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, 2022

OR

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

Commission file number: 001-36500

CYMABAY THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3103561**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
7575 Gateway Blvd, Suite 110 Newark, CA	**94560**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant 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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022, was $218,053,044. This excludes 330,617 shares of the registrant's Common Stock held by executive officers, directors and stockholders affiliated with directors outstanding at June 30, 2022. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

The number of shares of common stock outstanding as of March 15, 2023, was 97,293,397.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2023 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, 2022, are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

CYMABAY THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended December 31, 2022

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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.

In addition, statements that "we believe" or "we expect" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information. These statements are inherently uncertain, and readers are cautioned not to unduly rely on these statements.

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 the information in this Form10-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 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 and other activities commensurate with the magnitude of the shortfall or our product development activities may cease altogether.
- Failure to remain in compliance with our obligations under the development financing agreement with Abingworth could lead to acceleration of potentially significant payments to Abingworth.
- 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 COVID-19

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

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.

Risks Related to Commercialization of Our Product Candidates

- 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 products, we may be unable to generate any revenue.
- The commercial success of our products is subject to significant competition from products that may be superior to, or more cost effective than, our products.

Risks Related to Our Intellectual Property

- 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 Owning 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.
- 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.

PART I

Item 1. Business

Overview

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

Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPARδ), a nuclear receptor that regulates genes directly or indirectly involved in the synthesis of bile acids/sterols, metabolism of lipids and glucose, inflammation and fibrosis. We are focused on developing seladelpar for the treatment of primary biliary cholangitis (PBC), an autoimmune disease that causes progressive destruction of the bile ducts in the liver resulting in impaired bile flow (cholestasis) and inflammation.

We reported net losses of approximately $106.0 million and $90.0 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had cash, cash equivalents and marketable securities totaling $135.5 million. We believe those funds, along with the upfront payment of $34.2 million received from Kaken Pharmaceutical Co., Ltd. pursuant to the Collaboration and License Agreement and $92.4 million obtained in connection with a public equity offering, as discussed in *Note 13—Subsequent Events*, are sufficient to fund our current operating plan through the third quarter of 2024.

Strategy

Our goal is to become a leading biopharmaceutical company focused on developing 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,
- Obtain regulatory approval and commercialize seladelpar for patients with PBC,
- Strengthen our patent portfolio and other means of protecting exclusivity, and
- Acquire or develop other products or product candidates.

Phase 3 Trials

We completed enrollment of 193 patients in a global, Phase 3 registration study (RESPONSE) to evaluate seladelpar in patients with PBC in July 2022 and anticipate releasing top line data for RESPONSE in the third quarter of 2023. We are also continuing the enrollment of a global long-term extension study (ASSURE) to evaluate seladelpar in patients with PBC that is intended to collect additional long-term safety and efficacy data to support registration. We have enrolled over 200 patients in ASSURE and expect to ultimately enroll over 300 patients.

CymaBay Pipeline Overview

Our pipeline includes two clinical stage product candidates: seladelpar (a PPARd agonist) and MBX-2982 (a GPR119 agonist).

Product Candidates	Disease/condition	Status	Description
Seladelpar (PPARd 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) Ongoing open-label, long-term extension study evaluating seladelpar in PBC patients (ASSURE)
MBX-2982 (GPR119 agonist)	Hypoglycemia in Type 1 Diabetics	Phase 2a	Ongoing proof-of-pharmacology Phase 2a study*

* 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 (PPARd). The PPARd receptor is a nuclear receptor that regulates genes involved in bile acid/sterol, lipid, and glucose metabolism, and regulation of certain inflammatory cells. Seladelpar has the potential to treat certain diseases of the liver and a variety of disorders of lipid metabolism.

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

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

In February 2019, the United States 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, three Phase 2 and one Phase 3 clinical study (ENHANCE) of seladelpar in PBC. In addition, we are in the process of conducting a second Phase 3 study (RESPONSE) with seladelpar in PBC and a Phase 3 long-term extension study (ASSURE) of seladelpar in PBC patients. 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 (10 mg/day) 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 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 completed Phase 2 and Phase 3 studies, and unlike the only approved second-line treatment currently available, we believe that seladelpar may reduce the incidence and severity of pruritus in PBC patients.

Target Indications for Seladelpar

We are actively pursuing PBC as our initial launch indication for seladelpar. We may look to develop seladelpar in other indications in the future. Following is a review of our development progress for seladelpar in PBC.

Primary Biliary Cholangitis (PBC)

Summary

PBC is a rare, chronic, progressive, autoimmune liver disease that predominantly affects middle-aged women. AT-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 ALP presence and/or the magnitude of antimitochondrial antibody (AMA presence) and liver biopsies, although biopsies are not 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, or without sufficient treatment, 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. The current first line therapy for PBC is ursodeoxycholic acid (UDCA), a secondary bile acid.

Studies of Seladelpar in PBC

RESPONSE (Phase 3)

In July 2022, we completed enrollment of our 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 has

enrolled 193 patients who have an inadequate response to, or intolerance to, UDCA, 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% 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. We expect to release top line data for RESPONSE in the third quarter of 2023.

ASSURE (Phase 3)

In 2021, we commenced a long-term open-label safety study (ASSURE) of seladelpar for patients with PBC. The study is open to patients from our prior Phase 2 open label study and our Phase 3 ENHANCE study, as well as patients completing treatment in RESPONSE and certain Phase 1 studies. The ASSURE trial is ongoing and has enrolled over 200 patients, with additional patients expected to enroll. We expect to ultimately enroll over 300 patients in ASSURE. ASSURE will provide us with additional efficacy and safety data to supplement our RESPONSE and ENHANCE trials as we continue to build a rich efficacy and safety database to support our NDA submission for seladelpar in PBC, including seladelpar treatment of over 400 unique PBC patients.

ENHANCE (Phase 3)

In October 2018 we commenced a global, Phase 3 registration study (ENHANCE) to evaluate seladelpar in patients with PBC. ENHANCE 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 had an inadequate response to, or were 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 had 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. Key secondary endpoints were the ALP normalization rate and changes from baseline in pruritus, as measured by 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 nonalcoholic steatohepatitis (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 reinstated clinical development of seladelpar in PBC.

In August 2020 we announced positive results from ENHANCE, which we believe support seladelpar as a safe, well-tolerated, and efficacious treatment for 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 those from 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 in 2020, we 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 and certain Phase 1 studies. The ASSURE trial is ongoing and has enrolled over 200 patients, with additional patients expected to enroll from other seladelpar PBC trials, including RESPONSE. We expect to ultimately enroll over 300 patients in ASSURE.

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 included the evaluation of 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 from the study 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, ≥15% 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 ALP normalization 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.

We subsequently reported on a 52-week analysis from the study 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 ≥ 40), substantial improvement in pruritus (VAS ≥ 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 supported further evaluation of seladelpar's potential benefit on pruritus.

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. The study is ongoing.

COVID-19

Through the date of filing of this Annual Report, the biggest impact of the COVID-19 outbreak on our operations, financial condition and liquidity has been the hybrid-remote operation of our operations personnel and what we believe to be slower enrollment timelines for our RESPONSE trial. As a result of the continuing COVID-19 situation, we may experience future disruptions that could impact these and additional aspects of our business, including our progress towards the completion of our clinical studies and other associated 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*. During the pandemic to date, our workforce has adapted to remotely working to maintain operations. Our operations are currently in a hybrid model with most employees working from our office for a portion of the week and working remotely for the rest of the week. 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 U.S. 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 have adapted to COVID-19 related restrictions and reduced access to work facilities through the use of remote working technologies and other measures as we continue to progress toward completion of our clinical trials. However, in the future, as we look to complete the clinical development of seladelpar and initiate other programs, our research and development personnel and vendors may not be able to sufficiently access their applicable work facilities as a result of facility closure orders and the possibility of other governmental action. Furthermore, patients in our clinical trials may also be impacted by any ongoing travel and facility access restrictions. Although we and our vendors continue to plan for and develop COVID-19-related risk mitigation strategies, it is uncertain whether these plans will be sufficient to fully offset the impact that travel and facility access

restrictions (or other unanticipated impediments) may have on our ability to execute our 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 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 continuing COVID-19 situation will have on our financial condition and operations. The impact of the COVID-19 situation on our company 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, this may negatively impact our business.

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 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.

Finance and Licensing Agreements

Our current significant finance and licensing arrangements are summarized below:

Kaken Pharmaceutical: In January 2023, we entered into a Collaboration and License Agreement (the License Agreement) with Kaken Pharmaceutical Co., Ltd. (Kaken). Pursuant to the License Agreement, we granted Kaken an exclusive license to commercialize seladelpar (the Licensed Product) for the prevention or treatment of PBC in Japan.

Pursuant to the terms of the License Agreement, Kaken will bear the cost of, and be responsible for, among other things, conducting the clinical studies and other developmental activities for the Licensed Product in PBC

in Japan as well as preparing and filing applications for regulatory approval in Japan and commercializing the Licensed Product in Japan. Kaken is obligated to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize, the Licensed Product in Japan, including obtaining pricing approval for the Licensed Product in Japan. We are obligated to supply to Kaken, its requirements of Licensed Product for clinical and commercial use in Japan, which obligation may be terminated upon specified circumstances and technology transfer.

In consideration of the license and other rights granted by us, Kaken made an upfront cash payment to us of $34.2 million and is obligated to pay potential milestone payments to us totaling up to ¥17.0 billion (approximately $128.0 million at contract inception date) for the achievement of certain regulatory and sales milestones. In addition, during the Royalty Term (as defined below), while we supply Licensed Product to Kaken, Kaken will make payments to us for each unit of Licensed Product that we supply at a percentage of the Japanese National Health Insurance price of the Licensed Product that equates to 20+% royalties. If we are not supplying product to Kaken during the Royalty Term, a lower royalty payment will be payable to us by Kaken based on Kaken net sales of Licensed Product in Japan. After the Royalty Term, if we are supplying Licensed Product to Kaken, we will receive payments for each unit of Licensed Product based on a percentage of the Japanese National Health Insurance price of the Licensed Product that is lower than during the Royalty Term.

The Royalty Term means the period ending on the latest to occur of (a) the expiration of the last valid claim of the royalty patents covering such Licensed Product in Japan, (b) the expiration of regulatory exclusivity for such Licensed Product in Japan, and (c) 10 years after the first commercial sale of such Licensed Product in Japan.

The License Agreement is effective until the date upon which (a) the Royalty Term has expired in Japan for the final Licensed Product, or (b) the License Agreement is earlier terminated (the Initial Term). After the Initial Term (except in the case of early termination), the License Agreement will be automatically renewed for 2-year periods, unless either party has given the other party a written notice not to renew the License Agreement no later than 12 months prior to the expiration of the Initial Term or any subsequent renewal term, in which case the License Agreement shall expire (and thus terminate) at the end of the then-existing term or, if applicable, shall earlier terminate upon an early termination.

The License Agreement may be early terminated by either party for material breach, upon a party's insolvency or bankruptcy or upon a challenge by one party of any patents of the other party, and Kaken may terminate in specified situations, including for a safety concern, clinical failure or termination of an underlying in-license to us from Janssen Pharmaceutica NV (see below), or at its convenience with specified prior notice. Upon an intentional or willful material breach of the License Agreement by us, Kaken also has an alternative remedy for material breach of the License Agreement that results in a reduction in the payments otherwise payable to us under the License Agreement. Upon early termination, (i) license rights granted under the License Agreement terminate, (ii) to the extent permitted by applicable law, Kaken is obligated to transfer to us copies of, and its entire right, title and interest in, all regulatory materials in Japan (subject to a royalty if such termination is by Kaken for our uncured material breach) and (iii) Kaken will automatically grant to us, with immediate effect, a non-exclusive, fully paid, royalty-free license under the Kaken program intellectual property solely for the exploitation of Licensed Products.

Pursuant to the License Agreement, we and Kaken agreed to establish a joint steering committee to provide strategic oversight of both our and Kaken's activities under the License Agreement. The License Agreement also contains customary representations, warranties and covenants by both us and Kaken, as well as customary provisions relating to indemnification, confidentiality, intellectual property and other matters.

Johnson & Johnson: In June 2006, we entered into a license agreement with Janssen Pharmaceutica 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. 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.

Abingworth: In July 2021, we entered into a Development Financing Agreement (the Financing Agreement) with ABW Cyclops SPV LP, an affiliate of Abingworth LLP (Abingworth), pursuant to which Abingworth provided us with $75 million of funding to support our development of seladelpar for the treatment of PBC. In return, we will pay to Abingworth (1) contingent upon the first to occur of regulatory approval of seladelpar for the treatment of PBC in the U.S., U.K., Germany, Spain, Italy or France (Regulatory Approval), fixed success payments equal to 2.0x of the funding provided, consisting of $10 million payable within 90 days after Regulatory Approval and thereafter payments due on the first six anniversaries of the Regulatory Approval in the amounts of $15 million, $22.5 million, $22.5 million, $25.0 million, $27.5 million and $27.5 million, respectively and (2) variable success payments equal to 1.1x of the funding provided, consisting of sales milestone payments of (x) $17.5 million and $27.5 million, respectively upon first reaching certain cumulative U.S. product sales thresholds, and (y) $37.5 million upon first reaching a specified U.S. product sales run rate.

We had an option to receive an additional $25.0 million (the Optional Funding) within approximately two months of enrollment completion of our Phase 3 RESPONSE clinical trial. We did not exercise the Optional Funding and the option has expired.

Promptly following receipt of Regulatory Approval, we are required to execute and deliver a promissory note to Abingworth to convert the fixed and variable success payments into a note payable. At the time that Abingworth receives, collectively, an aggregate of 3.1x of the funding provided (approximately $232.5 million), our payment obligations under the Financing Agreement will be fully satisfied. We have the option to satisfy our payment obligations to Abingworth upon Regulatory Approval, or a change of control of us, by paying an amount equal to the remaining payments payable to Abingworth subject to a mid-single-digit discount rate. Upon a change of control of us, an acceleration payment of 1.35x of the funding provided is payable, net of payments already made to Abingworth and creditable against future payments to Abingworth.

Pursuant to the Financing Agreement, we are required to use commercially reasonable efforts to develop seladelpar and complete our development program in accordance with the Financing Agreement and an agreed

timeline. In addition, an executive review committee was established between Abingworth and us to discuss our development of seladelpar.

Pursuant to the Financing Agreement, we granted Abingworth a security interest in all of our assets (other than intellectual property not related to seladelpar), provided that we are permitted to incur certain indebtedness. The security interest will terminate when we have paid Abingworth 2.0x of the funding provided or upon certain terminations of the Financing Agreement. The Financing Agreement also provides for negative, affirmative and additional covenants, with which we have agreed to comply.

The Financing Agreement terminates upon the payment of all payments owing to Abingworth, unless earlier terminated. The Financing Agreement may be earlier terminated by Abingworth if (i) we fail to use commercially reasonable efforts to develop seladelpar as set forth in the Financing Agreement or fail to make required payments (Fundamental Breach), (ii) we suffer a material adverse event, (iii) there is a material adverse patent impact on our intellectual property covering seladelpar, (iv) there are certain irresolvable disagreements within the executive review committee, (v) the security interests of Abingworth are invalidated or terminated other than as set forth in the Financing Agreement or (vi) the RESPONSE clinical trial is completed or terminated and (1) the primary endpoint is not met or (2) Abingworth reasonably determines that the results of the RESPONSE clinical trial do not support regulatory approval. The Financing Agreement may be earlier terminated by us if (i) Abingworth fails to fund as provided in the Financing Agreement, (ii) Abingworth fails to release its security interests as provided in the Financing Agreement or (iii) the RESPONSE clinical trial is completed or terminated and the primary endpoint is not met. The Financing Agreement may be terminated by either party (i) if the other party materially breaches the Financing Agreement (Material Breach), (ii) if seladelpar fails to receive regulatory approval in the U.S., U.K. or E.U., (iii) upon the bankruptcy of the other party, (iv) if a serious safety concern arises in a seladelpar clinical trial or (v) upon a change of control of us.

In certain instances, upon the termination of the Financing Agreement, we will be obligated to pay Abingworth a multiple of the amounts paid to us under the Financing Agreement, including specifically,

(i) 310% of such amounts in the event that Abingworth terminates the Financing Agreement due to (x) a Fundamental Breach, (y) our bankruptcy, or (z) a safety concern resulting from gross negligence on our part or due to a safety concern that was material on the effective date of the Financing Agreement and the material data showing such safety concern was not publicly known, disclosed to Abingworth, or in the diligence room made available to Abingworth,

(ii) 200% of such amounts in the event the Financing Agreement is terminated due to (x) our Material Breach or (y) the security interests of Abingworth being invalidated or terminated other than as set forth in the Financing Agreement, and

(iii) 100% of such amounts in the event of certain irresolvable disagreements within the executive review committee.

In addition, if, following certain terminations, we continue to develop seladelpar for the treatment of PBC and obtain Regulatory Approval, we will make the payments to Abingworth as if the Financing Agreement had not been terminated, less any payments made upon termination. We are not obligated to make any payments to Abingworth under certain instances of technical or regulatory failure of the development program.

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 approximately 30 United States patents and 270 foreign patents, as well as a number of United States patent applications and foreign and Patent Cooperation Treaty applications that are counterparts to certain United States patents and patent applications. In addition, we license from third parties 11 United States patents and 1 United States patent application and approximately 200 foreign patents and 6 foreign and Patent Cooperation Treaty applications that are counterparts to certain United States patents and patent applications. These patents and patent applications include claims covering various aspects of our product pipeline and research and development strategies, including certain PPARd agonists (including seladelpar), their compositions and uses both alone and in combination with other drugs as well as certain GPR119 agonist compositions.

The seladelpar portfolio consists of approximately 460 issued patents and 30 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 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, as well as manufacturing, the API, finished drug product and packaged product. 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 a description of the competition in this indication is 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, Inc.). Ursodiol decreases serum levels of ALP, bilirubin, alanine aminotransferase, aspartate aminotransferase, cholesterol, and immunoglobulin M, all of which are elevated in patients with PBC and can serve as biochemical markers of the disease. In a study that combined data from three controlled trials with a total of 548 patients, ursodiol significantly reduced the likelihood of liver transplantation or death after four years. Ursodiol also delayed the progression of hepatic fibrosis in early-stage PBC, but was not effective in advanced disease. It has been reported that up to 50% of PBC patients fail to respond adequately to ursodiol therapy. Ursodiol is available as a generic, is approved for other indications, and is priced at a discount to typical branded therapies used in rare populations.

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./Ipsen, S.A.) is a mixed PPARα/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 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. In December 2021 Genfit announced that it had entered into an exclusive licensing agreement with Ipsen for the development and commercialization of elafibranor. Another potential therapy in clinical development for PBC is the dual PPARα/g agonist saroglitazar (Zydus Lifesciences Limited, formerly known as Cadila Healthcare Limited). 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 saroglitizar had been granted Fast Track Designation for PBC and in January 2021 it received Orphan Drug Designation for PBC by the FDA. In December 2021, Zydus announced it had initiated a Phase 2(b)/3 study of saroglitazar in patients with PBC. Calliditas Therapeutics AB's selective NOX inhibitor setanaxib has also reported Phase 2 study data for PBC and in August 2021, Calliditas announced setanaxib had been granted Fast Track Designation for PBC by the FDA and that setanaxib has previously been granted orphan drug designation for PBC in the U.S. and Europe. In February 2022, Calliditas announced it had initiated a Phase 2b/3 study in PBC. In cholestatic pruritus, GSK2330672 (GSK plc) is an inhibitor of the Intestinal Bile Acid Transporter (IBAT), which is undergoing evaluation for decreasing symptoms of pruritus, including in PBC.

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.

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 to assure compliance with GCP. 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.

Orphan Drug Designation

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

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

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective. 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.

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), other healthcare professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals, and applicable manufacturers and group purchasing organizations to report annually certain ownership and investment interests held by physicians and their immediate family members.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements 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.

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 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. On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, 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 until 2031 unless additional congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. 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.

In addition, there have been several 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, for example, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. Further, the IRA, among other things (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. Additionally, the Biden administration released an additional executive order on October 14, 2022, directing HHS to report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our business.

International Regulation

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

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, 2022, and February 28, 2023, we had 60 and 63 full-time employees, respectively.

Information about our Executive Officers

As of February 28, 2023, our executive officers were as follows:

Name	Age	Position Held With CymaBay
Sujal Shah	49	President & Chief Executive Officer
Charles A. McWherter, Ph.D.	68	President of Research and Development and Chief Scientific Officer
Dennis Kim, M.D.	53	Chief Medical Officer
Lewis Stuart	63	Chief Commercial Officer
Klara Dickinson	56	Chief Regulatory and Quality Assurance Officer
Paul T. Quinlan	60	General Counsel and Chief Compliance Officer
Daniel Menold	53	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.. 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 President of Research and Development and Chief Scientific Officer since November 2022. Previously, he served as 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.

Dennis Kim, M.D. has served as our Chief Medical Officer since May 2021 and his employment with us will terminate on May 17, 2023. From November 2020 to March 2021 he served as Chief Medical Officer of Afyx Therapeutics, a topical drug delivery company, where he led clinical, medical and regulatory development for Rivelin, a novel mucoadhesive patch to deliver treatment for diseases such as oral lichen planus. Prior to this, from March 2019 to November 2020 he served as Chief Medical Officer of Emerald Health Sciences, a biotechnology company, where he was responsible for the general supervision of the company's clinical and medical affairs, and from September 2011 to February 2019 was Chief Medical Officer at Zafgen, Inc., a biotechnology company, where he was responsible for the general supervision of the company's clinical and medical affairs. Prior to this Dr. Kim served in senior leadership roles at Orexigen, EnteroMedics and Amylin Pharmaceutical. He received his medical degree from The Chicago School of Medicine, completed his internal medicine residency at Rush University Medical College, and specialty fellowship training in endocrinology/metabolism at University of California, San Diego (UCSD) Medical Center. He also holds a M.B.A. with emphasis in biotechnology structure and strategy from UCSD Rady School of Business.

Lewis Stuart has served as our Chief Commercial Officer since May 2021. From December 2019 to May 2021, Mr. Stuart served as Vice President and Prostate Cancer Franchise Leader for Myovant Sciences, a biopharmaceutical company. In this role he led the company's Prostate Cancer Launch Readiness cross functional team of commercial, medical, legal, and manufacturing functions. From 2013 to 2017, Mr. Stuart served as Vice President, US Oncology Franchise at Genomic Health, a healthcare company, in which role he was responsible for various commercial aspects of the company's oncology business. Prior to Genomic Health, Mr. Stuart held senior leadership roles at several leading biopharmaceutical companies including Genomic Health and CV Therapeutics. He received a B.A. in Communications and Marketing Management from Virginia Polytechnic & State University, with graduate studies at Northeastern 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 this, 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 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, 2022, we had cash, cash equivalents and marketable securities totaling $135.5 million. To date, we have raised capital primarily through equity financings, licensing transactions and a structured finance arrangement. For example, in January 2023, we entered into a Collaboration and License Agreement with Kaken Pharmaceutical Co., Ltd. (Kaken), granting Kaken an exclusive license to commercialize and market seladelpar for the prevention or treatment of primary biliary cholangitis (PBC) in Japan in consideration for an upfront payment to the Company of $34.2 million that was paid in January 2023, potential milestone payments to the Company totaling up to ¥17.0 billion (approximately $128.0 million at contract inception date) for the achievement of certain regulatory and sales milestones in Japan and additional payments to the Company for the supply of seladelpar to Kaken. In January 2023, we sold 11,821,428 shares of common stock at $7.00 per share and a pre-funded warrant to purchase 2,142,857 shares of common stock at $6.9999 per share in a public equity offering for total gross offering proceeds of $97.7 million. In July 2021, we entered into a Development Financing Agreement with an affiliate of Abingworth LLP pursuant to which Abingworth provided $75 million in funding to the Company. We may need to raise additional equity and/or debt capital or enter into strategic transactions to fund our continued operations, including clinical trials, other product development and pre-commercialization activities. 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 to finance our product development activities, we will curtail our product development activities and other activities commensurate with the magnitude of the shortfall and our product development activities may cease altogether. To the extent that the costs of 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 enter into 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;
- 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 our pre-commercialization activities;
- the costs of filing, prosecuting, defending and enforcing our 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 would have a material adverse effect on our business, operating results, prospects, and on our ability to develop our product candidates.

Failure to remain in compliance with our obligations under the Development Financing Agreement (the Financing Agreement) with Abingworth could lead to the acceleration of potentially significant payments to Abingworth.

In July 2021, we entered into a Development Financing Agreement (the Financing Agreement) with Abingworth, pursuant to which Abingworth has provided $75 million in funding to us to support our development of seladelpar for the treatment of PBC. Pursuant to the Financing Agreement, we are required to use commercially reasonable efforts to develop seladelpar and complete our development program in accordance with the Financing Agreement and an agreed timeline. In return, we are obligated to pay to Abingworth (1) upon the first to occur of regulatory approval of seladelpar for the treatment of PBC in the U.S., U.K., Germany, Spain, Italy or France (Regulatory Approval), fixed success payments equal to 2.0x of the funding provided and (2) variable success payments equal to 1.1x of the funding provided upon first reaching certain U.S. product sales milestones. At the time that Abingworth receives, collectively, an aggregate of 3.1x of the funding provided, our payment obligations under the Financing Agreement will be fully satisfied.

The Financing Agreement terminates upon the payment of all payments owing to Abingworth, unless earlier terminated. The Agreement may be earlier terminated in a number of circumstances including (i) by Abingworth if we fail to use commercially reasonable efforts to develop seladelpar as set forth in the Financing Agreement or if we fail to make required payments (Fundamental Breach) or (ii) by either party if the other party materially breaches the Agreement (Material Breach). In certain instances, upon the termination of the Financing

Agreement, we will be obligated to pay Abingworth a multiple of the amounts paid to us under the Agreement, including specifically,

(i) 310% of such amounts in the event that Abingworth terminates the agreement due to (x) a Fundamental Breach, (y) our bankruptcy, or (z) a safety concern resulting from gross negligence on our part or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Abingworth, or in the diligence room made available to Abingworth,

(ii) 200% of such amounts in the event the Agreement is terminated due to (x) our Material Breach or (y) the security interests of Abingworth being invalidated or terminated other than as set forth in the Financing Agreement, and

(iii) 100% of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing our development of seladelpar.

In addition, if, following certain terminations, we continue to develop seladelpar for the treatment of PBC and obtain Regulatory Approval, we will make the payments to Abingworth as if the Financing Agreement had not been terminated, less any payments made upon termination.

The payments required under the Financing Agreement are significant. Failure to raise sufficient capital or generate sufficient revenue to make such payments if and as they become due, or failure to otherwise finance such payments would have a material adverse effect on our business. In addition, if we are unable to comply with our obligations under the Financing Agreement and/or one of the termination events described above occurs our payments obligations thereunder may be accelerated. The acceleration of payments under the Financing Agreement would have a material impact on our business and we may not be able to make such payments at such time.

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.

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 products, 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, 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.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions could adversely affect our current financial condition and projected business operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (SVB), where we hold a small portion of our cash and cash equivalents, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC), as receiver. On March 12, 2023, the Department of the Treasury, the Federal Reserve and the FDIC jointly released a statement that depositors at SVB would have access to their funds, even those funds in excess of FDIC insurance limits, under a systemic risk exception. As of March 13, 2023, we had access to our cash and cash equivalents at SVB; however, there is uncertainty in the markets regarding the stability of regional banks and the safety of deposits in excess of the FDIC insured deposit limits. The ultimate outcome of these events cannot be predicted, but these events could have a material adverse effect on our business operations if our ability to access funds at SVB or any other banks we use is compromised.

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

We 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 receive biopsies may be insufficient to satisfy regulatory requirements;
- clinical investigators or study subjects may fail to comply with clinical study protocols;
- trial conduct and data analysis issues may occur, including, but not limited to, failure to collect and analyze data in a timely manner, data entry and/or labeling errors or data analysis 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;
- geo-political turmoil between Russia and Ukraine and/or continuing military actions in Ukraine may interfere with our wind down of clinical trials of seladelpar in Russia and analysis of relevant data;
- 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. For example, we expect to release top line data for RESPONSE in the third quarter of 2023, and if positive, to submit an NDA seeking approval from the FDA for seladelpar for the second line treatment of PBC. The combined data from our trials may be inconclusive or may not be sufficient to gain approval from the FDA.

Geo-political turmoil between Russia and Ukraine and continuing military actions in Ukraine have caused us to suspend clinical trial activity in Ukraine and wind down clinical trial activity in Russia.

