirement” (as defined in the Company’s benefit plans).

4. METHOD OF PAYMENT. You must pay the full amount of the exercise price for the shares you wish to exercise. You may pay the exercise price in cash or by check, bank draft or money order payable to the Company or in any other manner *permitted by your Grant Notice*, which may include one or more of the following:

(a) Provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a “broker-assisted exercise”, “same day sale”, or “sell to cover”.

(b) Provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. You may not exercise your option by delivery to the Company of Common Stock if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

(c) Subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your option and will not be exercisable thereafter if those shares (i) are used to pay the exercise price pursuant to the "net exercise," (ii) are delivered to you as a result of such exercise, and (iii) are withheld to satisfy your tax withholding obligations.

5. WHOLE SHARES. You may exercise your option only for whole shares of Common Stock.

6. SECURITIES LAW COMPLIANCE. In no event may you exercise your option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with all other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations (including any restrictions on exercise required for compliance with Treas. Reg. 1.401(k)-1(d)(3), if applicable).

7. TERM. You may not exercise your option before the Date of Grant or after the expiration of the option's term. The term of your option expires, subject to the provisions of Section 5(h) of the Plan, upon the earliest of the following:

(a) immediately upon the termination of your Continuous Service for Cause;

(b) three (3) months after the termination of your Continuous Service for any reason other than Cause, your Disability or your death (except as otherwise provided in Section 7(d) below); *provided, however*, that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in the section above relating to "Securities Law Compliance," your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service; *provided further*, if during any part of such three (3) month period, the sale of any Common Stock received upon exercise of your option would violate the Company's insider trading policy, then your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service during which the sale of the Common Stock received upon exercise of your option would not be in violation of the Company's insider trading policy. Notwithstanding the foregoing, if (i) you are a Non-Exempt Employee, (ii) your Continuous Service terminates within six (6) months after the Date of Grant, and (iii) you have vested in a portion of your option at the time of your termination of Continuous Service, your option will not expire until the earlier of (x) the later of (A) the date that is seven (7) months after the Date of Grant, and (B) the date that is three (3) months after the termination of your Continuous Service, and (y) the Expiration Date;

(c) twelve (12) months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 7(d)) below;

(d) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause;

(e) the Expiration Date indicated in your Grant Notice; or

(f) the day before the tenth (10th) anniversary of the Date of Grant.

8. EXERCISE.

(a) You may exercise the vested portion of your option (and the unvested portion of your option if your Grant Notice so permits) during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (i) the exercise of your option, (ii) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (iii) the disposition of shares of Common Stock acquired upon such exercise.

9. TRANSFERABILITY. Except as otherwise provided in this Section 9, your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

(a) **Certain Trusts.** Upon receiving written permission from the Board or its duly authorized designee, you may transfer your option to a trust if you are considered to be the sole beneficial owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust. You and the trustee must enter into transfer and other agreements required by the Company.

(b) **Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2) that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

(c) **Beneficiary Designation.** Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form approved by the Company and any broker designated by the Company to handle option exercises, designate a third party who, on your death, will thereafter be entitled to exercise this option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, your executor or administrator of your estate will be entitled to exercise this option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

10. OPTION NOT A SERVICE CONTRACT. Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

11. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your option, in whole or in part, and at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "same day sale" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

(b) Upon your request and subject to approval by the Company, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your option, share withholding pursuant to the preceding sentence shall not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding obligation to the date of exercise of your option. Notwithstanding the filing of such election, shares of Common Stock shall be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein, if applicable, unless such obligations are satisfied.

12. TAX CONSEQUENCES. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation. In particular, you acknowledge that this option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the "fair market value" per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the option.

13. NOTICES. Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

14. GOVERNING PLAN DOCUMENT. Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your option and those of the Plan, the provisions of the Plan will control. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

15. OTHER DOCUMENTS. You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting certain individuals to sell shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

16. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of this option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

17. VOTING RIGHTS. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

18. SEVERABILITY. If all or any part of this Option Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

19. MISCELLANEOUS.

(a) The rights and obligations of the Company under your option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

(c) You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.

(d) This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Option Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* * *

This Option Agreement will be deemed to be signed by you upon the signing by you of the Stock Option Grant Notice to which it is attached.

ATTACHMENT II

2020 NEW HIRE PLAN

ATTACHMENT III

NOTICE OF EXERCISE

CYMABAY THERAPEUTICS, INC.