We have a small number of clinical sites in Russia in our RESPONSE clinical trial and in our ASSURE clinical trial. Because of continuing military action in Ukraine we suspended all clinical trial activity in Ukraine. Ongoing geo-political turmoil and continuing military action in the region, together with widening sanctions imposed on Russia, have also caused us to begin to wind down clinical trial activity in Russia. We expect clinical trial activity in Russia to terminate by the end of the third quarter of 2023. The ongoing military action and sanctions may still affect our RESPONSE and ASSURE clinical trials in Russia prior to completion of our wind down. Shipments of seladelpar to Russia may become difficult, delayed or impossible. Shipments of clinical samples from Russia may also become difficult, delayed or impossible. In addition, sites, site personnel and patients may not be able to continue in the trials and we may need to suspend or terminate the trials in Russia prior to the end of our expected wind down. While we have only a small number of clinical sites and enrolled patients in Russia, these disruptions and potential suspensions could complicate the analysis of data from subjects in Russia.

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

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We may experience delays in clinical trials at any stage of development and testing of our product candidates and any delay could result in increased costs to us. Any clinical trials we undertake may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all. The impact of the ongoing COVID-19 situation is also uncertain, and may create additional delays in completing our clinical trials.

Events that may result in delays or unsuccessful completion of clinical trials include the following:

- reluctance of patients to enroll in our clinical trials due to COVID-19;
- personnel shortages at clinical sites due to the COVID-19 situation that impacts our timeline or operations at clinical trial sites participating in our clinical trials;
- competition for eligible patients from competing clinical trials;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA or other regulatory authorities on final trial design;
- imposition of a clinical hold following a reported safety event;
- an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites;
- delays in obtaining required institutional review board (IRB) approval at each site;
- delays in recruiting suitable patients to participate in a trial;
- delays in having subjects complete participation in a trial or return for post-treatment follow-up;
- delays caused by subjects dropping out of a trial due to side effects or otherwise;
- changes to treatment guidelines or the introduction of a new standard of care;
- delays caused by clinical sites dropping out of a trial;
- time required to add new clinical sites;
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials; and
- delays in importing clinical trial materials into foreign countries where our clinical trials are being conducted.

If initiation or completion of any 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, which would 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. 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.

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

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;
- regulatory authorities might not approve our third-party manufacturers' processes or facilities for clinical or commercial product;
- regulatory authorities may change their approval policies or adopt new regulations;
- regulatory authorities may disagree with the design or implementation of our clinical studies;
- regulatory authorities may not accept clinical data from studies that are conducted in countries where the standard of care is potentially different from the jurisdiction of that regulatory authority;
- the results of clinical studies may not meet the level of statistical significance required by 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 products or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Our products would be subject to additional ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report AEs and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. Furthermore, promotional materials must be approved by the FDA prior to use for any drug receiving accelerated approval.

In addition, manufacturers of drug products and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices (cGMP), and adherence to commitments made in the NDA. If we, or a regulatory agency, discover previously unknown problems with a product, such as quality issues or AEs of

unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requesting recall or withdrawal of the product from the market or suspension of manufacturing.

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

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

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

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

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

Even if we obtain FDA approval for our product candidates in the United States, we may never obtain approval for or commercialize our product candidates outside of the United States, which would limit our ability to realize their full market potential.

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

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

Market acceptance and sales of any products that we commercialize 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 products 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 will 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. Restrictions under applicable federal and state health care laws and regulations, include the federal Anti-Kickback Statute, the federal False Claims Act, 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.

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 efforts to repeal or replace certain aspects of the PPACA. For example, 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. It is unclear how litigation, and the healthcare reform measures of the Biden administration will impact the PPACA and our business.

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 situation.

Risks Related to COVID-19

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

While the COVID-19 pandemic did not materially adversely affect our business operations in the year ended December 31, 2022, economic and health conditions in the United States and across most of the globe have continued to change. As a result of the COVID-19 pandemic, we have experienced and may continue to experience disruptions that could impact aspects of our business, including our progress towards the completion of our clinical studies and other drug development activities. Possible future disruptions are currently difficult to foresee and include, but are not limited to, potential risk areas as noted below:

- We are currently managing clinical trials and expect to begin clinical trials in geographies that are affected by COVID-19. While we have not experienced material impacts to our clinical activities through December 31, 2022, we are observing impacts due to COVID-19, including reluctance of subjects to enroll in clinical studies, restrictions impacting study personnel and trial participants, personnel shortages at clinical sites and operations and facility restrictions impacting trial operations. We believe that COVID-19 will have a continuing impact on various aspects of our clinical activities in the future. For example, pandemic-related reluctance or restrictions, including curtailment of activities, could reduce or slow the rate of patient enrollment in our clinical trials, 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 required to delay, or alter, their approach to complete work on our trials.

- We have moved to a hybrid model of operations, with most employees working from our office for a portion of the week and working remotely for the rest of the week. 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 coronavirus.
- Our continuing 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.
- 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 situation continues to evolve. The emergence of additional COVID-19 variants may also continue to affect the impact of the situation. The extent to which COVID-19 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 and variants to COVID-19 that continue to arise and their relative transmissibility and virulence, as well as 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 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 products.

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

The facilities used by our contract manufacturers to manufacture the approved product must be approved by the FDA pursuant to inspections that will be conducted only after we submit an NDA to the FDA, if at all. A representative from the European Medicines Agency (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 products. 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 will need to enter into commercial agreements with contract manufacturers and with one or more pharmaceutical product packagers/distributors to ensure proper supply chain management once we are authorized to make commercial sales of our product candidates. However, we may be unable to maintain agreements or negotiate commercial supply agreements on commercially reasonable terms with contract manufacturers and pharmaceutical product packagers/distributors, which could delay our ability to launch commercial sales and/or have a material adverse impact upon our business.

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

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

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

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

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

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

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

We rely on contract service providers (CSPs), including clinical research organizations, clinical trial sites, central laboratories and other service providers to ensure the proper and timely conduct of our clinical trials. While we have agreements governing their activities, we have limited influence over their actual performance. We have relied and plan to continue to rely upon CSPs to monitor and manage data for 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 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 products will depend on a number of factors, including the following:

- demonstration of clinical safety and efficacy in our clinical trials;
- the risk/benefit profile of our products;
- 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 products 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;
- acceptance of the product by physicians, other health care providers and patients as a safe and effective treatment;
- the potential and perceived advantages of products over alternative treatments;
- the timing of market introduction of competitive products;
- pricing and cost-effectiveness;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- our ability to obtain formulary approval;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement, which may vary from country to country; and
- the effectiveness of our or any future collaborators' sales, marketing and distribution efforts.

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

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product, 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 products.

If we are unable to successfully manage pre-commercialization activities, including but not limited to building our own sales force (or negotiate one or more strategic partnership(s) for the commercialization of our products) or establish marketing and distribution channels, we may be forced to delay the potential commercialization of the product, or reduce the scope of our sales or marketing activities. If we elect to increase our expenditures to fund commercialization activities ourselves, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring the product to market or generate product revenue.

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

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

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

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

If our product candidates are approved for commercialization outside the United States, we expect that we will be subject to additional risks related to international operations, including the following:

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

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

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

The life sciences industry is highly competitive, and we face significant competition from other pharmaceutical, biopharmaceutical and biotechnology companies and possibly from academic institutions, government agencies and private and public research institutions that are researching, developing and marketing products designed to address diseases that we are seeking to treat. Our competitors generally have significantly

greater financial, manufacturing, marketing and drug development resources. Large pharmaceutical companies, in particular, have extensive experience in the clinical testing of, obtaining regulatory approvals for, and marketing of, drugs. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

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

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

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

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

We face an inherent risk of product liability exposure related to the testing of our 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 products;
- 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 products; 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 specific 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 products. There is no assurance that all of the potentially relevant prior art relating to our patents and patent applications has been found, which if it exists could be used to invalidate a patent or prevent a patent from issuing from 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. 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 started by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license it from the prevailing party, which may not be available on commercially reasonable terms or at all.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietaryknow-how that is not patentable, processes for which patents are difficult to enforce and other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any

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

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

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

Our commercial success depends in part on our avoiding infringement and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party re-examination proceedings before the United States Patent and Trademark Office (U.S. PTO) and its foreign counterparts. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we 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 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 have been involved in the past in legal proceedings alleging the misappropriation of trade secrets.

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 may enter into additional licenses in the future. For example, we rely on an exclusive license to certain patents and know-how from Janssen Pharmaceutical NV (Janssen NV), which include seladelpar and certain other PPARd compounds (the PPARd Products). Under the exclusive license with Janssen NV we have full control and responsibility over the research, development and registration of any PPARd Products and are required to use diligent efforts to conduct all such activities. If we fail to comply with our obligations under our agreement with Janssen NV, including our obligations to expend more than a de minimis amount of effort and resources on the research and/or development of at least one PPARd Product, to make any payment called for under the agreement, not to disclose anynon-exempt confidential information related to the agreement, or to use diligent efforts to promote, market and sell any PPARd Product under the agreement, such action would constitute a default under the agreement and Janssen NV may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license, including in the case of the Janssen NV license, seladelpar, which would have a materially adverse effect on our business.

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

Competitors may infringe or otherwise violate our patents, the patents of our licensors or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is invalid 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 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 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, in April 2020, a stockholder filed a preliminary proxy statement containing proposed opposition to our preliminarily filed proxy statement, including a proposal to elect three new directors to our Board of Directors and a proposal not to increase to 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 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, technical and sales and marketing 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 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 key executives or key employees, 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 and drug development programs, we are expanding our employee base to increase our managerial, clinical, scientific, sales and marketing 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 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 our current remote work schedule. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

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

programs and our reputation could be materially damaged. We could also be exposed to a risk of loss or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

Changes in and failures to comply with United States and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and 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 includes 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 was formerly listed on the Nasdaq Capital Market and since the second quarter of 2018 it has been trading on the Nasdaq Global Select Market under the symbol "CBAY". 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 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:

- delays in completing the RESPONSE clinical trial and our other clinical trials;
- adverse, delayed or inconclusive results in our clinical trials, particularly our RESPONSE clinical trial;
- adverse or inconclusive results or delays in preclinical testing;
- 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 enter into new collaborations;
- failure by us or our licensors 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 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 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;
- 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 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, we are 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 December 31, 2022 was 2,680,621 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 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. An Amended Complaint was filed on April 16, 2021 with substantially the same allegations. Genfit was seeking 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, have taken diligent steps to remove and quarantine it, and are not using any Genfit trade secrets in our clinical trials. On March 12, 2021, the court granted a Temporary Restraining Order (later converted to a Preliminary Injunction), prohibiting us from accessing or disseminating the protocol synopsis, using any Genfit trade secrets contained therein or destroying any evidence related thereto. We filed a Motion to Dismiss the Amended Complaint that was granted on September 9, 2021, with leave to amend. Genfit filed a Second Amended Complaint on October 15, 2021 with substantially the same allegations and claims for relief as in the original complaint. We filed a Motion to Dismiss the Second Amended Complaint that was granted on January 21, 2022, without further leave to amend. What remained in the complaint was an alleged misappropriation of the protocol synopsis as a whole. We filed our Answer to what remained of the Second Amended Complaint on February 4, 2022. On February 21, 2023, the parties entered into a Settlement Agreement and the action was dismissed with prejudice. We did not admit to any liability and the litigation has been resolved completely.

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, 2023, there were approximately 213 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. Under our Development Financing Agreement with Abingworth we are not permitted to pay dividends without the consent of Abingworth. Except for the restrictions under our agreement with Abingworth, our board of directors has complete discretion on whether to pay dividends. Even if our board of directors is able to and 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. [Reserved]

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. These statements appear throughout this Annual Report on Form 10-K and are statements regarding our current expectation, belief, or intent, primarily with respect to our operations and related industry developments. Examples of these statements include, but are not limited to, statements regarding our expectations with respect to the following: our business and scientific strategies; the progress of our product development programs, and the timing of results; regulatory submissions and approvals; the impact of COVID-19 on our company and operations; our drug discovery technologies; our research and development expenses; protection of our intellectual property; sufficiency of our cash and capital resources and the need for additional capital; and our operations and legal risks. You should not place undue reliance on these forward-looking statements. Our actual results and the timing of events may differ significantly from the results discussed in the forward-looking statements for many reasons. Factors that might cause such a difference include those discussed under the caption "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These and many other factors could affect our future financial and operating results. We undertake no obligation to update any forward-looking statement to reflect events after the date of this Annual Report.

Overview

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

Our lead product candidate, seladelpar, is a potent and selective agonist of peroxisome proliferator activated receptor delta (PPARd), a nuclear receptor that regulates genes directly or indirectly involved in the synthesis of bile acids/sterols, metabolism of lipids and glucose, inflammation, and fibrosis. We have been focused on 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.

Seladelpar—Primary Biliary Cholangitis (PBC)

In July 2022, we completed enrollment of 193 patients in RESPONSE, a52-week, double blind, placebo-controlled, randomized, global, Phase 3 registration study evaluating the safety and efficacy of seladelpar in PBC. The study enrolled patients who have an inadequate response to, or intolerance to, ursodeoxycholic acid (UDCA), 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 alkaline phosphatase (ALP) 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 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. We expect to release top line data for RESPONSE in the third quarter of 2023.

In addition to RESPONSE, we are also actively recruiting and enrolling eligible patients for our ASSURE trial, an open-label, long-term study intended to collect additional long-term safety and efficacy data to support registration. ASSURE 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 and certain Phase 1 studies. The ASSURE trial currently has over 200 subjects enrolled and is expected to ultimately enroll in excess of 300 patients.

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 Phase 2a proof-of-pharmacology study to assess whether MBX-2982 can enhance glucagon secretion during insulin-induced hypoglycemia in subjects with T1D. The study is actively enrolling patients. 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 we are currently exploring potential opportunities to advance development.

COVID-19

As a result of the COVID-19 situation, we may experience future disruptions that could impact aspects of our business, including our progress towards the initiation and completion of certain clinical trials, and other associated drug development activities. COVID-19 has disrupted, and may continue to disrupt, aspects of our business, in particular in regard to the initiation and operation of clinical trial sites in portions of the United States, in the U.K and in Europe. Possible future disruptions are currently difficult to foresee. We continue to monitor areas of potential risk which include, but are not limited to, the following:

- 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 U.S. 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 have adapted to COVID-19 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 clinical trials. Although we and our vendors continue to plan for and develop COVID-related risk mitigation strategies, it is uncertain whether these plans will continue to be sufficient to fully offset the potential impact COVID-19 may have on our ability to execute our development activities in a timely and cost-effective manner.
- 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.
- Remote workforce operations—To date, our workforce has adapted to remotely working to maintain operations. Our operations are currently in a hybrid model with most employees working from our office for a portion of the week and working remotely for the rest of the week. Our continued use of partially remote operations, however, 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.

Overall, we cannot at this time predict the specific extent, duration, or full impact that the continuingCOVID-19 situation will have on our future consolidated financial condition and operations. The impact of COVID-19 on our consolidated financial performance will depend on future developments, including emergence of additional COVID-19 variants, the duration and spread of the virus and related governmental advisories and

restrictions, which could result in unexpected costs to us. 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 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 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—Summary of Significant Accounting Policies* 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 providers invoice us monthly in arrears for services performed. We make estimates of prepayments to consume 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 to the extent they are refundable. Examples of 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 expensing 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, 2022 and 2021.

Development Financing Agreement

We account for our Development Financing Agreement with Abingworth (the Financing Agreement) as a debt instrument. Accordingly, we have recorded payments received under the Financing Agreement as part of a development financing liability in our consolidated balance sheet. The liability is recorded at amortized cost and accreted to the contractual success fee amounts based on the estimated timing of regulatory approval and attainment of certain sales milestones using an imputed interest rate. Certain transaction fees incurred specifically to complete the Financing Agreement were capitalized and recorded as a reduction to the carrying amount of the development financing liability and are being amortized to interest expense using the effective interest rate method.

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within our control. Therefore, we periodically reassess the estimated timing of regulatory approval and attainment of sales milestones, and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, we will prospectively adjust the accretion of the development financing liability and the imputed interest rate.

We identified certain contingent repayment features in the Financing Agreement that are required to be bifurcated from the debt host instrument as embedded derivative liabilities; however, we determined the fair value of these features, both individually and in aggregate, were immaterial at inception and as of December 31, 2022 and 2021. The fair value of these features will be assessed at each subsequent reporting date and will be marked to market, if material. To determine the amount to record for the embedded derivative liability, we must assess the probability of occurrence of various potential future events that could affect the timing and/or amount of future cash flows related to the Financing Agreement.

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 actual forfeitures as they occur. 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 and forfeitures are accounted 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. We determine our stock price volatility based on the sufficiency of our historical stock price data. 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 and evaluates the need to make changes when and if necessary. Any such changes to our valuation assumptions and methodologies could materially impact our fair value determination and the resulting stock-based compensation expense.

Results of Operations

General

To date, we have not generated any income from operations. As of December 31, 2022, we have an accumulated deficit of $872.9 million, primarily as a result of expenditures for research and development, general and administrative expenses and net interest expenses from inception to that date. Currently, our lead product candidate is at a later stage of development and will require additional work and regulatory approval before it can be fully 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 sufficient 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 equity offerings, debt financings or a combination of the foregoing.

Operating Results

Our results of operations for the years ended December 31, 2022 and 2021 are presented below (in thousands):

	Year Ended December 31,		Change
($ in thousands)	2022	2021	2022 vs 2021
Operating expenses:			
Research and development	$ 67,995	$ 64,542	$ 3,453
General and administrative	25,116	23,040	2,076
Total operating expenses	93,111	87,582	5,529
Loss from operations	(93,111)	(87,582)	(5,529)
Interest expense, net:			
Interest income	2,017	167	1,850
Interest expense	(14,907)	(2,583)	(12,324)
Total interest expense, net	(12,890)	(2,416)	(10,474)
Net loss	$(106,001)	$(89,998)	$ (16,003)

Research & Development Expenses

Conducting research and development is central to our business model. Research and development expenses increased $3.5 million to $68.0 million from $64.5 million for the years ended December 31, 2022 and 2021, respectively. We expect that our research and development expenses will increase in the future primarily due to costs associated with our ongoing late-stage development of seladelpar in PBC.

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

	Year Ended December 31,		Change
	2022	2021	2022 vs. 2021
Project costs:			
Seladelpar PBC clinical studies	$34,143	$35,007	$ (864)
Seladelpar drug manufacturing & development	6,585	5,531	1,054
Seladelpar and non-seladelpar other studies	907	3,196	(2,289)
Total project costs	41,635	43,734	(2,099)
Internal research and development costs	26,360	20,808	5,552
Total research and development	$67,995	$64,542	$ 3,453

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 materials and manufacturing drug products for use in clinical trial and other research activities; and
- other costs associated with development activities, including additional studies.

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

Total project costs decreased by $2.1 million to $41.6 million from $43.7 million for the years ended December 31, 2022 and 2021, respectively. Project costs for the year ended December 31, 2022 primarily consisted of clinical trial expenses related to the development of seladelpar for the treatment of patients with PBC. These cost decreases were driven primarily by the completion of enrollment of our RESPONSE trial and lower spending in other Phase 1 NDA-enabling clinical studies for PBC during the year ended December 31, 2022. Additionally,non-seladelpar other studies were lower due to the termination of clinical development in this area. Internal research and development costs increased by $5.6 million to $26.4 million from $20.8 million for the years ended December 31, 2022 and 2021, respectively, primarily due to an increase in headcount in research and development personnel to support our clinical studies. As we continue to progress late-stage development of seladelpar in PBC, we expect research and development expenses to increase in the future.

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 increased by $2.1 million to $25.1 million from $23.0 million for the years ended December 31, 2022 and 2021, respectively. The increase was driven primarily by an increase in headcount in general and administrative personnel as we continue to add administrative personnel and expand our infrastructure in support of our drug development activities. We expect these types of general and administrative expenses to continue to increase in the future as we further expand support for our ongoing drug development activities and as we begin to conduct initiatives to plan and prepare for potential commercialization of seladelpar in PBC.

Interest Expense, Net

Interest expense, net includes interest expense related to the accretion of the development financing liability recorded in connection with the July 2021 Abingworth Development Financing Agreement (the Financing Agreement) using the effective interest method, net of interest income earned on our marketable securities portfolio. Interest expense, net, increased $10.5 million to $12.9 million from $2.4 million for the years ended December 31, 2022 and 2021, respectively primarily due to an increase in interest expense of $12.3 million that was driven by additional proceeds received under the Financing Agreement in January 2022 and because interest was accrued for the full year in 2022 as compared to six months in 2021. This increase in interest expense was partially offset by $1.9 million of additional interest income earned on our investment portfolio, which benefited in 2022 from higher prevailing interest rates that enhanced the portfolio's overall yield compared to 2021.

Income Taxes

As of December 31, 2022, we had federal net operating loss carryforwards of $346.0 million and state net operating loss carryforwards of $214.9 million to offset future taxable income, if any. In addition, we had federal research and development tax credit carryforwards of $4.1 million, federal orphan drug tax credit carryforwards of $28.1 million, and state research and development tax credit carryforwards of $9.2 million. If not utilized, the federal net operating losses for the years beginning before January 1, 2018 of $79.1 million will expire beginning in 2024 through 2037, and the federal net operating losses for the tax years beginning after January 1, 2018 of $266.9 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 2033 through 2042, and the state tax credit will carry forward indefinitely. Current federal and state tax laws include substantial restrictions on the utilization of net operating losses and tax credits in the event of an ownership change. During 2022, we completed a study and determined historical ownership changes occurred through December 31, 2022 and accordingly, we have reduced our carryforwards to incorporate the effects of these federal and state restrictions. Carryforwards that remain available 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, 2022, we recorded a full valuation allowance against our deferred tax assets of approximately $144.7 million, as our management believes it is more likely than not that they will not be fully realized. Interest and penalties for the years ended December 31, 2022 and 2021 were not material.

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, 2022, cash, cash equivalents and marketable securities totaled $135.5 million, compared to $194.6 million at December 31, 2021.

Development Financing Agreement

On July 30, 2021, we entered into a Development Financing Agreement (the Financing Agreement) with Abingworth to obtain funding to support our development of seladelpar for the treatment of PBC. The Financing Agreement provided us up to $100.0 million in funding, of which $25.0 million was received in August 2021, $25.0 million was received in November 2021 and $25.0 million was subsequently received in January 2022. We had an option to receive an additional $25.0 million within approximately two months following enrollment completion of our Phase 3 RESPONSE clinical trial; however, we did not exercise the option to receive this additional funding.

Collaboration and License Agreement

On January 6, 2023, we entered into a Collaboration and License Agreement with Kaken Pharmaceutical Co., Ltd. Pursuant to the agreement, we granted Kaken an exclusive license to commercialize seladelpar for the

treatment of PBC in Japan. In exchange for the license and other rights granted by us, Kaken paid us ¥4.5 billion ($34.2 million) in January 2023 and they are also obligated to make aggregate potential future milestone payments to us totaling up to ¥17.0 billion ($128.0 million at exchange rates in effect at contract inception date) upon Kaken' achievement of certain regulatory and sales milestones. We are obligated to manufacture and supply seladelpar to Kaken for use in the territory in exchange for payments from Kaken as defined in the agreement. For further details, refer to *Note 13—Subsequent Events* of our consolidated financial statements included in this Annual Report.

Sale of Common Stock and Pre-funded Warrant

On January 23, 2023, we sold 11,821,428 shares of common stock at $7.00 per share and a pre-funded warrant to purchase 2,142,857 shares of common stock at $6.9999 per share in a public equity offering (the January 2023 public equity offering), for total gross offering proceeds of approximately $97.7 million. The net proceeds from this offering were $92.4 million after deducting underwriting and other offering expenses. We anticipate using the offering proceeds to fund ongoing development of seladelpar and for working capital and general corporate purposes. For further details, refer to *Note 13—Subsequent Events* of our consolidated financial statements included in this Annual Report.

At-the-Market (ATM) Facility

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 pursuant to the Controlled Equity Offering℠ Sales Agreement with Cantor Fitzgerald & Co. (Cantor), dated July 2, 2020 (the Sales Agreement). To date, we have not sold any shares of common stock under the ATM.

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,	
	2022	2021
Net cash (used in) operating activities	$ (84,080)	$ (69,431)
Net cash (used in) provided by investing activities	(45,985)	48,589
Net cash provided by financing activities	24,550	118,455
Net (decrease) increase in cash and cash equivalents	$(105,515)	$ 97,613

Cash Flows from Operating Activities

Net cash used in operating activities for the year ended December 31, 2022 increased by $14.6 million to $84.1 million compared to $69.4 million in the prior year. The increase in cash used was primarily due to a $16.0 million increase in our net loss to $106.0 million from $90.0 million in the prior year period as a result of the expansion of late-stage clinical trial activities related to the seladelpar development program. In addition, cash was used to fund changes in our working capital.

Cash Flows from Investing Activities

Net cash used in investing activities was $46.0 million for the year ended December 31, 2022 compared to $48.6 million provided by investing activities in the prior year, primarily due to the timing of our purchases of investments and maturities of marketable securities and portfolio risk management.

Cash Flows from Financing Activities

Net cash provided by financing activities was $24.6 million for the year ended December 31, 2022 compared to $118.5 million in the prior year. In 2022, we received $25 million in proceeds pursuant to our Financing Agreement with Abingworth. Financing proceeds in 2021 were comparatively higher and included $70.5 million in net proceeds received from our November 2021 public equity offering and $47.7 million in net proceeds received from our Financing Agreement with Abingworth.

Capital Requirements

We have incurred operating losses since inception and had an accumulated deficit of $872.9 million at December 31, 2022. As of December 31, 2022, we had cash, cash equivalents and marketable securities of approximately $135.5 million. We believe these existing funds, together with the $34.2 million upfront payment received from Kaken in January 2023 pursuant to the Collaboration and License Agreement and the $92.4 million of net proceeds received in connection with our January 2023 public equity offering, are sufficient to fund our current operating plan through the third quarter of 2024.

We expect to continue to incur substantial expenses related to our development activities for the foreseeable future as we continue product development for seladelpar and begin to prepare for its potential commercialization in PBC. 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.

Contractual Obligations and Other Cash Requirements

Our long-term contractual obligations as of December 31, 2022 include monthly rental payments for our corporate office lease, which 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.

Our non-cancellable contractual obligations as of December 31, 2022, which relate to our operating lease, are presented in the table below (amounts in thousands):

Year ending December 31,	
2023	$707
2024	30
Total undiscounted future minimum lease payments	$737

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.

In the normal course of business, we also enter into various firm purchase commitments and other contractual obligations with other vendors, which are generally cancelable within ninety days or less.

We have significant potential payment obligations under the Financing Agreement that are contingently payable by us to Abingworth upon regulatory approval of seladelpar in PBC and achievement of certain sales for seladelpar. Specifically, we will pay to Abingworth fixed and variable success payments, including (1) contingent upon the first to occur of regulatory approval of seladelpar for the treatment of PBC in the U.S., U.K., Germany, Spain, Italy or France (Regulatory Approval), fixed success payments equal to 2.0x of the funding provided, consisting of $10 million payable within 90 days after Regulatory Approval and thereafter payments due on the first six anniversaries of the Regulatory Approval in the amounts of $15 million, $22.5 million, $22.5 million, $25.0 million, $27.5 million and $27.5 million, respectively and (2) variable success payments equal to 1.1x of the funding provided, consisting of sales milestone payments of (x) $17.5 million and $27.5 million, respectively upon first reaching certain cumulative U.S. product sales thresholds, and (y) $37.5 million upon first reaching a specified U.S. product sales run rate. See *Note 6—Development Financing Agreement* of our consolidated financial statements in this Annual Report for a more complete description of our financial obligations under the Financing Agreement. We were in compliance with all terms and covenants related to the Financing Agreement as of December 31, 2022.

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 Rules13a-15(e) and 15d-15(e) under the Exchange Act), our chief executive officer and principal financial officer have concluded that, as of the end of the period covered by this report, the design and operation of our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our President and Chief Executive Officer and our Vice President, Finance to provide reasonable assurance regarding the reliability of financial reporting and the preparation of 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, 2022.

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, 2022.

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, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Not applicable.

Item 9C. ***Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.***

Not applicable.

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 1–Election of Directors" in our proxy statement for our 2023 annual meeting of stockholders, or the 2023 Proxy Statement. The information required by this item with respect to late Section 16 filings, if any, is incorporated by reference to the information set forth under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in the 2023 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 2023 Proxy Statement.

If the 2023 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report onForm 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.