Attention: [Stock Plan Administrator]
7575 Gateway Boulevard, Suite 110
Newark, California 94560

Date of Exercise: _____

This constitutes notice to CymaBay Therapeutics, Inc. (the "*Company*") under my stock option that I elect to purchase the below number of shares of Common Stock of the Company (the "*Shares*") for the price set forth below.

Type of option:	Nonstatutory
Stock option dated:	_____
Number of Shares as to which option is exercised:	_____
Certificates to be issued in name of:	_____
Total exercise price:	\$ _____
Cash payment delivered herewith:	\$ _____
Value of _____ Shares delivered herewith ¹ :	\$ _____
Value of _____ Shares pursuant to net exercise ² :	\$ _____
Regulation T Program (cashless exercise ³):	\$ _____

- ¹ Shares must meet the public trading requirements set forth in the option. Shares must be valued in accordance with the terms of the option being exercised, and must be owned free and clear of any liens, claims, encumbrances or security interests. Certificates must be endorsed or accompanied by an executed assignment separate from certificate.
- ² The Company must have established net exercise procedures at the time of exercise, in order to utilize this payment method.
- ³ Shares must meet the public trading requirements set forth in the option.

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the CymaBay Therapeutics, Inc. 2020 New Hire Plan, and (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this option.

Very truly yours,



Cymabay Therapeutics
7575 Gateway Blvd.
Suite 110
Newark, CA 94560
www.cymabay.com
510-293-8800 office
510-293-9090 fax

August 27, 2020

Paul Quinlan

Dear Paul:

Cymabay Therapeutics, Inc. (the "Company") is pleased to offer you employment as General Counsel on the following terms, effective as of the date upon which you commence employment with the Company:

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

2. Compensation and Employee Benefits.

2.1 Base Salary. Your base salary will be three hundred ninety-four thousand dollars (\$394,000) on an annualized basis, less payroll deductions and required withholdings, paid according to the Company's regular payroll schedule and procedures. Subject to the other terms of this letter agreement, your base salary may be modified by the Company in its sole discretion.

2.2 Discretionary Bonus. You will be eligible to participate in the Company's annual bonus program pursuant to the terms of that program and you will be eligible to receive a bonus of up to forty percent (40%) of your annual base salary. Your actual bonus, if any, will be determined by the Company's Board of Directors (the "Board"), or the Compensation subcommittee thereof, in its sole discretion, based upon its evaluation of your performance, the Company's performance, and any other considerations it deems relevant. For your initial year of employment, your bonus will be pro-rated for the time elapsed in the bonus period for which you were employed by the Company. You must be employed through the bonus payment date to be eligible for, and to earn, any such bonus. Bonuses are typically paid within sixty (60) days after the end of the calendar year. Any bonus payment will be subject to payroll deductions and required withholdings.

2.3 Employee Benefits. You will be entitled to all employee benefits, including vacation accrual of twenty (20) days per year and health and disability benefits for which you are eligible under the terms and conditions of the standard Company benefit plans that may be in effect from time to time and provided by the Company to its senior executive-level employees generally. Currently, such benefits include twelve (12) paid holiday days, as well as paid sick leave of up to five (5) days per year. Notwithstanding the foregoing, the Company reserves the right to adopt, amend or discontinue any employee benefit plan or policy, including changes required by applicable law.

2.4 Stock Options. Subject to the approval of the Board, or the Board's Compensation Committee, pursuant to the Company's equity incentive plan you will be granted a stock option covering two hundred and seventy-five thousand (275,000) shares of Company common stock at a per share exercise price equal to the per share fair market value of the Company's common stock on the grant date. The term of such stock option will be ten (10) years, subject to earlier expiration in the event of the termination of your service with the Company. Such stock option will vest and be exercisable as to twenty-five percent (25%) of the shares covered by the option on the first year anniversary of your employment commencement date and the remaining seventy-five percent (75%) of the shares covered by the option will vest in thirty-six (36) equal monthly installments with the first monthly installment vesting one month following the first year anniversary of your employment commencement date, as long as you remain in continuous service with the Company. Notwithstanding the foregoing, a portion of the shares subject to your outstanding option may vest on an accelerated basis pursuant to Articles 7 or 8. Except as provided herein, such stock option will be subject to the provisions of the equity incentive plan of the Company under which the options are granted and the applicable form of stock option agreement thereunder (the "Plan Documents").