Item 11. ***Executive Compensation***

Reference is made to the information to be included under the headings "Executive Compensation" and "Director Compensation" in our 2023 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 with respect to security ownership of certain beneficial owners and management will be set forth in our 2023 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 2023 Proxy Statement under the caption "Securities Authorized for Issuance under Equity Compensation Plans—Equity Compensation Plan Information" and is incorporated herein by reference.

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

The information required by this item will be set forth in our 2023 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 2023 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

1. Financial Statements

2. Financial Statement Schedules

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

(b) List of Exhibits

		Incorporation By Reference			
Exhibit Number	**Exhibit Description**	**Form**	**SEC File No.**	**Exhibit**	**Filing Date**
3.1	Amended and Restated Certificate of Incorporation.	10/A	000-55021	3.1	10/17/2013
3.2	Certificate of Amendment of the Amended and Restated Certificate of Incorporation.	8-K	001-36500	3.1	6/26/2020
3.3	Amended and Restated By-Laws.	10/A	000-55021	3.2	10/17/2013
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.				
4.2	Description of Common Stock.	10-K	001-36500	4.2	3/25/2021
4.3	Form of Warrant to Purchase Shares of Common Stock.	8-K	001-36500	4.1	11/18/2021
4.4	Form of Warrant to Purchase Shares of Common Stock.	8-K	001-36500	4.1	1/25/2023
10.1*	2003 Equity Incentive Plan.	10	000-55021	10.1	8/12/2013
10.2*	Form of 2003 Equity Incentive Plan Stock Option Agreement.	10	000-55021	10.2	8/12/2013
10.3*	Form of 2003 Equity Incentive Plan Early Exercise Stock Option Agreement.	10	000-55021	10.3	8/12/2013
10.4*	2013 Equity Incentive Plan.	8-K	001-36500	10.1	6/7/2018
10.5*	Form of Option Grant Notice and Option Agreement under the 2013 Equity Incentive Plan.	10/A	000-55021	10.26	10/17/2013
10.6*	Form of Incentive Award Grant Notice under the 2013 Equity Incentive Plan.	10-K	000-55021	10.22	3/31/2014
10.7*	2020 New Hire Plan.	10-K	001-36500	10.7	3/25/2021
10.8*	Form of Stock Option Grant Notice and Option Agreement under the 2020 New Hire Plan.	10-K	001-36500	10.8	3/25/2021
10.9	Form of CymaBay Indemnity Agreement.	10-K	001-36500	10.7	3/15/2018

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
10.10#	PPAR-d License Agreement, dated June 20, 2006, by and between Metabolex, Inc. and Janssen Pharmaceutical NV.	10-Q	001-36500	10.1	11/14/2022
10.11#	Development Financing Agreement, dated July 30, 2021, by and between CymaBay Therapeutics, Inc. and ABW Cyclops SPV LP.	10-Q	001-36500	10.1	11/10/2021
10.12#+	Collaboration and License Agreement, dated January 6, 2023, between CymaBay Therapeutics, Inc. and Kaken Pharmaceutical Co., Ltd.				
10.13	Lease, dated November 8, 2013, between CymaBay Therapeutics, Inc. and BMR-Pacific Research Center, L.P.	10-Q	000-55021	10.27	11/25/2013
10.14	First Amendment to Lease, dated April 16, 2018, between CymaBay Therapeutics, Inc. and BMR-Pacific Research Center, LP.	10-Q	001-36500	10.1	5/8/2018
10.15*	Offer Letter, dated December 6, 2013, between CymaBay Therapeutics, Inc. and Sujal Shah.	10-K	000-55021	10.24	3/31/2014
10.16*	Offer Letter, dated November 21, 2013, between CymaBay Therapeutics, Inc. and Charles A. McWherter.	10-K	000-55021	10.26	3/31/2014
10.17*	Offer Letter, dated August 2, 2017, between CymaBay Therapeutics, Inc. and Daniel Menold.	10-Q	001-36500	10.4	8/10/2017
10.18*	Offer Letter, dated September 4, 2018, between CymaBay Therapeutics, Inc. and Klara Dickinson.	10-K	001-36500	10.16	2/28/2019
10.19*	Offer Letter, dated August 27, 2020, between CymaBay Therapeutics, Inc. and Paul Quinlan.	10-K	001-36500	10.18	3/25/2021
10.20*	Offer Letter, dated March 24, 2021, between CymaBay Therapeutics, Inc. and Lewis Stuart.	10-Q	001-36500	10.1	8/12/2021
10.21*	Offer Letter, dated April 30, 2021, between CymaBay Therapeutics, Inc. and Dennis D. Kim.	10-Q	001-36500	10.2	8/12/2021
10.22*	Notice of Resignation and Transition, effective February 20, 2023, between CymaBay Therapeutics, Inc. and Dennis Kim.	8-K	001-35600	10.1	2/23/2023
10.23*	Non-Employee Director Compensation Program.	10-K	001-36500	10.17	2/28/2019
10.24	Controlled Equity Offering℠ Sales Agreement, dated July 2, 2020, between CymaBay Therapeutics, Inc. and Cantor Fitzgerald & Co.	S-3	333-239670	1.2	7/2/2020
21.1+	List of subsidiaries of the Registrant.				
23.1+	Consent of Independent Registered Public Accounting Firm.				

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
24.1+	Power of Attorney. (Incorporated by reference to the signature page of this Annual Report on Form 10-K.)				
31.1+	Certification of President and Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13-a-14(a) or Rule 15(d)-14(a) of the Exchange Act.				
31.2+	Certification of Vice President, Finance (Principal Financial Officer) pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Exchange Act.				
32.1++	Certification of President and Chief Executive Officer (Principal Executive Officer) and Vice President, Finance (Principal Financial Officer) pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS+	Inline XBRL Instance Document				
101.SCH+	Inline XBRL Taxonomy Extension Schema Document				
101.CAL+	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF+	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB+	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE+	Inline XBRL Taxonomy Extension Presentation Document				
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in exhibit 101)				

\+ Filed herewith.
++ Furnished herewith.
* Indicates management contract or compensatory plan.
\# Certain portions of this exhibit have been omitted because the omitted portions are both not material and is the type of information that CymaBay treats as private or confidential.

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

CymaBay Therapeutics, Inc.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CymaBay Therapeutics, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the years then ended, 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 Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. 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.

San Mateo, California
March 23, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 20,291	$ 125,806
Marketable securities	115,194	60,729
Prepaid expenses and other current assets	2,588	4,564
Total current assets	138,073	191,099
Property and equipment, net	701	1,178
Non-current marketable securities	—	8,067
Operating lease right-of-use asset	169	254
Other assets	2,909	1,720
Total assets	$ 141,852	$ 202,318
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,096	$ 2,728
Accrued research and development expenses	6,530	9,752
Other accrued liabilities	7,815	5,886
Total current liabilities	15,441	18,366
Development financing liability	90,227	50,320
Long-term portion of operating lease liability	30	695
Total liabilities	105,698	69,381
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock, $0.0001 par value: 200,000,000 shares authorized; 84,681,063 and 84,677,939 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	8	8
Additional paid-in capital	909,329	899,798
Accumulated other comprehensive loss	(326)	(13)
Accumulated deficit	(872,857)	(766,856)
Total stockholders' equity	36,154	132,937
Total liabilities and stockholders' equity	$ 141,852	$ 202,318

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 67,995	$ 64,542
General and administrative	25,116	23,040
Total operating expenses	93,111	87,582
Loss from operations	(93,111)	(87,582)
Interest expense, net:		
Interest income	2,017	167
Interest expense	(14,907)	(2,583)
Total interest expense, net	(12,890)	(2,416)
Net loss	$ (106,001)	$ (89,998)
Other comprehensive loss:		
Unrealized loss on marketable securities, net of tax	(313)	(21)
Total other comprehensive loss	(313)	(21)
Comprehensive loss	$ (106,314)	$ (90,019)
Basic and diluted net loss per common share	$ (1.21)	$ (1.27)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	87,804,063	71,055,331

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, 2020	68,946,092	$ 7	$819,549	$ 8	$ (676,858)	$ 142,706
Issuance of common stock upon exercise of stock options	106,847	—	219	—	—	219
Stock-based compensation expense	—	—	9,996	—	—	9,996
Issuance of common stock and pre-funded warrants, net of $4,965 issuance costs	15,625,000	1	70,034	—	—	70,035
Net loss	—	—	—	—	(89,998)	(89,998)
Net unrealized loss on marketable securities	—	—	—	(21)	—	(21)
Balances as of December 31, 2021	84,677,939	$ 8	$899,798	$ (13)	$ (766,856)	$ 132,937
Issuance of common stock upon exercise of stock options	3,124	—	9	—	—	9
Issuance costs related to issuance of common stock and pre-funded warrants	—	—	5	—	—	5
Stock-based compensation expense	—	—	9,517	—	—	9,517
Net loss	—	—	—	—	(106,001)	(106,001)
Net unrealized loss on marketable securities	—	—	—	(313)	—	(313)
Balances as of December 31, 2022	84,681,063	$ 8	$909,329	$ (326)	$ (872,857)	$ 36,154

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2022	2021
Operating activities		
Net loss	$ (106,001)	$ (89,998)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	710	688
Stock-based compensation expense	9,517	9,996
Write-off of deferred financing costs	—	312
Accretion of development financing liability	14,907	2,583
Net accretion and amortization of investments in marketable securities	(874)	637
Changes in assets and liabilities:		
Prepaid expenses and other current assets	1,976	386
Other assets	(1,189)	(1,513)
Accounts payable	(1,444)	2,309
Accrued research and development expenses	(3,222)	5,054
Other accrued liabilities	1,540	115
Net cash (used in) operating activities	(84,080)	(69,431)
Investing activities		
Purchases of property and equipment	(148)	(87)
Purchases of marketable securities	(174,977)	(78,084)
Proceeds from maturities of marketable securities	129,140	126,760
Net cash (used in) provided by investing activities	(45,985)	48,589
Financing activities		
Proceeds from issuance of common stock pursuant to equity award plans	9	219
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	(459)	70,499
Proceeds from development financing, net of transaction costs	25,000	47,737
Net cash provided by financing activities	24,550	118,455
Net (decrease) increase in cash and cash equivalents	(105,515)	97,613
Cash and cash equivalents at beginning of period	125,806	28,193
Cash and cash equivalents at end of period	$ 20,291	$ 125,806
Supplemental disclosure		
Cash paid for amounts included in the measurement of lease liabilities	$ 686	$ 666
Supplemental non-cash investing and financing activities		
Unpaid financing costs	$ —	$ 464

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 innovative therapies for patients with liver and other chronic diseases with high unmet medical need. The Company's lead clinical development candidate is seladelpar. Seladelpar has been primarily under development for the treatment primary biliary cholangitis (PBC), a rare liver disease. 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, 2022, the Company incurred a net loss of $106.0 million and used $84.1 million of cash in operations. At December 31, 2022, the Company had an accumulated deficit of $872.9 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.

During and subsequent to the year ended December 31, 2022, the Company completed certain transactions as follows:

- In January 2022, the Company received the third installment of $25.0 million of the Company's Development Financing Agreement (the Financing Agreement) with ABW Cyclops SPV LP, an affiliate of Abingworth LLP (Abingworth), pursuant to which Abingworth committed to provide $75.0 million in funding in three equal quarterly installments. For further details, refer to *Note 6—Development Financing Agreement.*
- On January 6, 2023, the Company entered into a Collaboration and License Agreement with Kaken Pharmaceutical Co., Ltd (Kaken). Pursuant to the agreement, the Company granted Kaken an exclusive license to commercialize seladelpar for the treatment of PBC in Japan and received an upfront cash payment of $34.2 million. For further details, refer to *Note 13—Subsequent Events.*
- On January 23, 2023, the Company sold 11,821,428 shares of common stock at $7.00 per share and a pre-funded warrant to purchase 2,142,857 shares of common stock at $6.9999 per share in a public equity offering, for total net proceeds of $92.4 million, after deducting underwriting and other offering expenses. For further details, refer to *Note 13—Subsequent Events.*

As of December 31, 2022, the Company had cash, cash equivalents and marketable securities totaling $135.5 million. As the Company continues to advance its clinical studies of seladelpar, the Company believes its existing funds, together with the $34.2 million upfront payment received from Kaken in January 2023 pursuant to the Collaboration and License Agreement and the $92.4 million in net proceeds raised in connection with the January 2023 public equity offering, are sufficient to fund the Company's current operating plan for at least twelve months from the issuance date of its financial statements.

The Company has historically obtained, and expects to obtain in the future, additionalfinancing 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 could also adversely impact the Company's ability to access capital when and as needed. Failure to raise sufficient capital when needed could require the Company to significantly delay, scale back or discontinue its product development programs or commercialization efforts or other aspects of its business plans, and its operating results and financial condition would be adversely affected.

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.

Fair Value of Financial Instruments

The Company's financial instruments during the periods reported consist of cash, cash equivalents, marketable securities, accounts payable, certain accrued liabilities, and the development financing liability.

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 minimizes the use of unobservable inputs and is as follows:

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

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

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

The carrying amounts of cash equivalents approximate their related fair value due to the short-term nature of these instruments. Cash equivalents are classified as level 1 under the fair value hierarchy.

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

	As of December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$9,770	$ —	$ —	$ 9,770
Total cash equivalents	9,770	—	—	9,770
Marketable securities:				
U.S. and foreign commercial paper	—	46,121	—	46,121
U.S. and foreign corporate debt securities	—	24,807	—	24,807
Supranational debt securities	—	12,890	—	12,890
U.S. agency securities	—	7,759	—	7,759
U.S. treasury securities	—	23,617	—	23,617
Total marketable securities	—	115,194	—	115,194
Total assets measured at fair value	$9,770	$115,194	$ —	$124,964

	As of December 31, 2021			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$85,638	$ —	$ —	$ 85,638
Total cash equivalents	85,638	—	—	85,638
Marketable securities:				
U.S. and foreign commercial paper	—	28,760	—	28,760
U.S. and foreign corporate debt securities	—	23,535	—	23,535
Asset-backed securities	—	8,522	—	8,522
U.S. treasury securities	—	7,979	—	7,979
Total marketable securities	—	68,796	—	68,796
Total assets measured at fair value	$85,638	$68,796	$ —	$154,434

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.

The fair value of the Company's development financing liability is $79.5 million. The development financing liability is classified as level 3 under the fair value hierarchy as its valuation is based on a discounted cash flow model that uses unobservable inputs such as the estimated timing of regulatory approval, attainment of certain sales milestones and the discount rate.

Cash, Cash Equivalents, and Marketable Securities

The Company considers all highly liquid investments with an original maturity of90 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. These securities consist primarily of corporate debt, commercial paper, asset-backed securities, U.S. treasury, U.S. agency securities and supranational debt securities and are classified as “available-for-sale.” The Company considers marketable securities as short-term investments if the maturity date is less than or equal toone year from the balance sheet date. The Company considers marketable securities as long-term investments if the maturity date is in excess of one year 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 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. The Company maintains deposits in excess of FDIC insured deposit limits with its financial institutions.

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, includingright-of-use operating lease assets, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets

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

Leases

The Company has one lease, a non-cancelable operating lease agreement for its corporate 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 the Company's consolidated balance sheets at December 31, 2022 and 2021. 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.

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 its 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. 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 to the extent they are nonrefundable.

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 expensing 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. In 2022 and 2021, there have been no material differences from the Company's estimates to the amounts actually incurred.

Development Financing Agreement

The Company accounts for the Development Financing Agreement with Abingworth as a debt instrument. Accordingly, the Company has recorded payments received under the Financing Agreement as part of a development financing liability in the Company's consolidated balance sheet. The liability is recorded at amortized cost and accreted to the contractual success fee amounts based on the estimated timing of regulatory approval and attainment of certain sales milestones using an imputed interest rate. Certain transaction fees incurred specifically to complete the Financing Agreement were capitalized and recorded as a reduction to the carrying amount of the development financing liability and are being amortized to interest expense using the effective interest rate method.

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Company's control. Therefore, the Company periodically reassesses the estimated timing of regulatory approval and attainment of sales milestones, and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, the Company will prospectively adjust the accretion of the development financing liability and the imputed interest rate.

The Company identified certain contingent repayment features in the Financing Agreement that are required to be bifurcated from the debt host instrument as embedded derivative liabilities; however, the Company determined the fair value of these features, both individually and in the aggregate, was immaterial at inception and as of December 31, 2022. The fair value of these features will be assessed at each reporting date and will be marked to market, if material. To determine the amount to record for the embedded derivative liabilities, the Company must assess the probability of occurrence of various potential future events that could affect the timing and/or amount of future cash flows related to the Financing Agreement.

Pre-funded Warrants

Pursuant to the Company's public equity offering completed in November 2021, the Company issued pre-funded warrants to purchase 3,125,000 shares of common stock at a price of $3.9999 per share. These pre-funded warrants have an exercise price of $0.0001 per share, were fully exercisable upon issuance, and have no expiration date. The Company determined that the pre-funded warrants should be equity classified because they are freestanding financial instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of shares of common stock upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. Accordingly, the proceeds from the issuance of the warrants were recorded as additional paid-in capital on the Company's consolidated balance sheet as of December 31, 2022. Refer to *Note 9—Stockholders' Equity* for additional information.

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.

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.

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 and common stock equivalents outstanding during the period. The weighted-average common shares outstanding as of December 31, 2022 and 2021 includes pre-funded warrants to purchase up to 3,125,000 shares of common stock that were issued in connection with the November 2021 public offering, as discussed in *Note 9—Stockholders' Equity*. 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 and incentive awards were excluded from the calculation of net loss per share because the effect would be antidilutive.

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

	Year Ended December 31,	
	2022	2021
Numerator:		
Net loss	$ (106,001)	$ (89,998)
Denominator:		
Weighted average number of:		
Common stock shares outstanding	84,679,063	70,712,865
Pre-funded warrants outstanding	3,125,000	342,466
Total	87,804,063	71,055,331
Net loss per share	$ (1.21)	$ (1.27)

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,	
	2022	2021
Common stock options	13,930	10,791
Incentive awards	101	101
Total	14,031	10,892

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 this ASU on January 1, 2023 and does not expect a material impact to its consolidated financial statements and related disclosures.

3. Marketable Securities

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

	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
As of December 31, 2022:				
Cash equivalents:				
Money market funds	$ 9,770	$ —	$ —	$ 9,770
Total cash equivalents	9,770	—	—	9,770
Current marketable securities:				
U.S. and foreign commercial paper	46,121	—	—	46,121
U.S. and foreign corporate debt securities	24,964	—	(157)	24,807
Supranational debt securities	12,946	—	(56)	12,890
U.S. agency securities	7,782	16	(39)	7,759
U.S. treasury securities	23,707	2	(92)	23,617
Total current marketable securities	115,520	18	(344)	115,194
Total marketable securities	$125,290	$ 18	$ (344)	$124,964

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
As of December 31, 2021:				
Cash equivalents:				
Money market funds	$ 85,638	$ —	$ —	$ 85,638
Total cash equivalents	85,638	—	—	85,638
Current marketable securities:				
U.S. and foreign commercial paper	28,760	—	—	28,760
U.S. and foreign corporate debt securities	15,476	—	(8)	15,468
Asset-backed securities	8,524	1	(3)	8,522
U.S. treasury securities	7,982	—	(3)	7,979
Total current marketable securities	60,742	1	(14)	60,729
Non-current marketable securities:				
U.S. corporate debt securities	8,067	3	(2)	8,068
Total marketable securities	$154,447	$ 4	$ (16)	$154,435

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 and have similar credit quality and risk characteristics. 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.

There were no realized gains and losses for the years ended December 31, 2022 and 2021.None of our investments have been in a continuous unrealized loss position for more than 12 months as of December 31, 2022 and 2021. The Company may sell certain of its marketable securities prior to their stated maturities for reasons including, but not limited to, managing liquidity, credit risk, duration and asset allocation.

The following table shows the fair value of the Company's marketable securities, by contractual maturity, as of December 31, 2022 (in thousands):

Due less than 1 year	$ 115,194
Due between 1 and 2 years	—
Total fair value	$ 115,194

4. Certain Balance Sheet Items

Property and equipment are recorded at cost and consist of the following (in thousands):

	December 31, 2022	December 31, 2021
Leasehold improvements	$ 2,429	$ 2,429
Office and computer equipment	290	290
Purchased software	44	44
Furniture and fixtures	687	539
Total	3,450	3,302
Less: Accumulated depreciation and amortization	(2,749)	(2,124)
Property and equipment, net	$ 701	$ 1,178

Depreciation and amortization expense for the years ended December 31, 2022 and 2021 was approximately $0.7 million and $0.7 million, respectively, and was recorded straight-line in both research and development expense and general and administrative expense in the consolidated statements of operations and comprehensive loss. All the Company's property and equipment is located in the U.S.

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

	December 31, 2022	December 31, 2021
Accrued compensation	$ 5,779	$ 3,986
Accrued professional fees and other	1,372	1,333
Current portion of operating lease liability	664	567
Total other accrued liabilities	$ 7,815	$ 5,886

5. In-License Agreement

Janssen Pharmaceutica NV

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 Pharmaceutica 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. 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, 2022 and 2021.

6. Development Financing Agreement

On July 30, 2021 (the Effective Date), the Company entered into a Development Financing Agreement (the Financing Agreement) with Abingworth to provide funding to the Company to support its development of seladelpar for the treatment of primary biliary cholangitis (PBC). The Financing Agreement provided the Company up to $75.0 million in base funding, of which $25.0 million was provided in August 2021, $25.0 million was provided in November 2021, and $25.0 million was provided in January 2022.

The use of proceeds from the funding is limited to PBC "Development Program" costs incurred or paid as defined in the Financing Agreement. In return, the Company will pay to Abingworth:

(1) contingent upon the first to occur of regulatory approval of seladelpar for the treatment of PBC in the U.S., U.K., Germany, Spain, Italy or France (Regulatory Approval), fixed success payments equal to 2.0x of the funding provided, consisting of $10 million payable in 90 days after the Regulatory Approval and thereafter, payments due on the first six anniversaries of the Regulatory Approval in the amounts of $15.0 million, $22.5 million, $22.5 million, $25.0 million, $27.5 million and $27.5 million, respectively and

(2) variable success payments equal to 1.1x of the funding provided, consisting of sales milestone payments of (x) $17.5 million and $27.5 million, respectively upon first reaching certain cumulative U.S. product sales thresholds, and (y) $37.5 million upon first reaching a specified U.S. product sales run rate.

Promptly following receipt of Regulatory Approval, the Company is required to execute a note agreement and deliver a promissory note to Abingworth within two business days to convert the fixed and variable success payments into a note payable. At the time that Abingworth receives, collectively, an aggregate of 3.1x of the funding provided (approximately $232.5 million), the Company's payment obligations under the Financing Agreement will be fully satisfied. The Company has the option to satisfy its payment obligations to Abingworth upon Regulatory Approval, or a change of control of the Company, by paying an amount equal to the remaining payments payable to Abingworth subject to a mid-single-digit discount rate. Upon a change of control of the Company, an acceleration payment of 1.35x of the funding provided is payable, net of payments already made to Abingworth and creditable against future payments to Abingworth.

Pursuant to the Financing Agreement, the Company granted Abingworth a security interest in all its assets (other than intellectual property not related to seladelpar), provided that the Company is permitted to incur certain indebtedness. The security interest will terminate when the Company has paid Abingworth 2.0x of the funding provided or upon termination of the Financing Agreement.

The Financing Agreement provides for negative, affirmative and additional covenants, which the Company must comply with for the duration of the Financing Agreement term. As of December 31, 2022, the Company was in compliance with all covenants stipulated in the Financing Agreement.

In certain instances, upon the termination of the Financing Agreement, the Company will be obligated to pay Abingworth a multiple of the amounts paid to the Company under the Financing Agreement, including specifically:

(i) 310% of such amounts in the event that Abingworth terminates the Financing Agreement due to (x) a Fundamental Breach, as defined in the Financing Agreement, (y) the bankruptcy of the Company, or (z) a safety concern resulting from gross negligence on the part of the Company or due to a safety concern that was material on the Effective Date and the material data showing such safety concern was not publicly known, disclosed to Abingworth, or in the diligence room made available to Abingworth,

(ii) 200% of such amounts in the event the Financing Agreement is terminated due to (x) Material Breach, as defined in the Financing Agreement,by the Company or (y) the security interests of Abingworth being invalidated or terminated other than as set forth in the Financing Agreement, and

(iii) 100% of such amounts in the event of certain irresolvable disagreements within the executive review committee overseeing the Company's development of seladelpar.

In addition, if, following certain terminations, the Company continues to develop seladelpar for the treatment of PBC and obtains regulatory approval, it will make the payments to Abingworth as if the Financing Agreement had not been terminated, less any payments made upon termination.

The Company shall not be obligated to make any payments to Abingworth under certain instances of technical or regulatory failure of the PBC development program as defined in the Financing Agreement.

As part of the arrangement, an executive review committee was established between the Company and Abingworth to discuss the Company's development of seladelpar.

The Company evaluated the Financing Agreement and determined it to be a research and development funding arrangement with the characteristics of a debt instrument as the transfer of financial risk to Abingworth was not considered substantive and genuine. Accordingly, the Company has recorded payments received under the Financing Agreement as part of a development financing liability in its consolidated balance sheets. The Company accounts for the overall development financing liability at amortized cost based on the estimated timing of regulatory approval and attainment of certain sales milestones and the contractual success fee payments expected to be due therefrom, as discounted using an imputed interest rate. The development financing liability is being accreted as interest expense to its expected future repayment amount over the expected life of the agreement using the effective interest rate method. Certain legal and financial advisory fees incurred specifically to complete the Financing Agreement were capitalized and recorded as a reduction to the carrying amount of the development financing liability and are also being amortized to interest expense using the effective interest method.

There are several factors that could affect the estimated timing of regulatory approval and attainment of sales milestones, some of which are not entirely within the Company's control. Therefore, the Company periodically reassesses the estimated timing of regulatory approval and attainment of sales milestones, and the expected contractual success fee payments due therefrom. If the timing and/or amount of such expected payments is materially different than original estimates, the Company will prospectively adjust the accretion of the development financing liability and the imputed interest rate.

The Company identified certain contingent repayment features in the agreement that are required to be bifurcated from the debt host instrument as embedded derivative liabilities; however, the fair value of these features was immaterial at the Effective Date and as of December 31, 2022 and 2021. The fair value of the embedded derivative liabilities will be assessed at subsequent reporting dates if material.

The following table sets forth a summary of the changes in the carrying value of the Company's development financing liability (in thousands):

Balance at December 31, 2021	$50,320
Cash received	25,000
Accretion of development financing liability	14,907
Balance at December 31, 2022	$90,227

As of December 31, 2022, the development financing liability was classified as a long-term liability as the Company expects the related repayments to take place between 2024 and 2030 for purposes of the model used to

calculate its carrying value. The imputed interest rate on the unamortized portion of the development financing liability was approximately 19.2% as of December 31, 2022.

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, 2022 and December 31, 2021, the Company's lease portfolio had a weighted average remaining term of 1.1 years, and 2.1 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 of 12.6% as the discount rate when measuring operating lease liabilities. The incremental borrowing rate represents an estimate of the interest rate the Company would incur at lease commencement to borrow an amount equal to the lease payments on a collateralized basis over the term of a lease within a particular currency environment. The Company used an incremental borrowing rate as of the date of adoption for leases that commenced prior to January 1, 2019.

For the years ended December 31, 2022 and 2021, the Company incurred $0.7 million and $0.6 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, 2022 and December 31, 2021, the Company's operating lease right-of-use asset totaled $0.2 million and $0.3 million, respectively, and the operating lease liability totaled $0.7 million and $1.3 million, respectively. As of December 31, 2022, the short-term portion of the operating lease liability was 0.7 million and is contained within other accrued liabilities on the balance sheet, with an immaterial amount reported on the balance sheet as the long-term portion of operating lease liability.

As of December 31, 2022, the maturities of the Company's operating lease liabilities were as follows (in thousands):

Year ending December 31,	
2023	$707
2024	30
Total undiscounted future minimum lease payments	737
Less imputed interest	43
Total operating lease liability	694
Less: current portion of operating lease liability	664
Long-term portion of lease liability	$ 30

8. 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, 2022 and 2021. 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 primary biliary cholangitis. An Amended Complaint was filed on April 16, 2021 with substantially the same allegations. Genfit was seeking damages in an unspecified amount as well as injunctive relief.On March 12, 2021, the Court granted a Temporary Restraining Order (later converted to a Preliminary Injunction), prohibiting the Company from accessing or disseminating the protocol synopsis, using any Genfit trade secrets contained therein or destroying any evidence related thereto. The Company filed a Motion to Dismiss the Amended Complaint that was granted on September 9, 2021, with leave to amend. Genfit filed a Second Amended Complaint on October 15, 2021 with substantially the same allegations and claims for relief as in the original complaint. The Company filed a Motion to Dismiss most of the Second Amended Complaint that was granted on January 21, 2022, without further leave to amend. What remained in the complaint was an alleged misappropriation of the protocol synopsis as a whole. The Company filed its Answer to what remained of the Second Amended Complaint on February 4, 2022. On February 21, 2023, the parties entered into a Settlement Agreement and the action was dismissed with prejudice. The Company did not admit to any liability and the litigation has been resolved completely.

9. Stockholders' Equity

Preferred and Common Stock Authorized

The Company is authorized to issue 10,000,000 shares of preferred stock as of December 31, 2022 and 2021, and200,000,000 shares of common stock as of December 31, 2022 and 2021.

Common Stock Reserved for Future Issuance

As of December 31, 2022 and 2021, the Company had reserved shares of common stock for future issuances as follows:

	December 31,	
	2022	2021
Pre-funded warrants to purchase common stock	3,125,000	3,125,000
Equity award plans:		
Options and incentive awards outstanding, all equity plans	14,031,377	10,892,613
Equity awards available for future grant - 2013 Plan	2,680,621	1,588,613
Equity awards available for future grant - 2020 Plan	—	—
Total shares of common stock reserved for future issuance	19,836,998	15,606,226

Sale of Common Stock and Pre-funded Warrants

In November 2021, pursuant to a shelf registration statement on Form S-3, the Company completed the sale of common stock and pre-funded warrants pursuant to an underwritten public equity offering. The pre-funded warrants to purchase 3,125,000 shares of common stock were issued at a price of $3.9999 per share, have an exercise price of $0.0001 per share, were fully exercisable upon issuance, and have no expiration date. The Company determined that the pre-funded warrants should be equity classified because they are freestanding financial instruments, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, permit the holders to receive a fixed number of shares of common stock upon exercise, are indexed to the Company's common stock and meet the equity classification criteria. In addition, such pre-funded warrants do not provide any guarantee of value or return. Accordingly, the proceeds from the issuance of the warrants were recorded as additional paid-in capital on the Company's consolidated balance sheet as of December 31, 2022. None of the pre-funded warrants have been exercised, and therefore they remain outstanding as of December 31, 2022.

On January 23, 2023, the Company issued 11,821,428 shares of its common stock at $7.00 per share in an underwritten public offering. The Company also issued a pre-funded warrant to purchase up to an aggregate of 2,142,857 shares of common stock at a purchase price of $6.9999 per share and has an exercise price of $0.0001 per share. Refer to *Note 13—Subsequent Events* for further information.

10. 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 Plan may be increased at the discretion of and approval by the board of directors.

Stock Plan Activity

As of December 31, 2022, there were 2,680,621 and no shares available for grant under the 2013 and 2020 Plans, respectively. On January 1, 2023, in accordance with the annual share increase provision in the 2013 Plan, the Company added 4,234,053 shares to the 2013 Plan share reserve.

The following table summarizes activity in the Company's stock option grants:

	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, 2021	10,791,431	$ 6.01		
Options granted	3,692,868	2.94		
Options exercised	(3,124)	2.94		
Options forfeited	(403,210)	4.08		
Options expired	(147,770)	5.24		
Outstanding as of December 31, 2022	13,930,195	$ 5.26	6.96	$ 26,089
Vested and expected to vest as of December 31, 2022	13,930,195	$ 5.26	6.96	$ 26,089
Exercisable as of December 31, 2022	9,004,373	$ 6.00	6.08	$ 13,858

The total intrinsic value of options exercised was immaterial and $0.2 million for the years ended December 31, 2022 and 2021, respectively.

The total fair value of options vested was $0.6 million and $0.7 million for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, unamortized stock-based compensation expense of $14.7 million is expected to be recognized over a weighted average period of 2.4 years.

Incentive Awards

In December 2013, January 2014, and April 2014, as permitted by the 2013 Plan, the Company issued certain incentive awards to directors, employees and a consultant which are subject to 252,752 shares of the Company's common stock and are exercisable at a weighted average price of $5.21 per share when vested. The Company may determine at its option whether to settle exercised awards in shares of common stock or in cash. The incentive awards were fully vested as of December 31, 2022 and 2021 and have a term of 10 years.

Incentive awards outstanding totaled 101,182 as of December 31, 2022 and 2021.

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,	
	2022	2021
Research and development	$4,274	$4,470
General and administrative	5,243	5,526
Total stock-based compensation expense	$9,517	$9,996

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,	
	2022	2021
Expected term (years)	6.0	6.1
Expected volatility	101%	104%
Risk-free interest rate	1.8%	0.9%
Expected dividend yield	—	—
Weighted-average grant date fair value per share	$2.33	$3.91

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 due to the lack of sufficient prior exercise data available. Therefore, for stock option grants made during the years ended December 31, 2022 and 2021, 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 Company will reevaluate this methodology at a point in time when sufficient exercise data becomes available. The expected term represents the period of time that options are expected to be outstanding.

Expected Volatility

The Company estimates expected volatility by measuring the historical volatility of its common stock price over a historical period commensurate with the expected term of the related award.

Risk-Free Interest Rate

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

Expected Dividend Yield

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

11. 401(k) Plan

The Company provides a qualified 401(k) savings plan for its employees. All employees are eligible to participate, provided they meet the requirements of the plan. As is permitted under the plan, the Company has elected to match employee contributions up to $750 and accordingly matching contributions totaling an insignificant amount were made in the years ended December 31, 2022 and 2021.

12. Income Taxes

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

	December 31,	
	2022	2021
Deferred tax assets:		
Federal and state net operating loss carryforwards	$ 87,681	$ 129,898
State and federal research and development tax credit carryforwards	32,016	31,951
Intangibles and capitalized research and development	16,912	5,670
Stock-based compensation	6,624	5,329
Other	1,574	1,222
Total deferred tax assets	144,807	174,070
Deferred tax liabilities:		
Depreciation and amortization	(79)	(158)
Other	(36)	(53)
Total deferred tax liabilities	(115)	(211)
Valuation allowance	(144,692)	(173,859)
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 valuation allowance decreased by $29.2 million primarily due primarily to a $38.4 million write-off of tax attributes pursuant to certain Section 382 limitations and to a lesser extent the utilization of net operating losses during the year ended December 31, 2022, These valuation allowance reductions were offset in part by valuation allowance increases to cover additions to the Company's capitalized research and development and other deferred tax assets during the year ended December 31, 2022. The valuation allowance increased by $14.7 million primarily due to an increase in the Company's taxable loss during the year endedDecember 31, 2021.

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

	December 31,	
	2022	2021
Income tax benefit at federal statutory tax rate	$(22,260)	$(18,900)
Change in valuation allowance	(29,165)	14,739
Impairment of tax attributes	38,398	—
Research credits	(2,640)	(2,802)
Cancelled options	49	141
Development financing liability	12,301	6,654
Permanent differences	511	429
State income taxes, net of federal benefit	2,806	(267)
Other, net	—	6
Income tax (benefit) expense	$ —	$ —

Pursuant to Internal Revenue Code (IRC) Sections 382 and 383 and similar state laws, 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% within a three-year period. In 2022, the Company completed an ownership change analysis and determined that its net operating losses and research and development credits were subject to limitations due to historical changes in ownership that occurred through December 31, 2022. Accordingly, the net operating loss carryforwards reflected in the deferred tax assets at December 31, 2022 have been reduced to reflect Section 382 limitations resulting from these changes. As the Company is expected to incur additional losses in the future, any future ownership changes that might occur could further restrict the Company's ability to utilize its net operating loss and research and development carryforwards.

As of December 31, 2022, the Company had federal net operating loss carryforwards of $346.0 million and state net operating loss carryforwards of $214.9 million to offset future taxable income, if any. In addition, the Company had federal research and development tax credit carryforwards of $4.1 million, federal orphan drug tax credit carryforwards of $28.1 million, and state research and development tax credit carryforwards of $9.2 million. If not utilized, the federal net operating losses for the years beginning before January 1, 2018 of $79.1 million will expire beginning in 2024 through 2037, and the federal net operating losses for the tax years beginning after January 1, 2018 of $266.9 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 2033 through 2042, and the state tax credit will carry forward indefinitely. The following table summarizes activity related to the Company's gross unrecognized tax benefits (in thousands):

Balances as of December 31, 2020	$ 7,205
Increases related to prior year tax positions	9
Increases related to 2021 tax positions	783
Balances as of December 31, 2021	7,997
Decreases related to prior year tax positions	(1,223)
Increases related to 2022 tax positions	730
Balances as of December 31, 2022	$ 7,504

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 in the future for unexpected or unusual items for items that may arise in the ordinary course of business.

The Company's major income tax filing jurisdictions are the U.S. federal and California state and is not currently under examination by federal, state, or local taxing authorities for any open tax years. Due to net operating loss carryforwards, the tax years 2004 to 2022 remain open for income tax examination by tax authorities in the U.S. and states in which the Company files tax returns. Interest and penalties for the years ended December 31, 2022 and 2021 were not material.

In August 2022, the Inflation Reduction Act of 2022 (IRA) was signed into law. The IRA provides several tax incentives, including the expanded Internal Revenue Code (IRC) Section 179D deduction, increased ability to leverage the R&D credit to offset payroll taxes for eligible start-up businesses, and 15% alternative minimum tax (AMT) for corporations with average income of more than $1 billion for the past three tax periods. The IRA did not have a material impact on the Company's consolidated financial statements; however, the Company continues to examine the impacts the above-mentioned tax legislations may have on its business, results of operations, financial condition and liquidity.

13. Subsequent Events

Collaboration and License Agreement with Kaken Pharmaceutical Co., Ltd.

In January 2023, the Company entered into a Collaboration and License Agreement (the License Agreement) with Kaken Pharmaceutical Co., Ltd. (Kaken). Pursuant to the License Agreement, the Company granted Kaken an exclusive license to commercialize seladelpar (the Licensed Product) for the treatment of PBC in Japan.

Kaken will bear the cost of, and be responsible for, conducting clinical studies and other developmental activities, preparing and filing applications for regulatory approval and commercializing seladelpar in Japan. The Company is generally obligated to supply seladelpar to Kaken for use in Japan, at a supply price per unit as defined in the agreement.

In consideration of the license and other rights granted by the Company, Kaken made an upfront cash payment to the Company of $34.2 million in January 2023 and is obligated to make potential milestone payments to the Company totaling up to ¥17.0 billion (approximately $128.0 million using exchange rates in effect at the contract inception date) contingent upon Kaken's achievement of certain regulatory and sales milestones as defined in the agreement.

Sale of Common Stock and Pre-funded Warrant

On January 23, 2023, pursuant to a shelf registration statement on Form S-3, the Company sold 11,821,428 of its common shares at $7.00 per share in an underwritten public equity offering and a pre-funded warrant to purchase 2,142,857 shares of common stock at a purchase price of $6.9999 per share, which represents the per share public offering price for the common stock less the $0.0001 per share exercise price of the pre-funded warrant. The Company received net proceeds of $92.4 million from this public equity offering after deducting underwriting and other offering expenses.

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 23, 2023
Date

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Sujal Shah and Daniel Menold, as his or her true and lawful attorney-in-fact and agent, with full power of substitution for him or her, and in his or her 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 or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Name and Signature	Title	Date
/s/ Sujal Shah Sujal Shah	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 23, 2023
/s/ Daniel Menold Daniel Menold	Vice President, Finance *(Principal Financial and Accounting Officer)*	March 23, 2023
/s/ Robert J. Wills Robert J. Wills	Director	March 23, 2023
/s/ Kurt von Emster Kurt von Emster	Director	March 23, 2023
/s/ Caroline Loewy Caroline Loewy	Director	March 23, 2023
/s/ Thomas G. Wiggans Thomas G. Wiggans	Director	March 23, 2023
/s/ Janet Dorling Janet Dorling	Director	March 23, 2023
/s/ Éric Lefebvre Éric Lefebvre	Director	March 23, 2023

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE OF INFORMATION THAT CYMABAY TREATS AS PRIVATE OR CONFIDENTIAL.

EXECUTION COPY

COLLABORATION AND LICENSE AGREEMENT

This COLLABORATION AND LICENSE AGREEMENT (this "**Agreement**"), dated as of January 6, 2023 (the "**Effective Date**"), is entered into by and between **CymaBay Therapeutics, Inc.**, a Delaware corporation ("**CymaBay**"), and **Kaken Pharmaceutical Co., Ltd.**, a company organized under the laws of Japan ("**Kaken**"). CymaBay and Kaken may be referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**".

RECITALS:

WHEREAS, CymaBay is a clinical-stage biopharmaceutical company involved in the research, development and commercialization of pharmaceutical therapies for liver and other chronic diseases with high unmet need;

WHEREAS, Kaken is involved in and possesses expertise and experience in developing, manufacturing, marketing and selling pharmaceutical products worldwide; and

WHEREAS, CymaBay and Kaken desire to enter into an agreement under which they shall collaborate to develop and commercialize CymaBay's Seladelpar product for use in particular indications solely in Japan, as more fully described in this Agreement.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

Unless specifically set forth to the contrary herein, the following capitalized terms, whether used in the singular or plural, will have the respective meanings set forth below:

1.1 "**Abbreviated New Drug Application**" or "**ANDA**" has the meaning set forth in the FD&C Act 21 U.S.C. § 355(b)(2), 21 U.S.C. § 355(j) and 21 C.F.R. § 314.3 as amended, or such analogous provisions of Applicable Law outside the United States.

1.2 "**Accounting Standards**" means: (a) with respect to CymaBay, generally accepted accounting principles as practiced in the United States, and (b) with respect to Kaken and its Related Parties, generally accepted accounting principles as practiced in Japan or IFRS, as applicable, in each of case (a) and (b) as generally and consistently applied throughout the Party's organization. Each Party will promptly notify the other in the event that it changes the Accounting Standards pursuant to which its records are maintained; *provided, however*, that each Party may only use internationally recognized accounting principles (e.g. IFRS, GAAP, etc.).

1.3 "**Acquirer**" has the meaning ascribed to such term, with respect to a particular Change of Control, as set forth in Section 1.18.

1.4 "**Additional Indication**" means a human disease or pathological condition intended to be treatable by a therapeutic product other than the Initial Indication.

1.5 "**Additional Indication Japan License**" has the meaning set forth in Section 10.6.

1.6 "**Additional Indication Notice**" has the meaning set forth in Section 10.6.

1.7 "**Affiliate**" means, with respect to a Person, any other Person that controls, is controlled by, or is under common control with, such Person, at the applicable time during the Term of this Agreement. For purposes of this definition, "control" means (with corresponding meanings for the terms "controlled by" and "under common control with") that the applicable Person owns or controls, directly or indirectly, more than fifty percent (50%) of the equity securities of the applicable other Person entitled to vote in the election of directors (or, in the case that such other Person is not a corporation, for the election of the corresponding managing authority), or otherwise has the power to direct the management and policies of such other Person. The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside the United States, the maximum percentage ownership permitted by Applicable Law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage will be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management and policies of such entity. For clarity, a Person may be or become an Affiliate of another Person and may cease to be an Affiliate of such Person, in each case, during the Term of this Agreement.

1.8 "**Agreement**" has the meaning set forth in the preamble.

1.9 "**Alliance Manager**" has the meaning set forth in Section 2.1.

1.10 "**Anti-Corruption Laws**" has the meaning set forth in Section 10.2.17.

1.11 "**Applicable Law**" means all laws, statutes, rules, regulations, orders, judgments, injunctions, ordinances or other pronouncements having the binding effect of law of any Governmental Authority, in each case to the extent applicable to the particular circumstance or obligation under this Agreement, and including if either Party is or becomes subject to a legal obligation to a Regulatory Authority or other Governmental Authority (such as a corporate integrity agreement or settlement agreement with a Governmental Authority).

1.12 "**Auditor**" has the meaning set forth in Section 8.7.

1.13 "**Bankrupt Party**" has the meaning set forth in Section 7.5.

1.14 "**Bankruptcy Code**" has the meaning set forth in Section 13.6.

1.15 "**Brief**" has the meaning set forth in Section 14.3.4.2(b).

1.16 "**Business Day**" means a day other than a Saturday, Sunday or a bank or other public holiday in New York, United States or in Tokyo, Japan.

1.17 "**CDISC**" means the Clinical Data Interchange Standards Consortium, which is an interdisciplinary nonprofit organization that establishes international standards for data collection, interchange, application, and storage for the purpose of promoting interoperation of clinical research data.

1.18 "**Change of Control**" means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the direct or indirect beneficial owner of more than fifty percent (50%) of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's and its controlled Affiliates' assets. With respect to any such Change of Control of a particular Party, the Third Party referenced in subclause (a), (b) or (c) (as applicable to such Change of Control), and including all of such Third Party's Affiliates, shall be referred to herein as the "Acquirer" of such Party in such Change of Control. Notwithstanding the foregoing, any transaction or series of transactions effected for the primary purpose of financing the operations of the applicable Party or changing the form or jurisdiction of organization of such Party will not be deemed a "Change of Control" for purposes of this Agreement.

1.19 "**Claims**" has the meaning set forth in Section 11.1.

1.20 "**Clinical Failure**" means, as determined by Kaken acting reasonably, that either (a) [***] or (b) [***].

1.21 "**Clinical Study**" means, with respect to any product, a Phase 1 Study, Phase 2 Study, Phase 3 Study, Post-Marketing Study, Supplemental Study or other study (including a non-interventional study) in humans to obtain information regarding such product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging and/or efficacy of such product.

1.22 "**Clinical Supply Agreement**" has the meaning set forth in Section 6.2.1.

1.23 "**Clinical Transfer Price**" means the supply price calculated as set forth in the Clinical Supply Agreement.

1.24 "**CMC**" means chemistry, manufacturing and controls with respect to a product, which includes (a) Manufacturing process development records for such product, (b) all chemistry, Manufacturing and control procedures necessary for the Manufacture of such product, and (c) sourcing and testing of all raw materials and components used in the Manufacture of such product.

1.25 "**CMC Activities**" has the meaning set forth in Section 3.6.

1.26 "**CMC Work Plan**" has the meaning set forth in Section 3.4.3.

1.27 "**Collaboration**" means the collaboration of the Parties under this Agreement for the Development, Manufacture and Commercialization of Licensed Products in the Field of Use in the Kaken Territory.

1.28 "**Combination Product**" means a pharmaceutical product containing (a) Licensed Compound and (b) one or more additional active pharmaceutical ingredients (other than Licensed Compound) having a meaningful pharmaceutical therapeutic effect (whether co-formulated or co-packaged with any of the compounds of clause (a)). For the avoidance of doubt, (i) equipment, devices or packaging used to administer or deliver any of the foregoing, and (ii) formulation substances or materials (including substances intended to increase or modify bioavailability), will not be deemed an "additional active pharmaceutical ingredient" for the purposes of the definition of "Combination Product."

1.29 "**Commercial Supply Agreement**" has the meaning set forth in Section 6.2.3.

1.30 "**Commercialization**" or "**Commercialize**" means, with respect to any product, any and all activities directed to marketing, promoting, distributing, importing, exporting, using, offering to sell, selling or otherwise commercializing such product, and any and all activities directed to obtaining any Pricing Approvals for such product, as applicable.

1.31 "**Commercially Reasonable Efforts**" means, with respect to the efforts and resources to be expended by a Party with respect to any objective, obligation or task under this Agreement, [***].

1.32 "**Committee**" means the Joint Steering Committee or any joint subcommittee of the JSC.

1.33 "**Competing Product**" means, other than any Licensed Product, any pharmaceutical product [***], excluding (a) [***] and (b) [***]; for clarity, a pharmaceutical product that [***].

1.34 "**Competitive Infringement**" means the circumstance where the making, using, selling, offering for sale, or importing, by any Third Party (other than any Sublicensee or authorized purchaser or other authorized transferee of Licensed Product by either Party), of any pharmaceutical product is Covered by a Valid Claim of any CymaBay Licensed Patent or a Kaken Controlled Patent. For clarity, the filing of an Abbreviated New Drug Application with any applicable Regulatory Authority with respect to a Licensed Product as the reference product by any such Third Party will be deemed to be Competitive Infringement.

1.35 "**Competitive (CymaBay) Infringement**" means any Competitive Infringement occurring in the CymaBay Territory, but for clarity does not include any Competitive (Kaken) Infringement.

1.36 "**Competitive (Kaken) Infringement**" means any Competitive Infringement occurring in the Kaken Territory, but for clarity does not include any Competitive (CymaBay) Infringement.

1.37 "**Confidential Information**" means, with respect to a Party, any and all confidential or proprietary information and data and all other scientific, pre-clinical, clinical, regulatory, Manufacturing, marketing, financial and commercial information or data, whether communicated in writing or orally or by any other method, that is or has been provided by one Party or any of its Affiliates to the other Party or any of its Affiliates in connection with this Agreement.

1.38 "**Contract**" means any contract, agreement, lease, sublease, license, sales order, purchase order, loan, credit agreement, bond, debenture, note, mortgage, indenture, guarantee, undertaking, instrument, arrangement, understanding or other commitment, whether written or oral, that is or was binding on any Person or any part of its property under Applicable Law, whether in effect or if expired or terminated solely with respect to any provisions surviving such expiration or termination as of the Effective Date, including all amendments related to any of the foregoing.

1.39 "**Control**" means, with respect to any particular Patents or Know-How, that the applicable Party owns or has a license (or sublicense) or other rights (other than by a license, sublicense or other right granted (but not assignment) pursuant to this Agreement) to such Patents or Know-How and has the ability and right to assign or grant to the other Party the licenses, sublicenses or rights to access and use such Patent(s) or Know-How as provided for in this Agreement, without (a) violating the terms or conditions of any agreement or other arrangement with any Third Party in existence as of the time such Party would be required hereunder to grant such license, sublicense, or rights of access and use, and (b) paying, or owing an obligation to pay, any consideration to any Third Party, except for that which a Party in-licenses and under which the other Party elects to take a sublicense and agrees to make the associated payments pursuant to this Agreement, which will be considered under the Control of such Party. Notwithstanding anything in this Agreement to the contrary, if a Party undergoes a Change of Control, such Party will be deemed not to Control any Patents or Know-How that are owned or in-licensed (other than from such Party) by the Acquirer in such Change of Control, except that such Party shall be deemed to Control any particular Patents or Know-How of Acquirer: (a) arising from active participation by employees or consultants of the Acquirer in the Collaboration after such Change of Control, (b) that are included in or used in furtherance of the Collaboration by the Acquirer after such Change of Control, or (c) that (i) constitute improvements (or direct improvements to such improvements) to the CymaBay Licensed Technology or Program IP (as applicable) in existence prior to such Change of Control and (ii) are developed or conceived by any employees or consultants of the Acquirer.

1.40 "**Controlling Party**" has the meaning set forth in Section 12.6.4.

1.41 "**Cover**", "**Covering**" or "**Covered**" means, with respect to a particular claim in a Patent, and to a particular Licensed Product under this Agreement or product of a Third Party, that the manufacture, use, sale, offer for sale or importation of such Licensed Product or such product, as applicable, in the Field of Use in the relevant Territory by an unauthorized Person (*i.e.,* the Person does not possess a valid license or sublicense under such claim) would infringe such claim, or with respect to a claim in a pending patent application, would infringe such if issued in a patent.

1.42 "**CymaBay**" has the meaning set forth in the preamble.

1.43 "**CymaBay Indemnitees**" has the meaning set forth in Section 11.1.

1.44 "**CymaBay Licensed Know-How**" means any and all Know-How (including applicable New CymaBay IP or CymaBay's interest in the Joint Program IP) that is Controlled by CymaBay or its Affiliates (solely or jointly with a Third Party) and (a) is in existence as of the Effective Date, or arises during the Term, and (b) is necessary or reasonably useful for the Exploitation of Licensed Products in the Field of Use.

1.45 "**CymaBay Licensed Patents**" means any and all Patents (including applicable Patents within New CymaBay IP) in the Kaken Territory that are Controlled by CymaBay or its Affiliates (solely or jointly with a Third Party) and (a) are in existence as of the Effective Date, or arise during the Term, and (b) are necessary or reasonably useful for the Exploitation of any Licensed Products in the Field of Use. To the Knowledge of CymaBay, the CymaBay Licensed Patents existing as of the Effective Date are set forth on Schedule 1.45.

1.46 "**CymaBay Licensed Technology**" means, collectively, the CymaBay Licensed Know-How and the CymaBay Licensed Patents.

1.47 "**CymaBay Supply Termination**" has the meaning set forth in Section 6.3.

1.48 "**CymaBay Supply Termination Notice**" has the meaning set forth in Section 6.3.

1.49 "**CymaBay Territory**" means all countries, territories and possessions of the world, except Japan.

1.50 "**Develop**" and "**Development**" means, with respect to any Licensed Product, any and all nonclinical, preclinical and clinical drug development activities conducted before or after obtaining Regulatory Approval for such product that are reasonably related to or leading to the development, preparation, or submission of data and information to a Regulatory Authority for the purpose of obtaining, supporting or expanding Regulatory Approval of such product, together with all activities related to pharmacokinetic profiling, design and conduct of Nonclinical Studies and Clinical Studies (including Post-Marketing Studies) of such product, and regulatory affairs, statistical analysis, report writing, and regulatory filing creation and submission related to the foregoing (including the services of outside advisors and consultants in connection therewith).

1.51 "**Development Costs**" means, with respect to a Licensed Product, those costs and expenses directly incurred in connection with the performance of any Development activities, including as set forth under the Initial Indication Development Plan, for such Licensed Product, including costs for scientific or technical persons, fees charged by Third Party service providers, and other Out-of-Pocket Costs, any and all costs and expenses incurred in connection with the performance of any Clinical Study for such Licensed Product, including the cost to manufacture the supply of drug product for such Licensed Product for any Clinical Studies, and costs related to preparing and filing applications for Regulatory Approval or submissions to Regulatory Authorities (including associated filing fees, translation expenses and legal and other professional service fees).

1.52 "**Dispute**" has the meaning set forth in Section 14.3.1.

1.53 "**Dollars**" or "$" means the legal tender of the United States.

1.54 "**Effective Date**" has the meaning set forth in the preamble.

1.55 "**Efficacy Concern**" means that [***].

1.56 "**Executive Officer**" means: (a) for CymaBay, its Chief Executive Officer or another senior executive designee with responsibilities and seniority comparable thereto, and (b) for Kaken, its president or another senior executive officer designee with responsibilities and seniority comparable thereto, including, in the case of Kaken, a *shikko yakuin*; provided that any of the foregoing individuals may designate the Chief

Financial Officer or, in the case of Kaken, its officer in charge of the accounting department, as his/her designee for financial related matters. In the event that the position of any of the Executive Officers identified in this Section 1.56 no longer exists due to a Change of Control, corporate reorganization, corporate restructuring or the like that results in the elimination of the identified position, the applicable Executive Officer will be replaced with another executive officer with responsibilities and seniority comparable to the eliminated Executive Officer.

1.57 "**Existing In-Licensing Agreements**" has the meaning set forth in Section 7.3.1.1.

1.58 "**Expedited Arbitration**" has the meaning set forth in Section 14.3.4.1.

1.59 "**Expedited Dispute**" has the meaning set forth in Section 14.3.4.1.

1.60 "**Exploit**" or "**Exploitation**" means, collectively, research, Develop, Manufacture, Commercialize, register or otherwise exploit the applicable pharmaceutical product.

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

1.62 "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended.

1.63 "**Field of Use**" means the prevention or treatment of the Initial Indication in human patients.

1.64 "**First Commercial Sale**" means the first commercial sale in an arms' length transaction of a particular Licensed Product to a Third Party by Kaken or any of its Related Parties in the Kaken Territory following receipt of applicable Regulatory Approval of such Licensed Product in the Kaken Territory.

1.65 "**GCP**" means the then current standards for clinical trials for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are required by Regulatory Authorities in the Kaken Territory.

1.66 "**Generic Competition Percentage**" means, with respect to a particular Licensed Product and as assessed on a Kaken FiscalQuarter-by-Kaken Fiscal Quarter basis, a fraction (expressed as a percentage), the numerator of which is the aggregate number of units of specific Generic Products (for such Licensed Product) sold in the Kaken Territory during the applicable Kaken Fiscal Quarter, and the denominator of which is the aggregate number of units of such specific Generic Products (for such Licensed Product) sold in the Kaken Territory during such Kaken Fiscal Quarter plus the aggregate number of units of such Licensed Product sold in the Kaken Territory during such Kaken Fiscal Quarter, based on [***] obtained by Kaken for such Generic Product, or if such data is not available, such other reliable data source as is reasonably determined by Kaken.