3. Other Activities During Employment

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

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

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

4. Company Policies; Confidential Information and Inventions Agreement As a condition of your employment, you are required to execute the Company's Employee Agreement on Confidential Information and Inventions, a copy of which is attached as Exhibit A. You further acknowledge your obligation to abide by the Company's rules, policies and procedures.

5. Immigration. The Immigration Reform and Control Act of 1986 requires that every person present proof to the Company of their identity and eligibility and/or authorization to accept employment with the Company. In order to comply with this law, and before you can become a Company employee, you must provide appropriate documentation to prove both your identity and legal eligibility to be employed at the Company. **Please be sure to bring this documentation with you to your employee orientation. If you are working in the United States on a VISA, you will need to provide copies of this documentation at your employee orientation. Failure to do so may result in over withholding of taxes.**

6. Your Representations and Warranties.

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

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

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

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

7. Termination of Employment

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

7.2 Termination for Cause.

(a) Subject to the terms of this Article 7 and to the terms of Article 8, if the Company terminates your employment at any time for Cause (as defined below), your salary shall cease on the date of termination and you shall not be entitled to severance pay, COBRA premium payments, pay in lieu of notice or any other such compensation other than payment of accrued salary and vacation and such other benefits as expressly required by applicable law or the terms of applicable benefit plans. Subject to the terms of this Article 7 and to the terms of Article 8, the continued vesting of any equity awards held by you shall cease on your employment termination date, and your right to exercise vested equity awards shall be governed by the Plan Documents.

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

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

7.3 Severance Benefits for Termination Without Cause or Resignation for Good Reason

(a) If the Company terminates your employment without Cause and other than as a result of your death or disability, or if you resign your employment for Good Reason (defined below), and provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "Separation from Service"), you will be eligible to receive the severance benefits described in this Section 7.3.

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

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

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

(e) Your receipt of any severance benefits under this Section 7.3 is contingent upon your signing and making effective within sixty (60) days after the termination date, a full, general release of all claims against the Company in a form acceptable to the Company containing the language set forth in the Release Agreement attached as Exhibit B on or after the termination date. The base salary and bonus severance will be paid in substantially equal installments over the twelve (12) month period following your Separation in Service according to the Company's payroll procedures; *provided, however*, that no payments will be made to you prior to the 60th day following your Separation from Service. On the first payroll pay day following the 60th day after your Separation from Service, the Company will pay you the cash severance amounts you would have received on or prior to such date in a lump sum in compliance with Code Section 409A and the effectiveness of the release, with the balance of the cash payments being made as originally scheduled.

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

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

7.5 Application of Section 409A. If the Company (or, if applicable, the successor entity thereto) determines that the severance payments and benefits provided for in this letter agreement (the "Agreement Payments") constitute "deferred compensation" under Section 409A of the Internal Revenue Code (together, with any state law of similar effect, "Section 409A") and you are a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A(a)(2)(B)(i) (a "Specified Employee"), then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Agreement Payments shall be delayed as follows: on the earliest to occur of (i) the date that is six months and one day after the termination date or (ii) the date of your death (such earliest date, the "Delayed Initial Payment Date"), the Company (or the successor entity thereto, as applicable) shall (A) pay to you a lump sum amount equal to the sum of the Agreement Payments that you would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the Agreement Payments had not been delayed pursuant to this Section 7.5 and (B) commence paying the balance of the Agreement Payments in accordance with the applicable payment schedules set forth in this letter agreement. For the avoidance of doubt, it is intended that (1) each installment of the Agreement Payments provided in this letter agreement is a separate "payment" for purposes of Section 409A, (2) all Agreement Payments satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under of Treasury Regulation 1.409A-1(b)(4) and 1.409A-1(b)(9)(iii), and (3) the Agreement Payments consisting of COBRA premiums also satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulation 1.409A-1(b)(9)(v).

8. Change in Control.

8.1 Definitions.

(a) "Change in Control" shall mean an Ownership Change Event (as defined below) or a series of related Ownership Change Events (collectively, a "Transaction") wherein the stockholders of the Company immediately before the Transaction do not retain direct or indirect beneficial ownership of more than fifty percent (50%) of the total combined voting power of the outstanding securities of the Company or, in the case of a Transaction described in Section 8.1(b)(iii), the corporation or other business entity to which the assets of the Company were transferred (the "Transferee"), as the case may be. For purposes of the preceding sentence, indirect beneficial ownership shall include, without limitation, an interest resulting from ownership of the voting securities of one or more corporations or other business entities that own the Company or the Transferee, as the case may be, either directly or through one or more subsidiary corporations or other business entities.