1.67 "**Generic Product**" means a Third Party product containing an active pharmaceutical ingredient that is the same or substantially the same chemical structure as that contained in a Licensed Product (whether approved under an ANDA, or other applicable abbreviated or expedited approval process), and where bioequivalence of such Third Party product to such Licensed Product has been asserted in the application for approval to a Regulatory Authority, and where such Third Party product is approved by the applicable Regulatory Authority based upon or in reliance upon safety and efficacy data generated by CymaBay, Kaken (or any of their respective Affiliates) or any Related Party for such Licensed Product.

1.68 [***].

1.69 "**Global Development Plan**" has the meaning set forth in Section 3.4.1.

1.70 "**GLP**" means the then current standards for laboratory activities for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good laboratory practice as are required by Regulatory Authorities in the Kaken Territory.

1.71 "**GMP**" means the then current standards for Manufacturing for pharmaceuticals, as set forth in the FD&C Act and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good manufacturing practice as are required by Regulatory Authorities in the Kaken Territory.

1.72 "**Governmental Authority**" means any applicable government authority, court, tribunal, arbitrator, agency, department, legislative body, commission or other instrumentality of (a) any government of any country or territory, (b) any nation, state, province, county, city or other political subdivision thereof, or (c) any supranational body.

1.73 "**Harmonization Principle**" means the principle that the Development and Commercialization of the Licensed Products in the Kaken Territory, including such activities as clinical indication selection, clinical study design (including dosing), Regulatory Approval strategy (including labelling), CMC, and marketing and commercialization strategy, (a) will be conducted so as to harmonize with the Development and Commercialization of the Licensed Products by or on behalf of CymaBay (and any CymaBay licensee of Licensed Product) in the CymaBay Territory, and (b) in no event will be conducted in a manner that would materially adversely affect the Development or Commercialization of the Licensed Products by or on behalf of CymaBay (or any CymaBay licensee of Licensed Product) anywhere in the CymaBay Territory.

1.74 "**ICC**" has the meaning set forth in Section 14.3.3.

1.75 "**IFRS**" means International Financial Reporting Standards, as consistently applied.

1.76 "**IND**" means any Investigational New Drug Application, as defined in 21 C.F.R. § 312, or any corresponding application in any country or jurisdiction other than the United States.

1.77 "**Indemnified Party**" has the meaning set forth in Section 11.3.

1.78 "**Indemnifying Party**" has the meaning set forth in Section 11.3.

1.79 "**Infringement Claim**" has the meaning set forth in Section 12.12.1.

1.80 "**Initial Indication**" means primary biliary cholangitis.

1.81 "**Initial Indication Development Plan**" has the meaning set forth in Section 3.4.2.

1.82 "**Initial Term**" has the meaning set forth in Section 13.1.

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

1.84 "**Janssen**" has the meaning set forth in Section 8.6.3.

1.85 "**Janssen License Agreement**" has the meaning set forth in Section 8.6.3.

1.86 "**Japanese Trademark**" has the meaning set forth in Section 12.11.1.

1.87 "**Joint Program IP**" has the meaning set forth in Section 12.2.3.

1.88 "**Joint Program IP Patents**" means all Patents within the Joint Program IP.

1.89 "**Joint Steering Committee**" or "**JSC**" has the meaning set forth in Section 2.2.1.

1.90 "**JRA Exception**" has the meaning set forth in Section 12.1.2.

1.91 "**Kaken**" has the meaning set forth in the preamble.

1.92 "**Kaken Background Technology**" means any Patents and Know-How Controlled by Kaken or its Affiliates (solely or jointly with a Third Party) (a) in existence as of the Effective Date or (b) arising during the Term but independently from this Agreement, that, in each case of (a) and (b), are necessary or reasonably useful for the Development, Manufacture or Commercialization of any Licensed Products in the Field of Use, and are used or practiced by Kaken or any of its Affiliates in connection with the Development, Manufacture or Commercialization of Licensed Products in the Field of Use in the Kaken Territory, and, for clarity, excluding the Kaken Program IP and Kaken's interest in the Joint Program IP.

1.93 "**Kaken Controlled Patents**" has the meaning set forth in Section 12.5.1.1.

1.94 "Kaken Fiscal Quarter" means one of the respective periods of three (3) consecutive calendar months ending on June 30, September 30, December 31 or March 31 of a particular Kaken Fiscal Year.

1.95 "**Kaken Fiscal Year**" means each successive period of twelve (12) months commencing on April 1 of any year and ending on March 31 of the succeeding year.

1.96 "**Kaken Indemnitees**" has the meaning set forth in Section 11.2.

1.97 "**Kaken Licensed Technology**" means, collectively the Kaken Program IP and Kaken's interest in the Joint Program IP.

1.98 "**Kaken Program IP**" has the meaning set forth in Section 12.2.2.

1.99 "**Kaken Program IP Patents**" means all Patents within the Kaken Program IP.

1.100 "**Kaken Territory**" means Japan.

1.101 "**Kaken Territory Commercialization Plan**" has the meaning set forth in Section 4.2.

1.102 "**Know-How**" means all commercial, technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, Manufacturing and quality control data and know-how, including regulatory data, study designs and protocols), and Materials, in all cases, whether or not confidential, proprietary, patented or patentable, in written, electronic or any other form now known or hereafter developed.

1.103 "**Knowledge of CymaBay**" means, with respect to a particular fact or item of information that such term is applied to under this Agreement, that based on their actual knowledge (after reasonable inquiry) as of the Effective Date, [***] are aware that such fact or item of information is not true.

1.104 "**Licensed Compound**" means Seladelpar, including any deuterated form, hydrate, solvate, salt, polymorph, prodrug, metabolite, isomer, stereoisomer, diastereomer, enantiomer and racemate of Seladelpar.

1.105 "**Licensed Product**" means any pharmaceutical product containing Licensed Compound as an active pharmaceutical ingredient, in any strengths, forms, formulations, and modes of administration and delivery. For clarity, a Combination Product is a Licensed Product, but is a different Licensed Product from a Licensed Product that contains Licensed Compound as the sole active pharmaceutical ingredient.

1.106 "**Lien**" means any lien, pledge, hypothecation, charge, mortgage, security interest, encumbrance, adverse claim, option, right of first refusal, preemptive right, community property interest or other restriction of any nature (including any restriction on the voting of any security, any restriction on the transfer of any security or other asset, any restriction on the receipt of any income derived from any asset, any restriction on the use of any asset and any restriction on the possession, exercise or transfer of any other attribute of ownership of any asset).

1.107 "**Losses**" has the meaning set forth in Section 11.1.

1.108 "**Manufacturing**" or "**Manufacture**" means, with respect to a particular product, all activities related to the manufacture of such product, including manufacturing active pharmaceutical ingredient and drug product for Development or Commercialization, packaging, in-process and finished product testing, release of such product or any component or ingredient thereof, quality assurance and quality control activities related to manufacturing and release of such product, ongoing stability tests, storage, shipment, and regulatory activities related to any of the foregoing.

1.109 "**Manufacturing Price**" means the Cost of Manufacturing (as such term is defined in the Commercial Supply Agreement).

1.110 "**Material Communications**" has the meaning set forth in Section 5.1.2.

1.111 "**Materials**" means all tangible compositions of matter, devices, articles of manufacture, assays, biological, chemical or physical materials and other similar materials.

1.112 "**MHLW**" means the Japanese Ministry of Health, Labour and Welfare or any successor agency thereto.

1.113 "**NDA**" means any New Drug Application as described in 21 C.F.R. § 314, or any corresponding application for Regulatory Approval in any country or jurisdiction other than the United States.

1.114 "**Negotiation Period**" has the meaning set forth in Section 10.6.

1.115 "**Net Recovery**" has the meaning set forth in Section 12.6.7.

1.116 "**Net Sales**" means, with respect to a Licensed Product, the gross amounts invoiced or otherwise charged by or on behalf of Kaken or any of its Related Parties for any Licensed Product sold to Third Parties (other than Sublicensees, but including wholesalers and distributors) in bona fide, arms-length transactions, as determined in accordance with Accounting Standards consistently applied, less the following permitted deductions to the extent actually taken or allowed with respect to such sales:

[***]

In the case of any sale or other disposal of a Licensed Product between or among Kaken and any of its Related Parties for resale, Net Sales will be calculated only on the value charged or invoiced on the first arm's-length sale thereafter to a Third Party (other than a Sublicensee, but including wholesalers and distributors). In the case of any sale or other disposal for value, such as barter or countertrade, of any Licensed

Product, or part thereof, other than in an arm's length transaction exclusively for money, Net Sales will be calculated on the value of the non-cash consideration received or the fair market price (if higher) of such Licensed Product(s) in the country of sale or disposal. In addition, in the case of any sale to a distributor or other Third Party other than in an arm's length transaction or in a transaction under which Kaken or any of its Related Parties receives cash consideration other than or in addition to that metered on units of Licensed Product, then for purposes of the calculation of Net Sales associated with such transaction, all amounts paid and other value provided by the distributor or other Third Party to Kaken or such Related Party will be equitably apportioned between the purchased units of Licensed Product and any other products or services provided by Kaken or such Related Party to the distributor or other Third Party and the amount apportioned to units of Licensed Product will be included in the calculation of Net Sales. Kaken will promptly deliver to CymaBay a written report setting forth such apportionment. If CymaBay disagrees with such apportionment, CymaBay will so notify Kaken, and the Parties will meet to discuss and resolve such disagreement in good faith. If the Parties are unable to agree in good faith on such apportionment within thirty (30) days, the matter will be submitted to Expedited Arbitration.

Notwithstanding the foregoing, the following will not be included in Net Sales: (i) samples of Licensed Product used to promote additional Net Sales, in amounts consistent with normal business practices of the selling party; and (ii) disposal or use of Licensed Products in Clinical Studies or under compassionate use, patient assistance, named patient use, or non-registrational studies or other similar programs or studies where the Licensed Product is supplied without charge.

If Kaken desires to sell a Licensed Product as part of a Combination Product, and the Parties agree (pursuant to Section 7.1.5) that Kaken may do so, then the Supply Transfer Price and Net Sales for purposes of calculating amounts owed hereunder for such Combination Product will be calculated in the manner as agreed to by the Parties pursuant to Section 7.1.5.

1.117 "**New-Controlling Party**" has the meaning set forth in Section 12.6.5.1.

1.118 "**New CymaBay IP**" has the meaning set forth in Section 12.2.1.

1.119 "**NHI**" means the National Health Insurance in Japan.

1.120 "**NHI Price**" means the NHI drug price in Japan (*yakka*) for Licensed Product, as established by the Central Social Insurance Medical Council (Chuikyo) of the MHLW (or successor agency).

1.121 "**Non-Bankrupt Party**" has the meaning set forth in Section 7.5.

1.122 "**Nonclinical Studies**" means all non-human studies, including preclinical studies and toxicology studies, of Licensed Products.

1.123 "**Non-Controlling Party**" has the meaning set forth in Section 12.6.4.

1.124 "**Out-of-Pocket Costs**" means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or its Affiliate to Third Parties and specifically identifiable and incurred to conduct such activities for a Licensed Product, including payments to contract personnel (including contractors, consultants and subcontractors).

1.125 "**Parties**" has the meaning set forth in the preamble.

1.126 "**Party**" has the meaning set forth in the preamble.

1.127 "**Patent**" means all patents and patent applications and all substitutions, divisions, continuations, continuations-in-part, any patent issued with respect to any such patent applications, any reissue, reexamination, utility models or designs, renewal or extension (including any supplementary protection certificate) of any such patent, and any confirmation patent or registration patent or patent of addition based on any such patent, and all counterparts and equivalents of any of the foregoing in any country or jurisdiction.

1.128 "**Patent Challenge**" has the meaning set forth in Section 13.7.

1.129 "**Patent Costs**" means the Out-of-Pocket Costs and expenses paid to outside legal counsel and other Third Parties (including to any licensor pursuant to any in-license), and filing and maintenance expenses, incurred in Prosecuting and Maintaining Patents and enforcing and defending them.

1.130 "**Person**" means any natural person, corporation, unincorporated organization, partnership, association, sole proprietorship, joint stock company, joint venture, limited liability company, trust or government, or Governmental Authority, or any other similar entity.

1.131 "**Phase 1 Study**" means a clinical study of an investigational product in healthy volunteers and patients with the primary objective of characterizing its safety, tolerability, and pharmacokinetics and identifying a recommended dose and regimen for future studies as described in 21 C.F.R. § 312.21(a), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.

1.132 "**Phase 2 Study**" means a clinical study of an investigational product in patients with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, and pharmacokinetics information as described in 21 C.F.R. § 312.21(b), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States including a human clinical trial that is also designed to satisfy the requirements of 21 C.F.R. § 312.21(a) or corresponding foreign regulations and is subsequently optimized or expanded to satisfy the requirements of 21 C.F.R. § 312.21(b) (or corresponding foreign regulations) or otherwise to enable a Phase 3 Study (e.g., a phase 1/2 trial).

1.133 "**Phase 3 Study**" means a clinical study of an investigational product in patients that incorporates accepted endpoints for confirmation of statistical significance of efficacy and safety with the aim to obtain Regulatory Approval in any country as described in 21 C.F.R. § 312.21(c), or a comparable clinical study prescribed by the relevant Regulatory Authority in a country other than the United States.

1.134 "**PMDA**" means Japan's Pharmaceuticals and Medical Devices Agency or any successor agency thereto.

1.135 "**Post-Marketing Study**" means a non-human or human clinical study of a Licensed Product initiated after receipt of Regulatory Approval for such Licensed Product in a country or territory, that is required by the Regulatory Authority in such country or territory to maintain the Regulatory Approval for such Licensed Product in such country or territory but excluding any Supplemental Study.

1.136 "**Pricing Approval**" means such governmental approval, agreement, determination, or decision establishing prices for a Licensed Product that can be charged or reimbursed in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price or reimbursement of pharmaceutical products.

1.137 "**Pricing Matters**" means all issues and decisions regarding (a) price, price terms and other contract terms with respect to Licensed Product sales, including discounts, rebates, other price concessions and service fees to payors and purchasers and (b) reimbursement programs applicable to a Licensed Product.

1.138 "**Proceeding**" means an action, suit or other similar proceeding before a governmental tribunal.

1.139 "**Promotional Materials**" has the meaning set forth in Section 4.4.

1.140 "**Prosecution and Maintenance**" means, with respect to a particular Patent, the preparation, filing, prosecution and maintenance of such Patent, as well as re-examinations, reissues and the like with respect to that Patent, together with the conduct of interferences, the defense of oppositions and other similar proceedings with respect to that Patent (and the foreign equivalents of any of the foregoing). "Prosecute and Maintain" and "Prosecuting and Maintaining" have corresponding meanings.

1.141 "**Regulatory Approval**" means all approvals issued by Regulatory Authorities necessary for the manufacture, marketing, importation and sale of a product for one or more indications in a country or regulatory jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, but not including any Pricing Approvals.

1.142 "**Regulatory Authority**" means any Governmental Authority involved in granting approvals for the Development, Manufacturing, Commercialization, Pricing Approval of pharmaceutical products, including the FDA, the European Medicines Agency, the European Commission, the MHLW and the PMDA.

1.143 "**Regulatory Exclusivity**" means, with respect to any product, any exclusive marketing rights or data exclusivity rights with respect to such product (other than provided by Patents Covering such product) conferred for the Kaken Territory by any Regulatory Authority or Applicable Law of the Kaken Territory.

1.144 "**Regulatory Filing**" means any submission to a Regulatory Authority, including all applications, registrations, licenses, authorizations and approvals (including Regulatory Approvals), together with any related correspondence and documentation submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents and all clinical studies and tests, relating to a product and all data contained in any of the foregoing, including all INDs, NDAs, regulatory drug lists, advertising and promotion documents, clinical data, adverse event files and complaint files, and includes any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment to any of the foregoing.

1.145 "**Regulatory Materials**" means any regulatory notification, communication, correspondence, Regulatory Filings, Regulatory Approvals and other filings made to, received from or otherwise conducted with a Regulatory Authority related to Developing, Manufacturing, obtaining marketing authorization, marketing, selling or otherwise Commercializing a pharmaceutical product in a particular country or jurisdiction.

1.146 "**Regulatory Milestone Event**" has the meaning set forth in Section 8.2.1.

1.147 "**Regulatory Milestone Payment**" has the meaning set forth in Section 8.2.1.

1.148 "**Related Party(ies)**" means (a) with respect to Kaken, Kaken's Affiliates and Sublicensees, and (b) with respect to CymaBay, CymaBay's Affiliates and Sublicensees.

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

1.150 "**Royalty Patents**" means [***].

1.151 "**Royalty Term**" has the meaning set forth in Section 8.4.3.

1.152 "**Safety Concern**" means, with respect to any Licensed Product, (a) [***], or (b) [***].

1.153 "**Sales Milestone Event**" has the meaning set forth in Section 8.3.1.

1.154 "**Sales Milestone Payment**" has the meaning set forth in Section 8.3.1.

1.155 "**SDEA**" has the meaning set forth in Section 5.5.

1.156 "**Securitization Transaction**" has the meaning set forth in Section 14.1.2.

1.157 "**Seladelpar**" means the molecule known as seladelpar and described on Schedule 1.157.

1.158 "**Serious Adverse Event**" means an adverse drug experience or circumstance that results in any of the following outcomes: (a) death, (b) life-threatening condition, (c) inpatient hospitalization or a significant prolongation of existing hospitalization, (d) persistent or significant disability or incapacity or substantial disruption of the ability to conduct normal life functions, (e) congenital anomaly/birth defect, or (f) significant intervention required to prevent permanent impairment or damage.

1.159 "**Sublicensee**" means a Third Party to which a Party or its Affiliate has granted or grants rights, as permitted under this Agreement, to Develop, Manufacture or Commercialize Licensed Product, or any further sublicensee of such rights (regardless of the number of tiers, layers or levels of sublicenses of such rights).

1.160 "**Supplemental Study**" means any Clinical Study (other than any Post-Marketing Study) for a Licensed Product beyond what is contemplated in the Initial Indication Development Plan.

1.161 "**Supply Agreements**" means the Clinical Supply Agreement and the Commercial Supply Agreement.

1.162 "**Supply Transfer Price**" means, with respect to Licensed Product delivered [***] by (or on behalf of) CymaBay to Kaken (or its Related Party) pursuant to the Commercial Supply Agreement, [***] of the amount that equals [***] NHI Price for the Licensed Product [***]. For example, if NHI Price is [***], the Supply Transfer Price shall be [***].

1.163 "**Technology Transfer Plan**" has the meaning set forth in Section 3.9.1.

1.164 "**Term**" has the meaning set forth in Section 13.1.

1.165 "**Territory**" means (a) with respect to CymaBay, the CymaBay Territory and (b) with respect to Kaken, the Kaken Territory.

1.166 "**Third Party**" means any Person other than Kaken, CymaBay or their respective Affiliates.

1.167 "**Third Party Action**" has the meaning set forth in Section 12.6.3.

1.168 "**Trademark**" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

1.169 "**United States**" or "**U.S.**" means the United States of America and its territories, possessions and commonwealths.

1.170 "**Valid Claim**" means a claim of a Patent that (a) has not been rejected, revoked or held to be invalid or unenforceable by a court or other authority of competent jurisdiction, from which decision no appeal can be further taken, or (b) has not been finally abandoned, disclaimed or admitted to be invalid or unenforceable through reissue or disclaimer. In order to be a Valid Claim, any claim being prosecuted in a pending patent application must be prosecuted in good faith and not have been pending for more than [***] from the filing date of the first utility patent application (or equivalent concept in any such country) in the patent application family of such patent application in the country in question, in which case it will cease to be considered a Valid Claim until the patent issues and recites said claim.

1.171 "**Withdrawing Party**" has the meaning set forth in Section 12.6.5.1.

1.172 "**Yen**" or "**JPY**" means the legal tender of Japan.

ARTICLE 2

GOVERNANCE

2.1 Alliance Managers. Promptly following the Effective Date, each Party will designate an individual to facilitate communication and coordination of the Parties' activities under this Agreement relating to Licensed Products for Commercialization in the Kaken Territory (each, an "**Alliance Manager**"). Each Alliance Manager may also serve as a representative of its respective Party on one or more Committees. For clarity, unless an Alliance Manager is a representative of its respective Party on a particular Committee, each Alliance Manager will have no voting right on any Committee unless otherwise agreed to in writing by the Parties.

2.2 Joint Steering Committee.

2.2.1 *Formation; Composition; Dissolution*. Within thirty (30) days after the Effective Date, the Parties will establish a committee to provide strategic oversight of the Parties' activities under the Collaboration (the "**Joint Steering Committee**" or "**JSC**"). Each Party will initially appoint three (3) representatives to the JSC. Each representative on the JSC shall have knowledge and expertise in the Development and Commercialization of molecules and products similar to the Licensed Products and having sufficient seniority within the applicable Party to provide meaningful input and make decisions arising within the scope of the JSC's responsibility. The JSC may change its size from time to time by mutual consent of the Parties, *provided* that the JSC will consist at all times of an equal number of representatives of each of CymaBay and Kaken. Each Party may replace one or more of its JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members to participate in the discussions and meetings of the JSC, *provided* that such participants are bound under written obligations of confidentiality and non-use no less protective of the Parties' Confidential Information than those set forth in this Agreement. For clarity, such non-member participants shall have no voting rights or authority at the JSC. The JSC will be chaired on a Kaken Fiscal Year basis by a chairperson alternately designated by CymaBay or Kaken. The initial chairperson of the JSC for the period commencing on the Effective Date and ending on March 31, 2024 will be a CymaBay designated chairperson, who will then be replaced by a Kaken designated chairperson on April 1, 2024, and so forth. The JSC chairperson's responsibilities will include conducting meetings of the JSC, including, when feasible, ensuring that objectives for each meeting are set and achieved. The JSC will exist for so long as there is Licensed Product being Developed or Commercialized under this Agreement.

2.2.2 *Specific Responsibilities of the JSC.* The JSC will have the following responsibilities in connection with the Collaboration:

2.2.2.1 reviewing, discussing and approving the Initial Indication Development Plan and any amendments to the Initial Indication Development Plan;

2.2.2.2 reviewing, discussing and approving the initial CMC Work Plan and any updates or amendments thereto;

2.2.2.3 reviewing, discussing and approving any proposed Post-Marketing Studies for any Licensed Product in the Kaken Territory;

2.2.2.4 approving the commercial positioning with respect to target patients of the Licensed Products in the Kaken Territory and approving any proposed material changes thereto;

2.2.2.5 approving the key promotional message with respect to the Licensed Products in the Kaken Territory and approving any proposed material changes thereto;

2.2.2.6 approving the Kaken Territory Commercialization Plan for each Licensed Product, including, in each case, any amendments thereto;

2.2.2.7 reviewing, discussing and providing input on the strategy with respect to Pricing Matters, including the price negotiation strategy with Regulatory Authorities for the Licensed Products in the Kaken Territory and other communications with Regulatory Authorities, and approving such strategy with respect to Pricing Matters (including the price bands for purposes of such strategy) for the Licensed Products in the Kaken Territory;

2.2.2.8 providing a forum for CymaBay to raise for discussion and resolution of any decision or action regarding the Development or Commercialization of the Licensed Products in the Kaken Territory perceived by CymaBay to be deviating from the Harmonization Principle;

2.2.2.9 coordinating the filing of Joint Program IP Patent applications;

2.2.2.10 discussing and, if appropriate, approving any Kaken request to conduct Development of Licensed Product outside the Kaken Territory;

2.2.2.11 determining and overseeing a reasonable and expeditious process to identify, and under which CymaBay will provide to Kaken, any submissions, filings or other material communications with a Regulatory Authority with respect to a Licensed Product in the CymaBay Territory to which Kaken needs access to support obtaining or maintaining a Regulatory Approval for a Licensed Product in the Kaken Territory;

2.2.2.12 facilitating the flow of information between the Parties with respect to the Commercialization of Licensed Products in the Kaken Territory, including information as to pricing for the Licensed Products;

2.2.2.13 reviewing Promotional Materials pursuant to the provisions of Section 4.4;

2.2.2.14 discussing strategies for abating a Competitive Infringement of any Licensed Product within either Party's respective Territory as contemplated by Section 12.6.1;

2.2.2.15 establishing such additional joint subcommittees of the JSC as it deems necessary to oversee activities relating to the Licensed Products in the Kaken Territory to achieve the objectives and intent of the Collaboration; and

2.2.2.16 resolving any issues escalated by, or disputes within, any joint subcommittee of the JSC.

2.2.3 *Meetings*. The JSC will meet (a) at least [***] prior to March 31, 2024, (b) at least [***] per Kaken Fiscal Year after March 31, 2024 and prior to obtaining Regulatory Approval for the Initial Indication in the Kaken Territory and (c) at least [***] per Kaken Fiscal Year after obtaining such Regulatory Approval, unless the Parties mutually agree in writing to not meet or to meet at a different frequency. The JSC may meet in person, by videoconference, or by teleconference. The first JSC meeting shall be held within [***]. Meetings of the JSC will be effective only if at least one (1) representative of each Party is present or participating in such meeting. Each Party will bear the expense of its respective JSC members' participation in JSC meetings, with any fees for interpretation being borne fifty percent (50%) by each Party. No later than five (5) Business Days prior to any meeting of the JSC (or such shorter time period as the Parties may agree), the Alliance Managers together will prepare and circulate an agenda for such meeting; *provided, however*, that either Party will be free to propose additional topics to be included on such agenda, either prior to or in the course of such meeting, and any Party that will be presenting to the JSC at any meeting as part of such agenda will prepare and provide detailed materials to the JSC representatives to support discussion. Either Party may also call a special meeting of the JSC (by videoconference, teleconference or in person) by providing at least ten (10) Business Days prior written notice to the other Party if such Party reasonably believes that a significant matter must be addressed prior to the next scheduled meeting, in which event such Party will work with the Alliance Managers to provide the members of the JSC no later than three (3) Business Days prior to the special meeting with an agenda for the meeting and materials reasonably adequate to enable an informed decision, with the reasonable fees for

interpretation at such a special meeting being borne entirely by the Party requesting the special meeting. The JSC chairperson will be responsible for preparing reasonably detailed written minutes of JSC meetings that reflect all decisions made and action items identified at such meetings. The JSC chairperson will send meeting minutes to each member of the JSC for review and approval within ten (10) Business Days after each JSC meeting. Minutes will be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within ten (10) Business Days of receipt. Any material changes proposed to any meeting minutes by either Party's members of the JSC will be promptly circulated by the JSC chairperson to each member of the JSC for review and approval within ten (10) Business Days of receipt, with such process repeating until the meeting minutes are approved by all JSC members. Minutes will be officially endorsed by the JSC at the next JSC meeting and will be signed by one (1) JSC representative of each Party.

2.2.4 *Decision-Making*. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. Approvals of the JSC will require unanimous agreement; *provided*, *however*, that if CymaBay has ceased its participation in the JSC pursuant to Section 2.4 or 13.8.3, approvals of the JSC will require only the vote of the representative appointed by Kaken. If the JSC cannot reach unanimous agreement on an issue that comes before the JSC within fifteen (15) days of the meeting where such issue was raised and over which the JSC has oversight, the Parties will refer such issue for resolution in accordance with Section 2.3.

2.3 Resolution of Committee Disputes.

2.3.1 *Referral to Executive Officers and Executive Management.* The JSC may refer any matter as to which the JSC cannot reach a consensus decision to the Executive Officers for resolution. If the JSC does so, the JSC will submit in writing the respective positions of the Parties to their respective Executive Officers. Such Executive Officers will use good faith efforts, in compliance with this Section 2.3.1, to resolve promptly such matter, which good faith efforts will include at least [***] between such Executive Officers within [***] Business Days after the JSC's submission of such matter to them. If the Executive Officers are unable to reach unanimous agreement on any such matter within [***] days of the matter being presented to them, then:

(a) if the matter escalated by the JSC relates to the Exploitation of the Licensed Products in the Field of Use in the Kaken Territory (including Pricing Matters, the Initial Indication Development Plan, the CMC Work Plan and the Kaken Territory Commercialization Plan), Kaken will have final decision-making authority over such matter (other than with respect to the matters covered by (c)); *provided*, *however*, that Kaken shall not have final decision-making authority over matters relating to (i) the Manufacture of the Licensed Products in the Field of Use in the Kaken Territory unless and until Kaken takes over the Manufacture of the Licensed Products and (ii) the Global Development Plan;

(b) if the matter escalated by the JSC relates to the Global Development Plan, to the extent not covered by clause (a) (other than with respect to the matters covered by (c)), CymaBay will have final decision-making authority over such matter; and

(c) if the matter escalated by the JSC relates to (i) whether a decision, strategy or implementation of a strategy is consistent with the Harmonization Principle, or (ii) if the matter otherwise does not fall within those specified in either clause (a) or clause (b), the Executive Officers will submit their respective positions on such matter to be resolved by Expedited Arbitration. Notwithstanding anything herein to the contrary, no exercise of a Party's decision-making authority on any matters may, without the other Party's prior written consent, (i) result in a material increase in the other Party's or its Related Parties' obligations, costs or expenses, including expenditure of such Party's resources, under this Agreement, the Initial Indication Development Plan, the CMC Work Plan or the Kaken Territory Commercialization Plan, (ii) unilaterally modify, amend or waive its own compliance with the terms or conditions of this Agreement, or (iii) otherwise conflict with this Agreement.

2.3.2 *Good Faith.* In conducting themselves on Committees, and in exercising their rights under this Section 2.3, all representatives of both Parties will consider diligently, reasonably and in good faith all input received from the other Party and will use reasonable efforts to reach unanimous agreement on all matters before them. In exercising any decision-making authority granted to it under this Section 2.3, each Party will act based on its good faith business judgment.

2.4 General Committee Authority. Each Committee has solely the powers expressly assigned to it in this ARTICLE 2. No Committee will have any power to amend, modify, or waive the terms or conditions of this Agreement or compliance with the terms and conditions of this Agreement. CymaBay may elect, in writing to Kaken, at any time to cease its participation in a particular Committee.

ARTICLE 3

DEVELOPMENT

3.1 Kaken Responsibility; Costs. Subject to the responsibilities of the JSC and the other terms and conditions of this ARTICLE 3 and this Agreement, Kaken will be responsible for conducting or having conducted, in accordance with the Initial Indication Development Plan and the Harmonization Principle, the additional Development of the Licensed Products in the Initial Indication in the Kaken Territory as are needed, in addition to the Nonclinical Study data, CMC data and Clinical Study data provided by CymaBay hereunder, for purposes of obtaining and maintaining Regulatory Approval of Licensed Products in the Initial Indication in the Kaken Territory and in support of Commercializing such Licensed Products in the Initial Indication in the Kaken Territory, including conducting Clinical Studies pursuant to the Initial Indication Development Plan and the preparation of electronic data with respect to such Clinical Studies that meets CDISC compliance in the Kaken Territory. Subject to the rest of this Section 3.1, Kaken will bear one hundred percent (100%) of the Development Costs incurred in connection with the foregoing Development activities, including the Development Costs that are related to preparing and filing applications for Regulatory Approval or submissions to Regulatory Authorities (including associated filing fees, translation expenses for translation into Japanese and legal and other professional service fees) in the Initial Indication in the Kaken Territory based upon data from Clinical Studies conducted by Kaken pursuant to the Initial Indication Development Plan for purposes of obtaining and maintaining Regulatory Approval of Licensed Products in the Initial Indication in the Kaken Territory and post-Regulatory Approval clinical research in support of Commercializing such Licensed Products in the Initial Indication in the Kaken Territory.

3.2 CymaBay Retained Rights. CymaBay retains the exclusive rights to conduct (or have conducted), and will have sole discretion and control over, the Development of the Licensed Products for purposes of obtaining and maintaining Regulatory Approval for Commercialization of such Licensed Products anywhere in the world, *other than* for use in the Initial Indication in the Kaken Territory. CymaBay will bear one hundred percent (100%) of the Development Costs incurred in connection with the foregoing Development activities.

3.3 CymaBay Cooperation. Upon Kaken's reasonable request, CymaBay shall provide reasonable cooperation and assistance to Kaken in connection with Kaken's Development activities in the Initial Indication in the Kaken Territory [***] subject to the reasonable availability of CymaBay's relevant resources. Such cooperation will include, but is not limited to [***], Third Party manufacturer compliance with [***], and referrals to relevant [***] as reasonably requested by Kaken.

3.4 Development Plans.

3.4.1 *Global Development Plan*. CymaBay's worldwide plan for the Development of the Licensed Products is attached hereto as Schedule 3.4.1 (as may be updated by CymaBay from time to time so long as such update (i) does not materially adversely impact the rights or increase the obligations of Kaken and (ii) is reported to the JSC at the next JSC meeting) (the "**Global Development Plan**"). CymaBay will keep Kaken reasonably informed of the status, progress and results of major Development activities for Licensed Products conducted by or on behalf of CymaBay.

3.4.2 *Initial Indication Development Plan*. No later than [***] following the Effective Date, Kaken will prepare and deliver to the JSC for its review and input and approval a reasonable written plan (the "**Initial Indication Development Plan**") that summarizes in reasonable detail Development activities that are necessary to be undertaken for the Licensed Product to support obtaining Regulatory Approval for the Initial Indication in the Kaken Territory as soon as reasonably practicable, including the anticipated timeline of such development. Such plan will include Development activities for the Licensed Products in the Field of Use in the Kaken Territory and will be consistent with the Harmonization Principle and the above timing goals. The JSC will review, discuss and approve the Initial Indication Development Plan and any amendments thereto in accordance with Section 2.2.2.1.

3.4.3 *CMC Work Plan*. As soon as practicable after the Effective Date, the Parties will work together to prepare and deliver to the JSC for its review, input and approval in accordance with Section 2.2.2.2, a reasonable written plan that summarizes the CMC Activities that are necessary to be undertaken for the Licensed Product to support obtaining Regulatory Approval for the Initial Indication in the Kaken Territory and subsequent Commercialization thereof in the Initial Indication in the Kaken Territory, which plan will include the applicable timetable and be consistent with the Harmonization Principle (the "**CMC Work Plan**"). The CMC Work Plan will be updated as appropriate fromtime-to-time and include all CMC activities related to all phases of Manufacturing the Licensed Product through and including the packaging of Licensed Product in the format determined by the JSC to be preferable for the Japanese market [***]. The JSC will also review from time-to-time updates and amendments to the CMC Work Plan submitted to it in accordance with Section 2.2.2.2.

3.4.4 *CymaBay Phase 3 Study.* If CymaBay (itself or through an Affiliate) desires to conduct a Phase 3 Study of a Licensed Product in an Additional Indication, then CymaBay will notify Kaken thereof in writing. If Kaken desires to participate in any such Phase 3 Study, CymaBay and Kaken will, through the JSC, discuss such participation, including applicable activities, terms and conditions of such participation. If CymaBay approves Kaken's participation in such Phase 3 Study, such approval not to be unreasonably withheld, conditioned, or delayed, then the Parties shall promptly prepare a development plan that reflects such participation, and Kaken may so participate in such Phase 3 Study in accordance with such agreed development plan.

3.5 Diligence; Standards of Conduct. Kaken will use Commercially Reasonable Efforts to perform and complete all the Development activities specified in the Initial Indication Development Plan on the timeline specified in such Plan, as it may be adjusted from time-to-time by the JSC consistent with the terms of this Agreement.

3.6 CMC Development. All Development relating to CMC required to be conducted to support obtaining and maintaining Regulatory Approval in the Kaken Territory for any Licensed Product in the Initial Indication that is the subject of the Initial Indication Development Plan, including all CMC activities related to all phases of Manufacturing the Licensed Product through and including the packaging of Licensed Product in the format determined by the JSC to be preferable for the Japanese market [***] for Commercialization in the Kaken Territory (the "**CMC Activities**"), will be conducted by CymaBay [***] in accordance with the Harmonization Principle and the CMC Work Plan. Any and all costs and expenses incurred in connection with the CMC Activities [***] that are specific to the Japan regulatory activities or Japan market will be borne solely by Kaken (and reimbursed to CymaBay by Kaken based on invoices submitted); *provided, however*, that [***]. With respect to any such costs and expenses borne by Kaken, if any of the data and related CMC information, that are generated by the CMC Activities paid for by Kaken, are later utilized by CymaBay or any of its licensees in the CymaBay Territory or outside the Field of Use in the Kaken Territory, then CymaBay will promptly notify Kaken of such utilization [***]. Costs and expenses payable to CymaBay by Kaken under this Section 3.6 shall be paid in Dollars pursuant to invoices provided to Kaken by CymaBay after the end of each Kaken Fiscal Quarter, due and payable by Kaken to CymaBay within [***] of Kaken's receipt of such invoice.

3.7 Third Parties. Subject to Section 7.1.4 and the rest of this Section 3.7, a Party will be entitled to subcontract to Third Parties, and to utilize the services of Third Parties to perform, its Development activities, if any, under this ARTICLE 3, *provided* that (a) such Party requires under any such agreement executed on or after the Effective Date that such Third Party operate in a manner consistent with this Agreement and reasonably acceptable to the other Party, (b) such Party remains at all times fully liable to the other Party for its Development responsibilities under this Agreement, and (c) such Party provides reasonable updates to the other Party (through JSC meetings) of the activities of such subcontractors and results of such activities. Such Party will be solely responsible for direction of and communications with such Third-Party service provider.

3.8 Scientific Records. Each Party will maintain scientific records, in sufficient detail and in sound scientific manner appropriate for Patent and regulatory purposes and in compliance with GLP, GCP and GMP, as applicable, with respect to all Development activities, and the results of such activities, intended to support or be submitted in regulatory filings covering Licensed Product, which records will fully and accurately reflect and document all work done and results achieved in the performance of the Development activities, Clinical Studies, and Supplemental Studies with respect to Licensed Products by such Party under this Agreement.

3.9 Technology Transfer.

3.9.1 As soon as practicable after the Effective Date, the Parties will negotiate in good faith and enter into a technology transfer plan to effect the transfer by CymaBay to Kaken [***] (as such period may be extended by mutual written agreement of the Parties) of all CymaBay Licensed Technology to be disclosed pursuant to this Section 3.9. Under such transfer plan, CymaBay will complete a transfer to Kaken of the CymaBay Licensed Know-How in existence as of the date of such transfer that is reasonably useful for the Exploitation of Licensed Products in the Field of Use in the Kaken Territory (but excluding Know-How solely related to Manufacturing of Licensed Product), which transfer will include [***], all solely to the extent Controlled by CymaBay and relating to the Licensed Products in the Initial Indication. Such technology transfer plan will set forth the CymaBay Licensed Know-How to be transferred in a format that meets [***] applicable in the U.S. and the Kaken Territory and the timing of such transfer to be completed (the "**Technology Transfer Plan**"). CymaBay will disclose to Kaken all of the CymaBay Licensed Know-How that is required to be disclosed pursuant to this Section 3.9.1 in accordance with the disclosure timing set forth in such transfer plan. For clarity, the transfer of any CymaBay Licensed Know-How relating solely to the Manufacturing of Licensed Product shall be conducted in accordance with Section 3.9.3, in order to facilitate Kaken's conditional Manufacturing rights as set forth in Section 7.1.3.

3.9.2 Without limiting the terms of the technology transfers contemplated in Section 3.9.1, CymaBay will promptly provide to Kaken the following on an ongoing basis during the Term: (a) all applicable data from CymaBay's [***] as needed to seek Regulatory Approval for the Licensed Products in the Initial Indication, (b) all Know-How that is Controlled by CymaBay and has been generated for Exploitation and pricing activities related to the Licensed Products worldwide, to the extent such Know-How is reasonably useful for such Exploitation or Pricing Matters in the Kaken Territory and is available and accessible to CymaBay, and (c) [***] a complete copy of any dossier for the Licensed Products, and minutes of meetings with Regulatory Authorities, all to the extent such information is Controlled by CymaBay and is reasonably necessary for Kaken to seek Regulatory Approval in the Kaken Territory. Further, CymaBay will use reasonable efforts to provide such other assistance reasonably requested by Kaken to enable Kaken to carry out its obligations under this Agreement. Any and all internal and third-party costs and expenses incurred in connection with providing such requested assistance, unless the terms of this Agreement allocate the particular costs to be borne by CymaBay, will be borne solely by Kaken (and reimbursed to CymaBay by Kaken based on invoices submitted); [***]. Notwithstanding the foregoing, CymaBay shall have no obligations under this Section 3.9.2 to the extent that providing the applicable information, data or assistance would violate Third Party rights or Applicable Law or would breach contract obligations of CymaBay to a Third Party, unless the requested information, data or assistance is required by Regulatory Authorities for Kaken to obtain Regulatory Approval in the Kaken Territory.

3.9.3 In the event CymaBay provides a CymaBay Supply Termination Notice, or in the event that the Parties otherwise agree that Kaken will Manufacture Licensed Products, then immediately after such notice or agreement, the Parties shall meet and discuss reasonably and enter into a manufacturing technology transfer plan to effect the transfer by CymaBay to Kaken of all needed CymaBay Know-How relating to the Manufacture of Licensed Product, including then-current Manufacturing process, manufacturing data and any other related information within such CymaBay Know-How as is necessary or reasonably useful for Manufacturing Licensed Products for use in the Field of Use. [***].

ARTICLE 4

COMMERCIALIZATION

4.1 Responsibility, Costs.

4.1.1 *Kaken.* Subject to the oversight of the JSC and to the other terms and conditions of this Section 4.1 and of this Agreement, Kaken will be responsible for all Commercialization activities relating to the Licensed Products in the Field of Use in the Kaken Territory, at its sole cost and expense, in accordance with the Kaken Territory Commercialization Plan and the Harmonization Principle.

4.1.2 *CymaBay.* CymaBay, at its sole cost and expense, will have sole responsibility and control of all Commercialization activities relating to the Licensed Product, *other than* in the Field of Use in the Kaken Territory.

4.2 Kaken Territory Commercialization Plan. No later than [***], Kaken will prepare and deliver to the JSC for its review, input and approval a reasonable written plan that summarizes the Commercialization activities (including any pre-Regulatory Approval activities in preparation for commercial launch) to be undertaken with respect to the Licensed Products in the Field of Use in the Kaken Territory, where such plan will include details of anticipated timing and all marketing and promotional activities for the Licensed Products in the Field of Use in the Kaken Territory aligned with the commercial positioning and the key message approved by the JSC and consistent with the Harmonization Principle, and of the resources to be allocated to such Commercialization efforts (the "**Kaken Territory Commercialization Plan**"). Updates and modifications of the Kaken Territory Commercialization Plan shall be proposed by Kaken for approval by the JSC, from time to time and no less frequently than once per Kaken Fiscal Year, based upon, among other things, Kaken's Commercialization activities and plans for activities with respect to the Licensed Products in the Field of Use in the Kaken Territory.

4.3 Diligence; Standards of Conduct. Kaken will use Commercially Reasonable Efforts to (a) Commercialize Licensed Products in the Kaken Territory for use in the Field of Use with the intent of maximizing sales, including performing the Commercialization activities specified in the Kaken Territory Commercialization Plan, (b) subject to the provisions of Section 5.2, obtain Pricing Approval for a Licensed Product in the Kaken Territory within a reasonable time after having received approval from the MHLW to Commercialize such Licensed Product in the Initial Indication, and (c) begin to Commercialize such Licensed Product in the Initial Indication in the Kaken Territory [***] of having obtained Pricing Approval for such Licensed Product in the Kaken Territory. Notwithstanding the foregoing, if CymaBay breaches any terms of this Agreement and such breach materially impedes Kaken's ability to perform its obligations under Section 3.1, this Section 4.3 or Section 5.2, then Kaken shall be relieved of performing such obligations to the extent that such breach impedes such performance, but only for so long as such breach continues (and will not be precluded from seeking legal and equitable remedies to such breach by CymaBay, but only for so long as such breach continues). [***]

4.4 Advertising and Promotional Materials. Kaken will be responsible for the creation, preparation, production, reproduction, and distribution of all relevant or needed written sales, promotion and advertising materials relating to each Licensed Product ("**Promotional Materials**") for use in the Field of Use in the Kaken Territory. All such Promotional Materials will be compliant with Applicable Law, consistent in all material respects with the Kaken Territory Commercialization Plan, and with the Harmonization Principle. CymaBay and Kaken will submit representative samples of its respective Promotional Materials developed by it for use in the CymaBay Territory and the Kaken Territory, respectively, to the JSC at least annually thereafter. Kaken will consider in good faith any timely comments CymaBay may have with respect to any such Promotional Materials, but will have final decision-making authority in the Kaken Territory with respect to such Promotional Materials. Notwithstanding the foregoing, Kaken will incorporate any changes to Promotional Materials requested by CymaBay in a timely fashion in cases where CymaBay indicates that it believes in good faith that such change is necessary to enable CymaBay to comply with any Applicable Law.

4.5 Reporting Obligations. Kaken will report to the JSC in writing, on an annual basis in the first Kaken Calendar Quarter of each Kaken Fiscal Year, beginning with the Kaken Fiscal Year following the first Regulatory Approval of a Licensed Product in the Field of Use in the Kaken Territory (for the period ending March 31 of the prior Kaken Fiscal Year), summarizing in reasonable detail Kaken's Commercialization activities for such Licensed Product performed to date and the results of such activities (or updating such report for activities performed since the last such report was given hereunder, as applicable). In addition, Kaken will provide CymaBay with written notice of the First Commercial Sale of each Licensed Product in the Field of Use in the Kaken Territory as soon as reasonably practicable after such event; *provided, however,* that, Kaken will inform CymaBay of such event prior to public disclosure of such event by Kaken. Kaken will provide such other information to the JSC as CymaBay may reasonably request with respect to Commercialization of Licensed Products in the Field of Use in the Kaken Territory and will keep the JSC reasonably informed of Kaken's Commercialization activities with respect to Licensed Products.

4.6 Booking of Sales and Handling of Returns

4.6.1 Kaken will be responsible for booking sales of the Licensed Products sold in the Field of Use in the Kaken Territory. CymaBay will be responsible for booking sales of the Licensed Products sold in the CymaBay Territory. Each Party may warehouse Licensed Products both inside and outside of such Party's Territory, *provided* that any sales with respect to such Licensed Products occur and are booked in such Party's Territory.

4.6.2 Kaken will be solely responsible for conducting and handling all aspects of Licensed Product order processing, invoicing and collection, distribution, inventory and receivables of Licensed Products sold in the Kaken Territory in the Field of Use. Kaken will be solely responsible for conducting and handling all rejections, returns, withdrawals and recalls of any Licensed Product sold in the Kaken Territory for the Field of Use.

4.7 Recalls, Market Withdrawals or Corrective Actions. In the event that any Regulatory Authority issues or requests a recall or withdrawal, or takes a similar action in connection with, a Licensed Product in a Territory, or in the event either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal of a Licensed Product in its Territory, the Party notified of such recall or similar action, or the Party that desires such recall or similar action, will as promptly as possible, notify the other Party's Alliance Manager, JSC representatives and applicable quality assurance representatives thereof by telephone or e-mail, and will discuss with the other Party the reasons for the recall, market withdrawal or similar action. Each Party will decide whether to conduct a recall or withdrawal of a Licensed Product in its own Territory and the manner in which any such recall will be conducted (except in the case of a government mandated recall, when such Party may act without such advance notice, but will notify the other Party as soon as possible thereafter). Except as may otherwise be agreed to by the Parties, each Party will bear the expense of any such recall or withdrawal in its own Territory. Each Party will make available all of its pertinent records that may be reasonably requested by the other Party in order for a Party to effect a recall of a Licensed Product in its Territory. The Parties' rights and obligations under this Section 4.7 will be subject to the terms and conditions of any supply agreement(s), including any SDEA or quality related agreements entered into between the Parties. In the event of a conflict between the provisions of any such supply agreement, SDEA or quality related agreements and this Section 4.7, the provisions of such supply agreement, SDEA or quality related agreements will govern with respect to the conflicting provision.

4.8 Ex-Territory Sales; Export Monitoring

4.8.1 *Ex-Territory Sales.* Subject to Applicable Law, neither Party will engage in any advertising or promotional activities relating to any Licensed Product directed primarily to customers or other buyers or users of such Licensed Product located outside of its Territory or accept orders for Licensed Products from or sell Licensed Products into such other Party's Territory for its own account (except for those rights retained by CymaBay outside the Field of Use in the Kaken Territory), and, if a Party (or one of its Related Parties) receives, or becomes aware of, any order for any Licensed Product in the other Party's Territory, it will refer such orders to the other Party, to the extent it is not prohibited from doing so under Applicable Law. For clarity, but subject to Kaken's rights under Section 10.6, nothing in this Section 4.8.1 will prevent CymaBay and its Related Parties from undertaking, or having undertaken, any of the foregoing activities with respect to any Licensed Product outside of the Field of Use in the Kaken Territory.

4.8.2 *Export Monitoring.* Each Party will use [***] to monitor and prevent exports of Licensed Products from its own Territory for Commercialization in the other Party's Territory using methods permitted under Applicable Law that are consistent with its past practice and commonly used in the industry in the relevant Party's Territory for such purpose (if any), and will promptly inform the other Party of any such exports of Licensed Products from its Territory, and any actions taken to prevent such exports, *provided that*, for clarity, the foregoing does not restrict CymaBay in performing its obligations under the Supply Agreements, or in exercising any of its retained rights outside the Field of Use. Each Party agrees to take reasonable actions requested in writing by the other Party that are consistent with Applicable Law and commonly used in the industry in the relevant Party's Territory for such purpose to prevent exports of Licensed Products from its Territory for Commercialization in the other Party's Territory. For clarity, but subject to Kaken's rights under Section 10.6, nothing in this Section 4.8.2 will prevent CymaBay and its Related Parties from exporting Licensed Products from the CymaBay Territory for Commercialization of such Licensed Products outside of the Field of Use in the Kaken Territory.

ARTICLE 5

REGULATORY

5.1 Regulatory Filings and Interactions.

5.1.1 *Regulatory Responsibilities*.

5.1.1.1 *Kaken*. Kaken, at its sole cost and expense, will be solely responsible for all regulatory matters relating to Licensed Product for use in the Field of Use in the Kaken Territory. Kaken shall use Commercially Reasonable Efforts to obtain all Regulatory Approvals needed to Commercialize a Licensed Product in the Field of Use in the Kaken Territory as soon as reasonably practicable, and to obtain [***] for Licensed Product in the Kaken Territory. Kaken will solely and exclusively own all Regulatory Materials with respect to such Licensed Product for use in the Field of Use in the Kaken Territory, including [***] by Kaken solely with respect thereto. Kaken, at its sole cost and expense, will have the sole and exclusive right to (a) oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, each Regulatory Authority in the Kaken Territory with respect to each Licensed Product for use in the Field of Use, (b) interface, correspond and meet with each Regulatory Authority in the Kaken Territory with respect to Licensed Product for use in the Field of Use, and (c) seek and maintain all Regulatory Filings in the Kaken Territory with respect to each Licensed Product for use in the Field of Use.

5.1.1.2 *CymaBay*. CymaBay, at its sole cost and expense, will be solely responsible for all regulatory matters relating to a Licensed Product, other than as relates to use in the Field of Use in the Kaken Territory, and will solely and exclusively own all Regulatory Materials with respect thereto, including [***] by or on behalf of CymaBay, but excluding, for clarity, any Regulatory Materials specifically with respect to Licensed Product for use in the Field of Use in the Kaken Territory. CymaBay, at its sole cost and expense, will have the sole and exclusive right to (a) oversee, monitor and coordinate all regulatory actions, communications and filings with, and submissions to, each Regulatory Authority with respect to each Licensed Product, (b) interface, correspond and meet with each Regulatory Authority with respect to each Licensed Product, and (c) seek and maintain all Regulatory Filings with respect to each Licensed Product, in each case of (a), (b) and (c), *other than* Licensed Products for use in the Field of Use in the Kaken Territory. As provided in Section 3.9.1, CymaBay will provide to Kaken all Nonclinical Study data, CMC data and Clinical Study data in its possession and Control that is reasonably required by Kaken to apply for Regulatory Approval for Licensed Product for use in the Field of Use in the Kaken Territory.

5.1.2 *Communications with Regulatory Authorities.* Kaken will notify the JSC, including a brief description in English, of the principal issues raised in each Material Communication with Regulatory Authorities with respect to each Licensed Product for the Initial Indication in the Kaken Territory within [***] days after receipt thereof. Upon CymaBay's request, Kaken will provide to CymaBay, at CymaBay's expense: (a) a summary translation of such Material Communications in English, (b) complete copies of the original correspondence with such Regulatory Authorities in their native language, or (c) a complete translation of such Material Communications in English, in each case of (a) through (c) within a reasonable period of time following such request. For the purposes of this Section 5.1.2, "**Material Communications**" with Regulatory Authorities include meetings with Regulatory Authorities, and Regulatory Authority questions or concerns, with respect to significant issues regarding Licensed Product, including issues as to any of the following: [***].

5.1.3 *Regulatory Meetings.* Kaken will provide CymaBay with reasonable advance notice of all substantive meetings with the Governmental Authorities in the Kaken Territory pertaining to Licensed Product for use in the Field of Use, with as much advance notice as practicable under the circumstances. Kaken will use Commercially Reasonable Efforts, to the extent reasonably practicable, to permit CymaBay to have, at CymaBay's expense, mutually acceptable representatives of CymaBay attend, solely as a non-participating observer, material, substantive meetings with any Governmental Authorities within the Kaken Territory pertaining to such Licensed Product for use in the Field of Use; *provided, however*, that (a) if required by the Governmental Authority, attendance by CymaBay will be permitted, (b) attendance by the representatives of CymaBay will not prevent participation of a representative of Kaken due to restrictions imposed by Regulatory Authorities on the number of attendees; and (c) Kaken will not be obligated to change the schedule of such meeting in order to accommodate the schedule of CymaBay's representatives.

5.1.4 *Submissions.* Kaken will provide CymaBay with written notice of each of the following events with regard to each Licensed Product for the Initial Indication in the Kaken Territory, within a reasonable period of time following the occurrence thereof, (a) the submission of any filings or applications for Regulatory Approval of such Licensed Product for the Initial Indication in the Kaken Territory to any Regulatory Authority, and (b) receipt or denial of Regulatory Approval for such Licensed Product for the Initial Indication in the Kaken Territory, *provided, however*, that Kaken will inform CymaBay such event under (a) or (b) prior to public disclosure of such event by Kaken. Kaken, within a reasonable period of time following CymaBay's written request, will provide to CymaBay, at CymaBay's cost and expense, a complete copy of any of the filings or applications of clause (a).

5.1.5 *Coordination*. The activities of Kaken and its Related Parties under this Section 5.1 will be subject to the coordination and other responsibilities of the JSC and the Harmonization Principle.

5.2 Diligence; Standards of Conduct. Kaken and its Related Parties will use Commercially Reasonable Efforts to conduct all such Development (including regulatory) activities needed to obtain Regulatory Approval for at least one Licensed Product in the Initial Indication in the Kaken Territory [***]; *provided, however,* that [***].

5.3 Costs of Regulatory Affairs. Except as otherwise indicated in this Agreement, each Party will be responsible for all costs and expenses incurred in connection with its efforts to apply for, obtain and maintain Regulatory Approval with respect to Licensed Products in its Territory, and its related regulatory affairs activities.

5.4 Right of Reference. Each Party, on behalf of itself and its Related Parties, hereby grants to the other Party, and at the request of the other Party will grant to the other Party's Related Parties, a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous law recognized outside of the United States), to, and a right to copy, access, and otherwise use, all information and data (including [***]) included in or used in support of any regulatory filing, Regulatory Approval, [***] or other Regulatory Materials maintained on behalf of such Party (or its Related Parties) that relates to Licensed Product, in each case to the extent necessary for, and solely for use in support of, the applicable Party to obtain Regulatory Approval of Licensed Product in the Kaken Territory or the CymaBay Territory, as applicable. Such other Party will provide a signed statement to this effect, if requested by the Party granted such rights of reference, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor or analogous Applicable Law outside of the United States). In addition, upon the reasonable request of either Party (on behalf of itself or any of its Related Parties), the other Party will, and will cause its Related Parties to, obtain and provide to the requesting Party certificates

or other formal or official attestations concerning the regulatory status of the Licensed Products in the Kaken Territory or the CymaBay Territory, as applicable (*e.g.*, Certificates of Free Sale, Certificates for Export, Certificates to Foreign Governments), at the requesting Party's request and cost, and provided further that such attestations are reasonably necessary for the requesting Party to exercise its rights under this Agreement. For clarity, Kaken's rights under this Section 5.4 may be exercised solely as is necessary to support filing for, obtaining and maintaining Regulatory Approval for a Licensed Product for use in the Field of Use in the Kaken Territory. Notwithstanding anything to the contrary in this Agreement other than for Safety Concerns, neither Party nor any of its Related Parties will withdraw or inactivate any Regulatory Filing that the other Party or the other Party's Related Parties references or otherwise uses pursuant to the rights of reference granted in this Section 5.4.