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

8.2 Severance. On the consummation of any Change in Control any remaining unvested portion of your equity awards will be accelerated such that fifty percent (50%) of your outstanding and then-unvested equity awards become fully vested and exercisable as of the date of the Change in Control (the "Acceleration"). If on or within twelve (12) months following a Change in Control, the Company or a successor corporation terminates your employment without Cause and other than as a result of your death or disability, or you resign for Good Reason (a "Change in Control Termination"), and provided that such termination constitutes a Separation from Service, then subject to your obligations below, and in lieu of any severance benefits set forth in Section 7.3 herein, you will be entitled to receive (collectively, the "Change in Control Severance Benefits"):

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

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

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

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

8.3 Parachute Payments.

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

(b) All determinations required to be made under this Section 8.3 including whether and when a Gross-Up Payment is required and the amount of such Gross-Up Payment and the assumptions to be utilized in arriving at such determination, shall be made by the nationally recognized certified public tax accounting firm used by the Company or, if such firm declines to serve, such other nationally recognized certified public tax accounting firm as you may designate (the "Accounting Firm"). The Accounting Firm may make reasonable assumptions and approximations concerning applicable taxes and may rely on reasonable, good-faith interpretations concerning the application of Sections 280G and 4999 of the Code. The Accounting Firm shall provide its calculations, together with detailed supporting documentation, to the Company and you within thirty (30) calendar days after the date on which your right to a Payment is triggered (if requested at that time by the Company or you) and/or at such other times as requested by the Company or you. If the Accounting Firm determines that no Excise Tax is payable with respect to a Payment, it shall furnish the Company and you with an opinion reasonably acceptable to you that no Excise Tax will be imposed with respect to such Payment. If the Accounting Firm determines that an Excise Tax is payable with respect to a Payment, it shall furnish to the Company and you an opinion reasonably acceptable to you of the amount of Excise Tax payable with respect to the Payments and the amount of Gross-Up Payment due to you. The Company will pay the Gross-Up Payment to you within thirty (30) days of the date the Company receives the Accounting Firm's opinion, but in no event later than the end of your tax year following your tax year in which you pay the Excise Tax. The Company shall bear all reasonable expenses with respect to the determinations by the Accounting Firm required to be made hereunder. Any determination by the Accounting Firm shall be binding upon the Company and you.

9. General Provisions.

9.1 Dispute Resolution. To aid in the rapid and economical resolution of any disputes that may arise under this letter agreement, the parties agree that any and all claims, disputes or controversies of any nature whatsoever arising from or regarding the interpretation, performance, negotiation, execution, enforcement or breach of this letter agreement, or your relationship with the

Company, including statutory claims, shall be resolved by confidential, final and binding arbitration conducted before a single arbitrator with Judicial Arbitration and Mediation Services, Inc. ("JAMS") in San Francisco, California, in accordance with JAMS' then-applicable employment arbitration rules (which may be reviewed at www.jamsadr.com/rules-employment-arbitration/). **The parties acknowledge that by agreeing to this arbitration procedure, they waive the right to resolve any such dispute through a trial by jury, judge or administrative proceeding.** The parties will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (i) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be available under applicable law in a court proceeding; and (ii) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The Company shall bear all JAMS' arbitration fees and administrative costs in excess of the amount of administrative fees (e.g., filing fees) that you would otherwise be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement shall prevent any party from obtaining injunctive or other provisional relief in court to prevent irreparable harm pending the conclusion of any arbitration proceeding.

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

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

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

9.5 Entire Agreement. This letter agreement, together with its exhibits, constitutes the entire and exclusive agreement between you and the Company, and it supersedes any prior agreement, promise, representation, or statement, written or otherwise, between you and the Company with regard to this subject matter. It is entered into without reliance on any promise, representation, statement or agreement other than those expressly contained or incorporated herein, and it cannot be modified or amended except in a writing signed by you and a duly authorized officer of the Company.

9.6 Counterparts. This letter agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same agreement. Copies of original signature pages sent by facsimile and/or PDF shall have the same effect as signature pages containing original signatures.

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

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

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

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

Enclosed is your Employee Agreement on Confidential Information and Inventions, which you should read carefully.

To indicate your acceptance of the Company's offer, please sign this letter agreement in the space provided below and return it to me along with the signed Exhibit A. This offer shall expire on September 3, 2020 if not accepted prior to such date. If you have any questions regarding this letter agreement, feel free to contact me.