5.5 Pharmacovigilance. The Parties will cooperate with regard to the reporting and handling of safety information involving the Licensed Products in accordance with all Applicable Law concerning pharmacovigilance and clinical safety, with CymaBay being responsible, at its cost, for maintaining a global safety database, and Kaken being responsible, at its cost, for pharmacovigilance and safety reporting in the Kaken Territory. No later than [***] prior to the enrollment of the first patient in a [***] for the Licensed Product in the Kaken Territory (as such period may be extended by mutual written agreement of the Parties, but within such time to ensure that all regulatory requirements are met), the Parties will negotiate in good faith and enter into a Safety Data Exchange Agreement ("**SDEA**"), which will define the pharmacovigilance responsibilities of the Parties and include safety data exchange procedures to enable each Party (and their respective related Third Parties, if any) to comply with all of its legal and regulatory obligations related to the Licensed Products.

ARTICLE 6

MANUFACTURE

6.1 Overview of Manufacturing and Supply Obligations The Parties agree that, except as otherwise provided below, CymaBay shall manufacture (or have manufactured) and supply to Kaken its and its Related Parties' [***] and commercial requirements of finished drug product for the Licensed Products for use and sale in the Kaken Territory in the Field of Use. Such supply shall be pursuant to the Supply Agreements and Section 6.2, and the commercial supply obligation shall be subject to termination by CymaBay after the applicable time, as provided in Section 6.3.

6.2 Supply Agreements and Quality Agreement

6.2.1 *Clinical Supply Agreement.* As soon as practicable following the execution of this Agreement, the Parties will enter into a clinical supply agreement (the "**Clinical Supply Agreement**"), substantially in the form attached as Schedule 6.2.1 of this Agreement (with such changes as the Parties may mutually agree to), pursuant to which CymaBay will supply Kaken's and its Related Parties' clinical requirements of [***] for the Licensed Products for the Kaken Territory for the Field of Use at the Clinical Transfer Price [***] and at [***].

6.2.2 *Non-Clinical Supply.* CymaBay will supply Kaken's and its Related Parties' requirements of [***] included in the Licensed Product to be used in connection with Kaken's Nonclinical Studies and CMC Activities. The price for such [***] shall be at [***].

6.2.3 *Commercial Supply Agreement.* [***], the Parties will negotiate reasonably and in good faith and enter into a commercial supply agreement (the "**Commercial Supply Agreement**") pursuant to which CymaBay will supply Kaken's and its Related Parties' commercial requirements of finished drug product for the Licensed Products for the Kaken Territory for the Field of Use, such Commercial Supply Agreement to be commercially reasonable and typical for the pharmaceutical industry, which will include customary commercial terms such as, by way of non-limiting examples, the right to receive a fair allocation of supply relative to CymaBay and its Affiliates and other licensees, sublicensees and distributors in the event of supply shortfall, and the right to require a second or alternative source of supply.

6.2.4 *Quality Agreement.* Simultaneously with the Clinical Supply Agreement and Commercial Supply Agreement, the Parties will negotiate reasonably and in good faith and enter into a quality agreement for non-clinical and clinical use as well as commercial use, respectively, governing all manufacturing and quality control and quality assurance aspects for the supply of Licensed Product to meet the requirements of Applicable Law and local market standards in the Kaken Territory and that will be commercially reasonable and typical for the pharmaceutical industry.

6.3 Supply Agreement Termination. No earlier than [***] after the date of First Commercial Sale of the first Licensed Product in the Kaken Territory, CymaBay may give notice (a "**CymaBay Supply Termination Notice**") to Kaken that CymaBay is terminating its supply obligations under the Supply Agreements and transferring to Kaken the manufacturing and supply rights regarding Licensed Compound and/or Licensed Product for sale in the Kaken Territory. The termination of such supply obligations under any such CymaBay Supply Termination Notice (the "**CymaBay Supply Termination**") shall become effective on the date that is the later of: (a) [***] after the date of such notice, or (b) the date on which either (i) Kaken or its designee obtains Manufacturing accreditation from the applicable Regulatory Authority for Manufacturing Licensed Products for use in the Field of Use for the Kaken Territory, or (ii) Kaken or its Affiliate or Sublicensee obtains the contract rights to purchase, from qualified Third Party manufacturers, its requirements for Licensed Product for sale in the Kaken Territory, *provided that* the CymaBay Supply Termination will in any event occur no later than [***] after such notice; *provided further,* that if Kaken (or its designee, if applicable) does not obtain such Manufacturing accreditation after good faith reasonable efforts to do so within such [***] period, and Kaken cannot obtain supply from CymaBay's Third Party manufacturer, the Parties shall discuss a further extension of the CymaBay Supply Termination in good faith. After receipt of a CymaBay Supply Termination Notice, Kaken (and its designee, if applicable) shall use good faith reasonable efforts to obtain as soon as possible Manufacturing accreditation from the applicable Regulatory Authority for Manufacturing Licensed Products for use in the Field of Use for the Kaken Territory, or the contractual rights to purchase Licensed Product for sale in the Kaken Territory. On and after the delivery of the CymaBay Supply Termination Notice, CymaBay shall conduct (and shall cause any of its applicable subcontractors to conduct) a technology transfer to Kaken of the Manufacturing technology as needed to manufacture Licensed Compound and/or the Licensed Product. Such transfer would be conducted as provided in Section 3.9.3 and is intended to ensure that Kaken has either (i) arrangements in place with CymaBay's Third Party manufacturers for supply of Licensed Compound and Licensed Product or (ii) the CymaBay manufacturing information needed to manufacture Licensed Product, in each case for sale to Kaken for use in the Kaken Territory in the Field of Use commencing a reasonable amount of time prior to the date of the CymaBay Supply Termination, [***].

ARTICLE 7

LICENSES

7.1 License Grants to Kaken.

7.1.1 *Development License*. Subject to the terms and conditions of this Agreement, CymaBay hereby grants Kaken anon-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Sections 3.7 and 7.1.4) license under the CymaBay Licensed Technology to Develop Licensed Products in the Field of Use; *provided*, that such license grant for Development is limited in each case solely for use as and to the extent permitted under this Agreement, and in each case, solely for purposes of obtaining Regulatory Approval of Licensed Products in the Field of Use in the Kaken Territory and Commercializing Licensed Products in the Field of Use in the Kaken Territory. Such Development license to Kaken is exclusive (even as to CymaBay and its Affiliates) to Kaken in the Kaken Territory, and may be exercised outside the Kaken Territory solely to the extent approved in writing by the JSC. Notwithstanding the foregoing license grant, CymaBay retains for clarity the right under the CymaBay Licensed Technology, with the right to grant licenses through multiple tiers in accordance with Section 7.2.4, which will apply *mutatis mutandis*, (a) (i) to Develop Licensed Products anywhere in the world for obtaining Regulatory Approval of Licensed Products in any indications in the CymaBay Territory and Commercializing Licensed Products in any indications in the CymaBay Territory, and (ii) to Develop Licensed Products anywhere in the world for obtaining Regulatory Approval of Licensed Products outside of the Field of Use in the Kaken Territory and Commercializing Licensed Products outside of the Field of Use in the Kaken Territory, but subject to Kaken's rights under Section 10.6, and (b) to perform, and have performed, its obligations under the Initial Indication Development Plan, including the CMC Work Plan.

7.1.2 *Commercialization License in the Kaken Territory*. Subject to the terms and conditions of this Agreement, CymaBay hereby grants Kaken a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.1.4), exclusive (even as to CymaBay and its Affiliates) license under the CymaBay Licensed Technology to Commercialize Licensed Products solely in the Field of Use in the Kaken Territory.

7.1.3 *Conditional Manufacturing License*. Subject to the terms and conditions of this Agreement, and exercisable only following delivery of a CymaBay Supply Termination Notice or as otherwise provided in the terms of the Supply Agreements, CymaBay hereby grants Kaken a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.1.4), non-exclusive license under the CymaBay Licensed Technology to Manufacture and have Manufactured Licensed Products anywhere in the world solely for (a) Development solely for purposes of obtaining Regulatory Approval of Licensed Products in the Field of Use in the Kaken Territory; and (b) Commercialization of Licensed Products in the Field of Use in the Kaken Territory. In no event, whether pursuant to rights under this Agreement or the Supply Agreements, will Kaken or any of its Related Parties have the right to Manufacture Licensed Products for Development (except as otherwise approved by the JSC) or Commercialization in the CymaBay Territory or for Development or Commercialization outside of the Field of Use in the Kaken Territory, but subject to Kaken's rights under Section 10.6. For clarity, notwithstanding the foregoing conditional license grant, CymaBay retains the right under the CymaBay Licensed Technology, with the right to grant licenses through multiple tiers in accordance with Section 7.2.4, to Manufacture and have Manufactured Licensed Products anywhere in the world: (i) (A) for Development of Licensed Products and Commercialization of Licensed Products in any indications in the CymaBay Territory, (B) for Development of Licensed Products and Commercialization of Licensed Products outside of the Field of Use in the Kaken Territory, but subject to Kaken's rights under Section 10.6, and (C) for Development of Licensed Products in the Field of Use in the Kaken Territory, and (ii) to supply (or have supplied) Licensed Products to Kaken pursuant to the Supply Agreements (or any other supply agreement covering Licensed Product that may be agreed to between the Parties).

7.1.4 *Kaken Sublicensing Terms.*

(a) In addition to its subcontracting rights pursuant to Section 3.7:

(i) Kaken will have the right to sublicense any of its rights under Sections 7.1.1, 7.1.2 and 7.1.3, to any of its Affiliates without the prior consent of CymaBay, but subject to the requirements of this Section 7.1.4; and

(ii) Kaken will have the right to sublicense any of its rights under Sections 7.1.1, 7.1.2 and 7.1.3 to any Third Party with CymaBay's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed), subject to the requirements of this Section 7.1.4; *provided*, *however*, that, for clarity, Kaken's appointment of a Third Party distributor will not constitute a sublicense of Kaken's rights under Section 7.1.2 requiring CymaBay's prior written consent, but any other sublicensing of Commercialization activities relating to Licensed Products in the Kaken Territory will be a sublicense requiring such CymaBay's prior written consent in accordance with the foregoing sentence.

(b) Without limiting Section 7.1.4(a)(i), each sublicense granted by Kaken pursuant to this Section 7.1.4, and sublicense or subcontracting agreement entered into by Kaken pursuant to Section 3.7, will be subject and subordinate to this Agreement and will contain provisions consistent with the terms and conditions of this Agreement. As soon as reasonably practicable after entry into any such sublicense or subcontracting agreement, Kaken will provide CymaBay with a copy of any such executed agreement that includes a material sublicense granted hereunder (which copy may be redacted to remove financial provisions and other provisions that are not necessary to monitor compliance with this Section 7.1.4). Each such sublicense agreement will contain the following provisions: (i) a requirement that the Sublicensee comply with the

confidentiality and non-use provisions of Section 9.1 with respect to CymaBay's Confidential Information, (ii) if such sublicense agreement contains a sublicense of rights granted under Section 7.1.2, such sublicense agreement will also contain the following provisions: (A) a requirement that the Sublicensee submit applicable sales or other reports to Kaken to the extent necessary or relevant to the reports required to be made or records required to be maintained under this Agreement, and (B) the audit requirement set forth in Section 8.7, (iii) a requirement that the Sublicensee comply with the applicable provisions under any in-license agreement, (iv) provisions whereby such sublicensee undertakes to indemnify and defend CymaBay for all matters covered by Section 11.1 for which sublicensee may be responsible, and (v) provisions whereby Kaken obtains ownership of, or a fully sublicensable non-exclusive (or exclusive) license (or an option to obtain such license) under and to, any Know-How and Patents that are developed by the Sublicensee in the performance of such agreement and are reasonably necessary or useful to the Development, Manufacture or Commercialization of Licensed Products in the Field of Use; *provided* that the foregoing requirement to obtain ownership of, or a fully sublicensable non-exclusive (or exclusive) license (or an option to obtain such license) will not apply to any improvements unless such improvements are reasonably necessary to the Development, Manufacture or Commercialization of those Licensed Products in the Field of Use.

(c) Notwithstanding any sublicense granted pursuant to this Section 7.1.4, Kaken will (i) remain primarily liable to CymaBay for the performance of all of Kaken's obligations under, and Kaken's compliance with all provisions of, this Agreement and (ii) be liable for any act or omission of any such Sublicensee that is a breach of any of Kaken's obligations under this Agreement as though the same were a breach by Kaken, and CymaBay shall have the right to proceed directly against Kaken without any obligation to first proceed against such Sublicensee for any such breach or liability. Each (sub)license by Kaken and its Affiliates will be subject to the applicable terms and conditions of this Agreement. For clarity, Kaken grants no rights hereunder to permit CymaBay to proceed directly against a Sublicensee.

7.1.5 *Rights Regarding Combination Products.*

(a) While the license rights granted by CymaBay to Kaken in Sections 7.1.1, 7.1.2, and 7.1.3 include the exclusive license rights with respect to Combination Products solely in the Kaken Territory in the Field of Use, the Parties agree that Kaken and its Related Parties shall not, and Kaken covenants that it and its Related Parties shall not, Develop or Commercialize any Combination Product, unless and until the Parties agree as to the financial and related terms for such activities, as provided in Section 7.1.5(b). Kaken hereby covenants that it and its Related Parties shall not Develop or Commercialize any Combination Product except as provided pursuant to such agreement of the Parties pursuant to Section 7.1.5(b).

(b) If Kaken desires to Develop and Commercialize in the Kaken Territory a particular Combination Product, Kaken shall notify CymaBay of such desire, which notice shall provide all the material details of the proposed Combination Product, and the proposed financial structure for compensating CymaBay for such Combination Product (which structure shall, as much as practicable, provide to CymaBay compensation equivalent to what it would receive for supply and sale of Licensed Product hereunder). If such a notice is given by Kaken, then the Parties shall meet thereafter and discuss Kaken's request and proposal, and shall negotiate reasonably and in good faith with the goal of reaching agreement and entering into an amendment to this Agreement that provides for the financial terms, and any other needed terms, for Kaken to have the right to Develop and Commercialize such Combination Product in Field of Use in the Kaken Territory.

7.1.6 *Limited Covenant Not To Sue.* CymaBay hereby covenants that, with respect to any Development work conducted hereunder by Kaken (or its Affiliate) outside the Kaken Territory on Licensed Product for use in the Field of Use that has been approved in writing by the JSC, CymaBay and its Affiliates shall not assert in a legal action against Kaken (or its Affiliate) any of its Intellectual Property rights relating to Licensed Product with respect to such Development work, to the extent such work is intended solely for use in the Kaken Territory in the Field of Use.

7.2 License Grants to CymaBay.

7.2.1 *Development Licenses*. Subject to the terms and conditions of this Agreement, Kaken hereby grants CymaBay anon-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.2.4), terminable (pursuant to the provisions of ARTICLE 13), nonexclusive, royalty-free and fully paid license under the Kaken Program IP (a) to Develop Licensed Products anywhere in the world solely for obtaining Regulatory Approval of Licensed Products in any indications in the CymaBay Territory and Commercializing Licensed Products in any indications in the CymaBay Territory, and (b) to Develop Licensed Products anywhere in the world solely for obtaining Regulatory Approval of Licensed Products outside of the Field of Use in the Kaken Territory and Commercializing Licensed Products outside of the Field of Use in the Kaken Territory, but subject to Kaken's rights under Section 10.6.

7.2.2 *Commercialization Licenses in the CymaBay Territory*. Subject to the terms and conditions of this Agreement, Kaken hereby grants CymaBay a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.2.4), terminable (pursuant to the provisions of ARTICLE 13), nonexclusive, royalty-free and fully paid license under the Kaken Program IP (a) to Commercialize Licensed Products in any indications in the CymaBay Territory, and (b) to Commercialize Licensed Products outside of the Field of Use in the Kaken Territory, but subject to Kaken's rights under Section 10.6.

7.2.3 *Manufacturing Licenses*. Subject to the terms and conditions of this Agreement and the Supply Agreements (or any other applicable supply agreement between the Parties), Kaken hereby grants CymaBay a non-transferable (except as provided in Section 14.1), sublicensable through multiple tiers (subject to Section 7.2.4), terminable (pursuant to the provisions of ARTICLE 13), nonexclusive, royalty-free and fully paid license under the Kaken Program IP to Manufacture and have Manufactured Licensed Products anywhere in the world solely (a) for Development of Licensed Products and Commercialization of Licensed Products in any indications in the CymaBay Territory, and (b) for Development of Licensed Products and Commercialization of Licensed Products outside of the Field of Use in the Kaken Territory, but subject to Kaken's rights under Section 10.6.

7.2.4 *Sublicensing Terms.*

(a) CymaBay will have the right to sublicense any of its rights under Sections 7.2.1, 7.2.2, and 7.2.3 to any of its Affiliates or to any Third Party (which sublicensed rights may be further sublicensable through multiple tiers) without the prior consent of Kaken, subject to the requirements of this Section 7.2.4.

(b) Each sublicense granted by CymaBay pursuant to this Section 7.2.4 will be subject and subordinate to this Agreement and will contain provisions consistent with the terms and conditions of this Agreement. Each such sublicense agreement will contain the following provisions: (i) a requirement that the Sublicensee comply with the confidentiality and non-use provisions of Section 9.1 with respect to Kaken's Confidential Information, and (ii) a requirement that the Sublicensee comply with the applicable provisions under any in-license agreement of Kaken under which CymaBay elects to take a sublicense pursuant to Section 7.3.2.

(c) Notwithstanding any sublicense granted pursuant to this Section 7.2.4, CymaBay will (i) remain primarily liable to Kaken for the performance of all of CymaBay's obligations under, and CymaBay's compliance with all provisions of, this Agreement and (ii) be liable for any act or omission of any such Sublicensee that is a breach of any of CymaBay's obligations under this Agreement as though the same were a breach by CymaBay, and Kaken shall have the right to proceed directly against CymaBay without any obligation to first proceed against such Sublicensee with respect to such breach or liability. For clarity, CymaBay grants no rights hereunder to permit Kaken to proceed directly against a Sublicensee.

7.3 Third Party In-Licenses; Payments.

7.3.1 *Existing In-Licensing Agreements.*

7.3.1.1 CymaBay will be responsible for all payments owed by CymaBay that are associated with any agreements to which CymaBay is a party related to the CymaBay Licensed Technology that exist as of the Effective Date ("**Existing In-Licensing Agreements**"), except as otherwise agreed by Kaken in writing.

[***]

7.3.2 *Needed Additional In-Licensing Agreements.* If Kaken reasonably determines that it is necessary during the Term to enter into an agreement with a Third Party to in-license any Intellectual Property rights controlled by such Third Party that are necessary for the Exploitation by Kaken of the Licensed Product in the Field of Use in the Kaken Territory where such Intellectual Property rights, but for such in-license, would be infringed, misappropriated or otherwise violated by the use, offer for sale or sale of the Licensed Product in the Kaken Territory in the Field of Use, as such Licensed Product existed on the Effective Date and was disclosed by CymaBay to Kaken in accordance with the technology transfer pursuant to the terms of Section 3.9, then Kaken may enter into a license agreement with such Third Party toin-license such Intellectual Property rights for use in the Exploitation of the Licensed Product in the Kaken Territory in the Field of Use (and also, to manufacture such Licensed Product, if applicable). If Kaken executes and enters into such an in-license agreement, Kaken shall be responsible for any payments owed under suchin-license agreement, and Kaken may credit (subject to the below limitation), against amounts owed to CymaBay hereunder, [***] of the royalty payments made by Kaken to the Third Party licensor under such agreement to the extent such royalty payments are payable based on the sales of Licensed Product in Japan by Kaken or its Related Party, *provided that* any such credit shall not reduce any amount owed to CymaBay hereunder by more than [***] of the amount otherwise owed. [***]

7.4 Combinations. Notwithstanding any other provision of this Agreement, for purposes of the license grants underSection 7.1 with respect to any Licensed Product that is a Combination Product, any such license grant covers only the grant of license rights with respect to the Seladelpar component of such Combination Product.

7.5 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a Party to the other are and will otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, a license of a right to "intellectual property" as defined under Section 101 of the Bankruptcy Code. The Parties acknowledge and agree that the Parties and their respective Sublicensees, as Sublicensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the Bankruptcy Code and any foreign counterpart thereto. The Parties further agree that upon commencement of a bankruptcy proceeding by or against a Party (the "**Bankrupt Party**") under the Bankruptcy Code, the other Party (the "**Non-Bankrupt Party**") will be entitled to a complete duplicate of, or complete access to (as theNon-Bankrupt Party deems appropriate), all such intellectual property and all embodiments of such intellectual property. Such intellectual property and all embodiments of such intellectual property will be promptly delivered to the Non-Bankrupt Party (a) upon any such commencement of a bankruptcy proceeding and upon written request by the Non-Bankrupt Party, unless the Bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under (a) above, upon the rejection of this Agreement by or on behalf of the Bankrupt Party and upon written request by the Non-Bankrupt Party. The Bankrupt Party (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) agree not to interfere with the exercise by the Non-Bankrupt Party or its Related Parties of its rights and licenses to such intellectual property and such embodiments of intellectual property in accordance with this Agreement, and agrees to assist the Non-Bankrupt Party and its Related Parties in obtaining such intellectual property and such embodiments of intellectual property in the possession or control of Third Parties as are reasonably necessary or desirable for the Non-Bankrupt Party to exercise such rights and licenses in accordance with this Agreement. The foregoing provisions are without prejudice to any rights the Non-Bankrupt Party may have arising under the Bankruptcy Code or other Applicable Law.

7.6 Kaken Background Technology. In the event that Kaken (or its Affiliate) uses, develops or acquires rights (including by in-license) to any Kaken Background Technology, Kaken shall give CymaBay written notice of such Kaken Background Technology, including a detailed description thereof. CymaBay shall have the option to obtain a non-exclusive, worldwide license to such Kaken Background Technology, solely (a) to Develop and Commercialize Licensed Products in any indications in the CymaBay Territory, and (b) to Develop and Commercialize Licensed Products outside of the Field of Use in the Kaken Territory, but subject to Kaken's rights under Section 10.6. CymaBay shall have the right to exercise such option to a license by providing Kaken written notice of its election. Upon such exercise, Kaken is deemed to grant the above license, *provided that* CymaBay shall pay to Kaken any amounts that Kaken would owe to a Third Party licensor of the applicable Kaken Background Technology, for CymaBay's (or its Affiliate's or sublicensee's) practice of such Kaken Background Technology under the above license.

7.7 No Other Rights. Except as otherwise expressly provided in this Agreement, under no circumstances will a Party or any of its Affiliates, as a result of this Agreement, obtain any ownership interest, license or other right (whether by implication, estoppel or otherwise) in or to any Know-How, Patents or other Intellectual Property rights of the other Party or any of such other Party's Affiliates, including tangible or intangible items owned, controlled or developed by the other Party or any of such other Party's Affiliates, or provided by the other Party or any of its Affiliates to the receiving Party or any of its Affiliates at any time, pursuant to this Agreement. Neither Party nor any of its Affiliates will use or practice any Know-How or Patents licensed or provided to such Party or any of its Affiliates outside the scope of or otherwise not in compliance with the rights and licenses granted to such Party and its Affiliates under this Agreement.

ARTICLE 8

PAYMENTS

8.1 Upfront Fee. Within [***] of receipt by Kaken of an invoice therefor, Kaken will pay to CymaBay a one-time, non-refundable, non-creditable payment of Four Billion Five Hundred Million Japanese Yen (4,500,000,000 JPY).

8.2 Regulatory Milestone Payments.

8.2.1 *Regulatory Milestones*. Kaken will make, pursuant to Section 8.2.2, one-time, non-refundable, non-creditable milestone payments to CymaBay (each, a "**Regulatory Milestone Payment**") upon the first achievement of each of the regulatory events as set forth in the below table with respect to Licensed Product (each, a "**Regulatory Milestone Event**") by Kaken or its Related Parties.

[***]

8.2.2 *Payment Terms for Regulatory Milestone Payments.* Kaken will notify CymaBay within five (5) Business Days after the achievement of a Regulatory Milestone Event by Kaken or its Related Parties. CymaBay will invoice Kaken after receipt of such notice for the applicable Regulatory Milestone Payment amount set forth in the above table of Section 8.2.1, and Kaken shall pay to CymaBay such amount within [***] after receipt of such invoice.

8.3 Sales Milestone Payments.

8.3.1 *Sales Milestones.* Kaken will make, pursuant to Section 8.3.2, one-time, non-refundable, non-creditable milestone payments to CymaBay (each, a "**Sales Milestone Payment**") when aggregate Net Sales of Licensed Products in the Kaken Territory in a given Kaken Fiscal Year first reach the JPY threshold values indicated in the table below (each, a "**Sales Milestone Event**") during the Term:

[***]

For clarity, the Sales Milestone Payments will each be paid only once, such that, the maximum total amount payable by Kaken to CymaBay under this Section 8.3 is [***] JPY (it being understood that the Sales Milestone Payments will be additive).

8.3.2 *Payment Terms for Sales Milestone Payments.* Within [***] after the end of each Kaken Fiscal Quarter, Kaken will notify CymaBay of the achievement of a Sales Milestone Event(s) during such Kaken Fiscal Quarter. CymaBay will thereafter invoice Kaken for the applicable Sales Milestone Payment amount set forth in the above table of Section 8.3.1, and Kaken shall pay to CymaBay such amount within [***] after receipt of such invoice; [***].

8.4 Supply Transfer Price; Back-Up Royalties.

8.4.1 *Supply Transfer Price During Royalty Term.* With respect to Licensed Product supplied by CymaBay to Kaken during the applicable Royalty Term for Licensed Product, and subject to Sections 8.4.3 and 8.6.2, Kaken will make non-refundable, non-creditable payments to CymaBay, on a Licensed Product-by-Licensed Product basis, in an amount, payable in JPY at the time of such supply, equal to the Supply Transfer Price then in effect for such Licensed Product (other than with respect to a Combination Product, [***] for which shall be calculated as provided in the agreement between the Parties under Section 7.1.5(b) for such Combination Product), for each unit of such Licensed Product that CymaBay supplies to Kaken under the Commercial Supply Agreement (or under any other commercial supply agreement between the Parties other than the Clinical Supply Agreement).

8.4.2 *Supply Transfer Price Post-Royalty Term.* On a Licensed Product-by-Licensed Product basis, after the Royalty Term expires for such Licensed Product and for so long as CymaBay continues to supply such Licensed Product pursuant to the Commercial Supply Agreement, Kaken will make non-refundable, non-creditable payments to CymaBay, on a Licensed Product-by-Licensed Product basis, in an amount, payable in JPY at the time of such supply, equal to [***] (other than with respect to a Combination Product, the [***] for which shall be calculated as provided in the agreement between the Parties under Section 7.1.5(b) for such Combination Product), for each unit of such Licensed Product that CymaBay supplies to Kaken under the Commercial Supply Agreement (or under any other agreement between the Parties).

8.4.3 *Back-Up Royalties.* If, at any time during the applicable Royalty Term for a Licensed Product, the Commercial Supply Agreement is terminated or is otherwise no longer in effect, including if there is a CymaBay Supply Termination, then, with respect to the sales or other commercial transfer of such Licensed Product in the Kaken Territory, Kaken will make non-refundable, non-creditable royalty payments in JPY to CymaBay at a royalty rate equal to [***] of Net Sales of such Licensed Product. On a Licensed Product-by-Licensed Product basis, the royalties due under this Section 8.4.3 will be payable until the latest to occur of (a) the expiration of the last Valid Claim of the Royalty Patents Covering such Licensed Product in the Kaken Territory, (b) the expiration of Regulatory Exclusivity for such Licensed Product in the Kaken Territory, and (c) ten (10) years after the First Commercial Sale of such Licensed Product in the Kaken Territory (the "**Royalty Term**", as to the applicable Licensed Product).

8.5 Additional Supply Transfer Price and Back-Up Royalty Terms.

8.5.1 *Only One Royalty*. In the event Section 8.4.3 applies as to sale of a Licensed Product, only one royalty will be due thereunder with respect to the sale of the same unit of Licensed Product, even if the manufacture, use, sale, offer for sale or importation of such Licensed Product is Covered by more than one claim of the Royalty Patents.