Sincerely,

CYMABAY THERAPEUTICS, INC.

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

Accepted and agreed:

/s/ Paul Quinlan

Paul Quinlan

Employment Commencement Date: October 12, 2020

EXHIBIT A – Employee Agreement on Confidential Information and Inventions

EXHIBIT B – Release Agreement

EXHIBIT A

EMPLOYEE AGREEMENT ON CONFIDENTIAL
INFORMATION AND INVENTIONS

THIS AGREEMENT is between CymaBay Therapeutics, Inc. a Delaware Corporation (the "Company"), and Paul Quinlan (the "Employee").

PURPOSE OF AGREEMENT

I want to be employed by the Company, and the Company wants to employ me, provided that, in so doing, it can protect its trade secrets and inventions, ideas, information, business, and good will.

In consideration of this purpose, and the mutual promises in this Agreement, I agree with the Company as follows:

1. Term

(A) My employment with the Company is an at-will relationship that may be terminated by either the Company or me with or without cause for any reason whatsoever at any time upon notice to the other party.

(b) If my employment is terminated for any reason, I will be entitled only to the compensation earned by me as of the date of termination.

2. Confidential Information. I will hold in confidence and use only for the benefit of the Company during the term of my employment and for five years after the termination of my employment all Confidential Information of the Company, its Affiliates, and all Confidential Information of companies or persons other than the Company given to the Company under an agreement prohibiting its disclosure. "Confidential Information" refers to valuable technical or business information that is not known by the public. By way of example, Confidential Information may include information relating to: inventions or products, including unannounced products; research and development activities; requirements and specifications of specific customers and potential customers; nonpublic financial information; and quotations or proposals given to customers.

These restrictions on disclosure do not apply if the information is or becomes publicly known through no wrongful act on my part or the information is explicitly approved for release under such circumstances by an officer of the Company.

3. Disclosure and Assignment of Inventions. I hereby assign to the Company my entire right, title and interest in all inventions. "Inventions" refer to (a) all technical or business innovations, whether or not patentable or copyrightable, made by me during the term of my employment; and (b) all technical or business innovations, whether or not patentable, based upon the Company's Confidential Information and made by me after leaving the Company's employ. I will keep adequate written records of all inventions made by me, such as notebooks, sketches,

program listings and the like, which are the property of the Company. Notwithstanding the foregoing, I am not required to assign to the Company, although I must disclose, any inventions: (a) for which no equipment, supplies, facilities or Confidential Information of the Company were used and which was developed entirely on my own time; (b) which at the time of conception or reduction to practice did not relate directly to the business of the Company or the Company's actual or demonstrably anticipated research or development and (c) which did not result from any work I performed for the Company. The disclosure of such inventions must be made so that the parties can make a determination whether such inventions do in fact qualify for exclusion from assignment to the Company. The Company will keep confidential any such information I disclose. I will take all steps necessary to assist the Company in securing any patents, copyrights or other protection for inventions which I am required to assign to the Company as provided above. If I am unable or unwilling, whether during my employment or after termination, to sign any papers needed to apply for or pursue any patent or copyright registrations for inventions, I agree that the Company is my attorney-in-fact for that purpose and can sign such papers as my agent and take any other actions necessary to pursue these registrations.

4. List of Inventions I Own. I have attached as Exhibit A a list of inventions I own, which is a complete list of all technical or business innovations I own either alone or jointly with others on the date of this Agreement. I agree that I will not incorporate any of these prior inventions into products being developed for the Company without the prior knowledge and written consent of the Company. Should the Company wish to use any of my inventions in its business, the Company will negotiate with me for a purchase of or license to use such invention on mutually agreeable terms. If no such list is attached, or if no such inventions are listed thereon, I represent that I do not own any inventions at the time of signing this Agreement.

5. Tangible Materials. All tangible materials that incorporate Confidential Information are the Company's property, and I will give all of these materials and any other documents and materials which are the property of the Company, including but not limited to all notes of any research or other work which I have performed for the Company and all biological materials created, used or held by me in the course of my work for the Company, back to the Company at the termination of my employment or earlier upon the Company's request.

6. Solicitation of Employees. I understand that information about the Company's employees, such as their skills, performance ratings, and salary histories, constitutes Confidential Information owned by the Company. I agree that, for a period of twelve (12) months after termination of my employment for any reason, I will not, either directly or indirectly, solicit, induce, recruit or encourage any of the Company's employees to leave their employment, or take away such employees, or attempt to do any of these things, whether on my own behalf or on behalf of any other person, since to do so would necessarily involve using Confidential Information.

8. Termination. In the event of termination of my employment for any reason, I agree that, as requested by the Company, I will sign and deliver a "Termination Certification" in the form attached to this Agreement as Exhibit B. I also agree that the Company may give notice to my new employer of my duties under this Agreement.

9. Duty of Loyalty. During my employment with the Company, I will not engage in any business activity (either for my own profit or for anyone else) that competes with the Company's business.

10. Duties to Third Parties. I represent that, to the best of my knowledge, compliance with the terms of this Agreement will not violate any duty that I may have to anyone other than the Company (such as a former employer) to keep such person's proprietary information in confidence or to refrain from using that person's patents or copyrights. If at any time during my employment with the Company, I am asked by the Company to perform work which I believe may cause me to violate a duty I have to someone other than the Company, I will immediately inform an officer of the Company so that an assessment of the situation may be made. I also agree that I will not, during my employment with the Company, bring onto the Company's premises, use or disclose to the Company any proprietary information or trade secrets of any former employer or any other person without that person's consent.

11. Miscellaneous. This is the only agreement between the Company and myself about confidential information and the ownership of inventions, and may not be modified, amended or terminated, in whole or in part, except in a writing signed by me and by an officer of the Company. Any later change in my title, compensation or duties will not affect this Agreement. This Agreement will survive termination of my employment for any reason, and will continue for the benefit of and will be binding upon the successors, assigns, heirs and legal representatives of the Company and myself. Any waiver by the Company of a breach of any of the obligations of this Agreement by me will not operate or be construed as a waiver of any other or subsequent breach by me. In the event any provision of this Agreement is held to be invalid, void or unenforceable, the remaining provisions will nevertheless continue in full force and effect without being impaired or invalidated in any way. The prevailing party in any legal action brought by one party against the other and arising out of this Agreement shall be entitled, in addition to any other rights and remedies it may have, to reimburse for its expenses, including court costs and reasonable attorney's fees. This Agreement will be governed by the laws of the State of California governing contracts between residents to be performed in the State of California.

CymaBay Therapeutics, Inc.

Employee

By: _____

By: _____

Sujal Shah
President and Chief Executive Officer

Signature
Paul Quinlan

Date

Date

EXHIBIT A

List of Inventions I Own (see para. 4.)

EXHIBIT B

Termination Certificate

This is to certify that I do not have in my possession, nor have I failed to return, any devices, records, data, notes, reports, proposals, lists, equipment, computer programs or listings, other documents or property or any reproductions of any of these materials belonging to CymaBay Therapeutics, Inc., a Delaware corporation, its subsidiaries, successors or assigns (collectively, the "Company").

I further certify that I have complied with all the terms of the Company's Employee Confidential Information and Inventions Agreement signed by me, including the reporting of any inventions and original works of authorship (as defined in that agreement) conceived or made buy me (solely or jointly with others) covered by that agreement.

I further agree that, in compliance with the Employee Confidential Information and Inventions Agreement, I will preserve as confidential all trade secrets, confidential knowledge, data or other proprietary information relating to inventions or products, including but not limited to unannounced products, research and development activities, requirements and specifications of specific customers and potential customers, nonpublic financial information, and quotations or proposals given to customers, including any information disclosed to the Company in confidence by any third party.

I further agree that for twelve (12) months from this date, I will not solicit, induce, recruit or encourage any of the Company's employees to leave their employment.

/template – do not sign/

Signature

Printed Name

Date

EXHIBIT B

RELEASE AGREEMENT

(To be signed on or after the Separation Date)

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

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

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

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

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

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

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

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

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

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

/template – do not sign/

Date

Paul Quinlan

List of Subsidiaries

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

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. 333-229670) 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 report dated March 25, 2021, with respect to the consolidated financial statements of CymaBay Therapeutics, Inc. included in this Annual Report (Form 10-K) of CymaBay Therapeutics, Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Redwood City, California
March 25, 2021

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 25, 2021

/s/ Sujal Shah

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

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 25, 2021

/s/ Daniel Menold

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

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, 2020, 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 25th day of March, 2021.

/s/ Sujal Shah

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

/s/ Daniel Menold

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

This certification accompanies the Form 10-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.