8.5.2 *Reduction for Loss of Patent Protection.* On a Licensed Product-by-Licensed Product basis, upon the expiration of the last Valid Claim of the Royalty Patents Covering such Licensed Product in the Kaken Territory then: (i) the amount owed by Kaken under Section 8.4.1 for supply by CymaBay of such Licensed Product after such occurrence shall be [***], and (ii) if applicable, the royalties payable to CymaBay under Section 8.4.3 will be [***]; *provided*, that no such reduction shall apply under this Section 8.5.2 if any reduction under Section 8.5.3 applies.

8.5.3 *Royalty Reduction for Generic Competition.* With respect to a particular Licensed Product being sold in the Kaken Territory, on a Licensed Product-by-Licensed Product basis and a Kaken Fiscal Quarter-by-Kaken Fiscal Quarter basis, if the Generic Competition Percentage in the Kaken Territory with respect to such Licensed Product for all sales in such Kaken Fiscal Quarter equals or exceeds [***], then beginning from the immediately following Kaken Fiscal Quarter: (i) the amount owed by Kaken under Section 8.4.1 for supply of such Licensed Product during such Kaken Fiscal Quarter shall be [***] (with applicable adjustments for amounts already paid by Kaken for such supply, if needed), or (ii) if applicable, the royalties on Net Sales payable to CymaBay under Section 8.4.3 shall be [***].

8.5.4 *Minimum Floor*. In no event will the Supply Transfer Price or, if applicable, the royalties payable to CymaBay underSection 8.4.3, be reduced for any particular amount owed by more than [***] of the amount that otherwise would have been due and payable to CymaBay but for the reductions set forth in Sections 8.5.2 and 8.5.3, and further, in no event will the Supply Transfer Price (whether during or after the Royalty Term) be reduced to the amount that is less than [***]. Kaken may not carry forward any reductions or credits that are not applied against the amounts payable to CymaBay hereunder as a result of the foregoing floor.

8.5.5 *Transfer Price Revisions*. In the event that at any time [***] for a Licensed Product is less than [***], the Parties will negotiate reasonably and in good faith to agree on a new Supply Transfer Price that is fair and reasonable to both Parties; *provided*, that, in such circumstance, until the Parties mutually agree on a new Supply Transfer Price, then: (a) the existing Supply Transfer Price will continue to apply, and (b) the Parties will submit the determination of such a new Supply Transfer Price to Expedited Arbitration under Section 14.3.4.

8.5.6 *Other Amounts Payable.* With respect to any amounts owed under this Agreement by one Party to the other for which no other invoicing and payment procedure is specified herein, within [***] after the end of each Kaken Fiscal Quarter, each Party will provide an invoice, together with reasonable supporting documentation, to the other Party for such amounts owed in respect of such Kaken Fiscal Quarter. The owing Party will pay any undisputed amounts within [***] of receipt of the invoice, and any disputed amounts owed by a Party will be paid within [***] of resolution of the dispute.

8.6 Payment Terms.

8.6.1 *Manner of Payment.* All payments to be made by Kaken hereunder will be made in Dollars or Yen, as the same has been specified in the applicable provision of this Agreement, by wire transfer to such bank account as CymaBay may designate.

8.6.2 *Reports and Back-Up Royalty Payments*. All amounts payable to CymaBay pursuant toSection 8.4.3, if applicable, will be paid in JPY within [***] after the end of each Kaken Fiscal Quarter. Each such payment of royalties due to CymaBay will be accompanied by a written report showing in JPY the amount of Net Sales of Licensed Products and the royalty due for such Kaken Fiscal Quarter. The report will include, at a minimum, the following information for the applicable Kaken Fiscal Quarter, each listed by Licensed Product: (a) the number of units of each Licensed Product on which royalties are owed to CymaBay hereunder sold either by Kaken or its Related Parties, (b) the gross amount received for such sales, (c) Net Sales (including all permitted deductions taken or applied), and (d) the royalties owed to CymaBay. All such reports will be treated as Confidential Information of Kaken.

8.6.3 *Reports for CymaBay Royalty Payments*. Kaken acknowledges that CymaBay has a royalty obligation payable to Janssen Pharmaceutica NV ("**Janssen**") pursuant to an in-license agreement dated as of June 6, 2006 (the "**Janssen License Agreement**"). To facilitate CymaBay's calculation of such royalty obligation for sales of Licensed Product by or on behalf of Kaken in the corresponding period, Kaken will provide CymaBay with a written report within [***] of the end of each Kaken Fiscal Quarter in which sales of Licensed Product have been made by or on behalf of Kaken. The report will include the following information (in JPY) for the applicable Kaken Fiscal Quarter: (a) the gross amount invoiced by Kaken and its Related Parties (including any distributors) to Third Party purchasers from the sale or distribution to Third Parties of Licensed Product, [***]. All such reports will be treated as Confidential Information of Kaken but CymaBay will be allowed to share such reports with Janssen in connection with CymaBay's payment of royalties pursuant to the Janssen License Agreement, including subject to its duties to maintain the confidentiality of such information.

8.7 Records and Audits. Kaken will keep, and will cause its Related Parties to keep, complete, true and accurate books and records in accordance with the applicable Accounting Standards in relation to this Agreement, including in relation to Net Sales and royalties and other amounts owed hereunder. Kaken will keep, and will cause its Related Parties to keep, such books and records for at least three (3) years following the Kaken Fiscal Year to which they pertain. CymaBay may, upon written request, cause an internationally recognized independent accounting firm (the "**Auditor**"), which is reasonably acceptable to Kaken, to inspect the relevant records of Kaken and its Affiliates to verify the payments made by Kaken and the related reports, statements and books of accounts, as applicable. Before beginning its audit, the Auditor will execute an undertaking reasonably acceptable to Kaken by which the Auditor agrees to keep confidential all information reviewed during the audit. The Auditor will have the right to disclose to CymaBay only its conclusions regarding any payments owed under this Agreement and the basis for such conclusions (if material to CymaBay). Kaken and its Affiliates will make their records available for inspection by the Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from CymaBay. The records will be reviewed solely to verify the accuracy of Kaken's royalties and other payment obligations and compliance with the financial and reporting terms of this Agreement. Such inspection right will not be exercised more than once in any Kaken Fiscal Year and not more frequently than once with respect to records covering any specific period of time. In addition, CymaBay will only be entitled to audit the books and records of Kaken for the three (3) Kaken Fiscal Years prior to the Kaken Fiscal Year in which the audit request is made. CymaBay agrees to hold in strict confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any Applicable Law or judicial order. The Auditor will provide its audit report and basis for any determination to Kaken at the time such report is provided to CymaBay before it is considered final. If the final result of the inspection reveals an underpayment or overpayment by Kaken, the underpaid or overpaid amount will be settled promptly, with Kaken paying to CymaBay any such underpayment within [***] of the report, and any overpayment being credited against any subsequent payment owed by Kaken. CymaBay will pay for such inspections, as well as its expenses associated with enforcing its rights with respect to any payments hereunder, except, if an underpayment of more than [***] of the total payments due hereunder for the applicable year is discovered, then the fees and expenses charged by the Auditor will be paid by Kaken.

8.8 Taxes.

8.8.1 Kaken may withhold from payments due to CymaBay amounts for payment of any withholding tax that is required by Applicable Law to be paid to any taxing authority on behalf of CymaBay with respect to such payments. Kaken will provide CymaBay all relevant documents and correspondence, and will also provide to CymaBay any other cooperation or assistance on a reasonable basis as may be necessary to enable CymaBay to claim exemption from such withholding taxes and/or to receive a refund of such withholding tax or claim a foreign tax credit. Kaken will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include (a) Kaken making payments from a single source in the U.S., where possible and necessary for enabling CymaBay to claim deductions, (b) CymaBay confirming that it is entitled to exemption from withholding tax on the royalties under this Agreement under the U.S.-Japan income tax convention, (c) if it is entitled to that exemption, CymaBay preparing and submitting to Kaken the applicable application form for the above income tax convention and any other attachment thereto so that Kaken for the benefit of CymaBay will file them with the relevant taxation office in Japan prior to the payment from Kaken to CymaBay pursuant to this Agreement, (d) Kaken making such filing in a timely manner, and (e) if such withholding tax is payable, Kaken filing the application for certification of tax payment that is duly prepared and submitted to Kaken by CymaBay with the relevant taxation office in Japan in a timely manner.

8.8.2 Apart from any taxes withheld by Kaken pursuant to the provisions ofSection 8.8.1 and those deductions expressly included in the definition of Net Sales, the amounts payable hereunder will not be reduced on account of any taxes, charges, duties or other levies.

8.9 Blocked Payments. In the event that, by reason of Applicable Law in the Kaken Territory, it becomes impossible or illegal for Kaken to transfer, or have transferred on its behalf, payments owed to CymaBay hereunder, Kaken will promptly notify CymaBay of the conditions preventing such transfer and such payments will be deposited in local currency in the Kaken Territory to the credit of CymaBay in a recognized banking institution designated by CymaBay or, if none is designated by CymaBay within a period of [***], in a recognized banking institution selected by Kaken, as the case may be, and identified in a written notice given to CymaBay pursuant to Section 14.10.

8.10 Interest on Late Payments. If a Party does not receive payment of any sum due to it on or before the due date therefor, interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a rate of [***] (recalculated and compounding as of the end of each Kaken Fiscal Quarter), or the maximum rate allowable by Applicable Law, whichever is less, and any such accrued interest shall be paid to such Party by the owing Party at the time the related payment is made; *provided*, *however*, that [***].

8.11 Mutual Convenience. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts owed to CymaBay.

ARTICLE 9

CONFIDENTIALITY AND PUBLICATION

9.1 Nondisclosure and Non-Use Obligations.

9.1.1 During the Term and for a period of five (5) years thereafter, all Confidential Information disclosed by one Party to the other Party under this Agreement will be maintained in confidence by the receiving Party (and its Affiliates) and will not be disclosed to a Third Party or used for any purpose except pursuant to the licenses granted under this Agreement as otherwise set forth herein, without the prior written consent of the disclosing Party, except that the foregoing obligations shall not apply to particular Confidential Information that the receiving Party can demonstrate:

(a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by the receiving Party's business records;

(b) is known to the public before its receipt from the disclosing Party, or thereafter becomes generally known to the public through no breach of this Agreement by the receiving Party;

(c) is subsequently disclosed to the receiving Party by a Third Party who is not known by the receiving Party to be under an obligation of confidentiality to the disclosing Party; or

(d) is developed by the receiving Party independently of and without use of or access to any Confidential Information received from the disclosing Party, as documented by the receiving Party's business records.

For clarity, all information and data relating to the inventions claimed by Patents within the New CymaBay IP and the CymaBay Licensed Technology and the Know-How specific thereto, will be Confidential Information of CymaBay, and all information and data relating to the inventions claimed by Patents within the Kaken Licensed Technology and the Know-How specific thereto, will be Confidential Information of Kaken. Specific aspects or details of Confidential Information will not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is encompassed by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information will not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

The existence and terms and conditions of this Agreement are hereby deemed to be the Confidential Information of each Party.

9.1.2 Notwithstanding the obligations of confidentiality and non-use set forth above in Section 9.1.1, a receiving Party may provide Confidential Information of the other Party, and may disclose the existence and particular terms and conditions of this Agreement, in each case, as may be reasonably required in order to perform its obligations or to exercise its rights under this Agreement, with the foregoing disclosures specifically limited to: (a) Related Parties, and their employees, directors, agents, consultants, or advisors to the extent reasonably needed for the performance of its obligations or exercise of its rights under this Agreement, in each case who are under an obligation of confidentiality with respect to such information that is no less stringent than the terms of this ARTICLE 9; (b) Governmental Authorities or Regulatory Authorities in order to obtain Patents or perform its obligations or exercise its rights under this Agreement, *provided* that such Confidential Information will be disclosed only to the extent reasonably necessary to do so, and where permitted, subject to confidential treatment; (c) those entitled to receive such information, pursuant to a disclosure that is required by Applicable Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity; (d) with respect to the terms and conditions of this Agreement only, any bona fide actual or prospective acquirers, merger partners, underwriters, investors, lenders or other financing sources and any bona fide actual or prospective collaborators, licensors, Sublicensees, licensees or strategic partners and to employees, directors, agents, consultants or advisers of such Third Party, in each case who are under obligations of confidentiality and non-use with respect to such information that are no less stringent than the terms of this ARTICLE 9 (but of duration customary in confidentiality agreements entered into for a similar purpose), or, with respect to recipients who are lawyers or certified accountants, are subject to professional obligations that impose such confidentiality and non-use requirement; and (e) to any Third Party licensor of rights hereunder to the extent a Party is required to do so pursuant to the terms and conditions of an in-license agreement with such Third Party relating to the intellectual property rights sublicensed by such Party hereunder. If a Party is required by Applicable Law to disclose Confidential Information of the other Party that is subject to the confidentiality or non-disclosure provisions of this ARTICLE 9, such Party will promptly inform the other Party of the disclosure that is being sought to provide the other Party an opportunity to challenge, limit, and/or seek a protective or similar order regarding the disclosure. Notwithstanding Section 9.1, Confidential Information that is permitted or required to be disclosed hereunder will remain otherwise subject to the confidentiality and non-use provisions of this ARTICLE 9. If either Party concludes that a copy of this Agreement must be filed with the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States, such Party will, a reasonable time prior to any such filing, provide the other Party with a copy of such agreement showing any provisions hereof as to which the Party proposes to request confidential treatment, will provide the other Party with an opportunity to comment on any such proposed redactions and to suggest additional redactions, and will take such Party's reasonable comments into consideration before filing such agreement and use reasonable efforts to have terms identified by such other Party afforded confidential treatment by the applicable regulatory agency.

9.2 Publication and Publicity.

9.2.1 *Publication*. Except for disclosures permitted pursuant to Sections 9.1 and 9.3.3, if a Party wishes to make a publication or public presentation that (x) contains the Confidential Information of the other Party, or (y) discloses or discusses any results of Development activities under this Agreement in the Kaken Territory, or (z) mentions Kaken or CymaBay with regards to this Agreement or any activities in connection with this Agreement in the Kaken Territory, such Party will deliver to the other Party a copy of the proposed written publication or presentation at least [***] prior to submission for publication or presentation. The other Party will have the right (a) to propose modifications to the publication or presentation for patent reasons or trade secret reasons or to remove Confidential Information of the other Party, and such Party will remove all Confidential Information of the other Party if so requested by the other Party and otherwise will incorporate the other Party's reasonable comments, or (b) to request a reasonable delay in publication or presentation in order to protect patentable information. If the other Party requests a delay, such Party will delay submission or

presentation for a period of [***] (or such shorter period as may be mutually agreed by the Parties) to enable the other Party to file patent applications protecting the other Party's rights in such information. With respect to any proposed publications or disclosures by investigators or academic or non-profit collaborators, such materials will be subject to review under this Section 9.2.1 to the extent that such Party has the right and ability (after using Commercially Reasonable Efforts to obtain such right and ability) to do so. Such Party will not submit or publish any article or other publication to or with any scientific journal or other publisher that requires, as a condition of publication, that such Party agrees to make available to the publisher or Third Parties any Materials that are the subject of the publication.

9.2.2 *Publicity*. Except as permitted in Section 9.1, 9.2.1 or 9.3, the terms and conditions of this Agreement may not be disclosed by either Party, and neither Party will use the name or any other Trademarks of the other Party or the name of its employees in any publicity, news release or other disclosure relating to this Agreement, its subject matter, or the activities of the Parties under the Collaboration without the prior express written permission of the other Party, except (a) as may be required by Applicable Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in any country other than the United States or of any stock exchange or listing entity, *provided* that the Party making such disclosure or use of the name or other Trademarks of the other Party or the name of its employees, gives the other Party reasonable prior notice and otherwise complies with Section 9.1.2, or (b) as expressly permitted by the terms and conditions of this Agreement.

9.3 Press Release.

9.3.1 The Parties will issue the press releases in Schedule 9.3.1 on January 9, 2023, or such other mutually agreed date.

9.3.2 Except as provided in Section 9.2.2 or this Section 9.3, neither Party will issue a press release or public announcement relating to this Agreement without the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed), except that a Party may (a) once a press release or other public statement is approved in writing by both Parties, make subsequent public disclosure of the information contained in such press release or other written statement without the further approval of the other Party, and (b) issue a press release or public announcement as required by Applicable Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity, *provided* that the Party issuing such press release gives reasonable prior notice to the other Party of and the opportunity to comment on the press release or public announcement, and otherwise complies with this ARTICLE 9. In addition, CymaBay may with Kaken's prior written approval, such approval not to be unreasonably withheld, conditioned or delayed, issue a press release regarding the payment or receipt of any milestone payments under this Agreement with respect to any Licensed Products, *provided*, that such press release complies with this Section 9.3.

9.3.3 Notwithstanding anything in this Section 9.3 to the contrary, either Party may issue a press release or make a public disclosure relating to such Party's Development, Manufacturing or Commercialization activities under this Agreement with respect to Licensed Products in such Party's Territory, *provided* that such press release or public disclosure does not disclose Confidential Information of the other Party. Prior to making any such disclosure under this Section 9.3.3 however, the disclosing Party will provide the other Party with a draft of such proposed disclosure within a reasonable time (but at least five (5) Business Days) prior to disclosure for the other Party's review and comment, and the disclosing Party will consider in good faith any timely comments provided by the other Party.

ARTICLE 10

REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Mutual Representations and Warranties. Each Party represents and warrants to the other Party that, as of the Effective Date:

10.1.1 such Party is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation or formation;

10.1.2 such Party has all requisite corporate power and corporate authority to enter into this Agreement and to carry out its obligations under this Agreement;

10.1.3 all requisite corporate action on the part of such Party, its directors and stockholders required by Applicable Law for the authorization, execution and delivery by such Party of this Agreement, and the performance of all obligations of such Party under this Agreement, has been taken;

10.1.4 the execution, delivery and performance of this Agreement, and compliance with the provisions of this Agreement, by such Party do not and will not: (a) violate any provision of Applicable Law or any ruling, writ, injunction, order, permit, judgment or decree of any Governmental Authority, (b) constitute a breach of, or default under (or an event which, with notice or lapse of time or both, would become a default under) or conflict with, or give rise to any right of termination, cancellation or acceleration of, or adversely affect any rights under, any agreement, arrangement or instrument, whether written or oral, by which such Party or any of its assets are bound (including, in the case of CymaBay, the CymaBay Licensed Technology and the Licensed Products), or (c) violate or conflict with any of the provisions of such Party's organizational documents (including any articles or memoranda of organization or association, charter, bylaws or similar documents); and

10.1.5 no consent, approval, authorization or other order of, or filing with, or notice to, any Governmental Authority or other Third Party is required to be obtained or made by such Party in connection with the authorization, execution and delivery by such Party of this Agreement.

10.1.6 this Agreement constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as enforceability may be limited by applicable equitable principles or bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally.

10.2 Additional Representations and Warranties of CymaBay. CymaBay represents and warrants to Kaken that, as of the Effective Date in the Kaken Territory, except as set forth on Schedule 10.2:

10.2.1 CymaBay or one of its Affiliates is the sole and exclusive owner, or has exclusive rights to, the CymaBay Licensed Technology existing as of the Effective Date. All of the CymaBay Licensed Technology is free and clear of any Liens. No Person has alleged in writing to CymaBay or any of its Representatives that any Third Party owns, in whole or in part, any of the CymaBay Licensed Technology, and to the Knowledge of CymaBay, there is no reasonable basis for any such allegation.

10.2.2 None of the issued CymaBay Licensed Patents existing as of the Effective Date has been adjudged invalid, unenforceable or unpatentable by any Governmental Authority of competent jurisdiction, and, to the Knowledge of CymaBay, there is no prior art or other facts regarding the issued CymaBay Licensed Patents existing as of the Effective Date that would cause such CymaBay Licensed Patents to be invalid or unenforceable.

10.2.3 To the Knowledge of CymaBay, (a) the Exploitation of Licensed Products as contemplated in this Agreement and based upon the CymaBay Licensed Technology as it exists on the Effective Date does not infringe any issued Patent or any pending and published Patent application (were its claims to issue in their form as of the Effective Date) of any Person, and (b) Kaken's use of the CymaBay Licensed Technology as contemplated in this Agreement, and exercise of its rights under the CymaBay Licensed Technology to Exploit Licensed Products as contemplated hereunder, does not infringe, misappropriate or otherwise violate the trade secret rights or copyrights of any other Person. No written claim or demand of any Third Party has been made, or to the Knowledge of CymaBay, is threatened, against CymaBay or any of its Affiliates, and to the Knowledge of CymaBay there is no Proceeding, or action, claim (including regarding infringement of Intellectual Property), complaint, demand, suit, proceeding, or arbitration brought by a Third Party, pending, or, to the Knowledge of CymaBay, threatened, as of the Effective Date, against CymaBay or any of its Affiliates, in each case that (x)

involves any of the CymaBay Licensed Technology or Licensed Products existing as of the Effective Date or the Exploitation of the foregoing and (y) (i) challenges any rights of CymaBay or any of its Affiliates in any such CymaBay Licensed Technology or Licensed Products, (ii) alleges that any issued Patent within such CymaBay Licensed Technology is invalid or unenforceable, (iii) alleges that the use of any CymaBay Licensed Technology existing as of the Effective Date infringes any issued Patent of a Third Party or infringes, misappropriates or otherwise violates the Intellectual Property rights of any Person, (iv) challenges the transactions contemplated by this Agreement or (v) asserts that the manufacture, use, sale, offer for sale or importation of Licensed Products or the processes used to make Licensed Products is or was infringing or otherwise violates or violated any Intellectual Property of any Person; *provided*, *however*, that, "Proceeding" for purposes of the representations and warranties of this Section 10.2.3 includes any notice of non-compliance, summons, subpoena, inquiry or investigation by a Governmental Authority, of any nature, whether civil, criminal, regulatory, or otherwise, in law or in equity, but excludes office actions or similar communications issued by any patent office or comparable registration authority in the ordinary course of prosecution of any patent application within the CymaBay Licensed Patents.

10.2.4 To the Knowledge of CymaBay, each of CymaBay and its Affiliates is and has been in compliance in all material respects with all Applicable Law applicable to and in connection with the Exploitation of the CymaBay Licensed Technology and the Licensed Products, except to the extent any non-compliance would not reasonably be expected to have a material adverse effect on the ability of Kaken to Exploit the Licensed Products in the Field of Use in the Kaken Territory in compliance with all Applicable Law. There are no, and there have not been any, issued judicial orders, writs, injunctions, decrees, judgments or stipulations in force against CymaBay or its Affiliates with respect to the CymaBay Licensed Technology or Licensed Products that would reasonably be expected to have a material adverse effect on the ability of Kaken to Exploit the Licensed Products in the Field of Use in the Kaken Territory in compliance with all Applicable Law.

10.2.5 To the Knowledge of CymaBay, no Third Party has infringed, misappropriated or otherwise violated any CymaBay Licensed Technology.

10.2.6 The CymaBay Licensed Patents owned by CymaBay are both Controlled by and prosecuted by CymaBay and, to the Knowledge of CymaBay, the CymaBay Licensed Patents Controlled but not prosecuted by CymaBay have been filed and diligently Prosecuted and Maintained in accordance with all Applicable Law, including disclosure of all prior art to the relevant patent authority to the extent required by Applicable Law, and with all applicable fees due with respect thereto having been paid.

10.2.7 To the Knowledge of CymaBay, the scientific, technical and other information relating to the CymaBay Licensed Technology and Licensed Products disclosed or made available by CymaBay or any of its Representatives to Kaken in writing in the electronic data room has been true and correct in all respects. Any experimental data therein that purports to be the result of work conducted by or on behalf of CymaBay or its Affiliates is based upon actual experimentation conducted by or on behalf of CymaBay or its Affiliates.

10.2.8 Except as set forth on Schedule 10.2.8, no IND has been filed by CymaBay with any Regulatory Authority in the Kaken Territory with respect to the Licensed Products. CymaBay is not currently assisting any Third Party in preparation for or in connection with filing an IND with respect to the Licensed Products in the Kaken Territory.

10.2.9 CymaBay has the unrestricted right to grant to Kaken the license rights under the CymaBay Licensed Technology in the Kaken Territory that are being granted to Kaken under this Agreement upon the terms set forth herein. Neither CymaBay nor any of its Affiliates has granted any license or sublicense to any rights in the CymaBay Licensed Technology in the Kaken Territory to any Third Party that are in conflict with the rights granted to Kaken in this Agreement.

10.2.10 To the Knowledge of CymaBay, Schedule 1.45 sets forth, with the countries, application numbers and application dates indicated, as applicable, all CymaBay Licensed Patents that have issued or that have been applied for and are pending issuance with any Governmental Authority. If it is subsequently discovered that there exists a Patent in CymaBay's Control that is a CymaBay Licensed Patent and is not listed

on Schedule 1.45, then as the sole remedy for such situation, the Parties shall amendSchedule 1.45 to add such CymaBay Licensed Patent to such Schedule. To the Knowledge of CymaBay, there is no information that, in CymaBay's reasonable judgment, would likely render any of the granted CymaBay Licensed Patents invalid or unenforceable and that is not part of the publicly available file history, except to the extent such invalidity or unenforceability would not reasonably be expected to have a material adverse effect on the ability of Kaken to Exploit the Licensed Products in the Field of Use in the Kaken Territory in compliance with all Applicable Law.

10.2.11 CymaBay and its Affiliates have taken reasonable and customary measures to maintain and protect, as applicable, the confidentiality of its or their owned Confidential Information within the CymaBay Licensed Technology. Notwithstanding the foregoing, it is acknowledged and agreed by Kaken that CymaBay and its Affiliates have disclosed Confidential Information to (a) Third Parties under an obligation of confidentiality with respect to such information, (b) Governmental Authorities or Regulatory Authorities in order to obtain Patents or develop or submit Regulatory Filings for products, and (c) the extent required by Applicable Law, including by the rules or regulations of the United States Securities and Exchange Commission or similar regulatory agency in a country other than the United States or of any stock exchange or listing entity.

10.2.12 All employees, consultants, contractors and other persons who have contributed to the design, creation, conception, reduction to practice or invention of any Intellectual Property in the applicable CymaBay Licensed Technology or CymaBay Licensed Patents owned by CymaBay have entered into written agreements with CymaBay assigning to CymaBay all rights relating to such design, conception, reduction to practice, or invention of the applicable CymaBay Licensed Technology.

10.2.13 Schedule 10.2.13 sets forth a true and complete list of all material Contracts to which CymaBay or any of its Affiliates is a party and under which CymaBay or its Affiliates have in-licensed Intellectual Property of a Third Party that comprises CymaBay Licensed Technology or is otherwise material to the Exploitation of the Licensed Products in the Field of Use in the Kaken Territory. Except as described in Schedule 10.2.13, none of such Contracts set forth on Schedule 10.2.13 prevent CymaBay from licensing or sublicensing rights to Kaken or require royalties to be paid in connection with a sublicense. True and correct copies of the Contracts set forth on Schedule 10.2.13 have been provided to Kaken, and such Contracts are in full force and effect and have not been modified or amended. Neither CymaBay or its Affiliates nor, to the Knowledge of CymaBay, the other party to such Contracts is in default with respect to a material obligation under, and none of such parties has claimed or, to the Knowledge of CymaBay with respect to such counterparty's claims against CymaBay or any of its Affiliates, has grounds upon which to claim that the other party is in default with respect to a material obligation under, such Contracts. None of CymaBay and its Affiliates has received any written notice of breach under any of the Contracts listed in Schedule 10.2.13. None of CymaBay and its Affiliates has waived or allowed to lapse any of its material rights under any Contracts listed in Schedule 10.2.13 with respect to Licensed Products, and no such rights have lapsed or otherwise expired or been terminated.

10.2.14 To the Knowledge of CymaBay, there are no Safety Concerns, adverse events or Efficacy Concerns in relation to Clinical Studies of the Licensed Products or issues with any Governmental Authorities in relation to the Regulatory Approval of the Licensed Products for the Initial Indication, other than as has previously been made available as of the Effective Date to Kaken in writing in the electronic data room, that would reasonably be expected to have a material adverse effect on the ability of Kaken or CymaBay to Exploit the Licensed Products in the Field of Use in the Kaken Territory in compliance with all Applicable Law. Without limiting the foregoing, to the Knowledge of CymaBay, CymaBay has made available to Kaken prior to the Effective Date in writing in the electronic data room all material adverse information in its possession with respect to the Safety Concerns, adverse events or Efficacy Concerns in relation to the Development of the Licensed Products or issues with any Governmental Authorities in relation to the Regulatory Approval of the Licensed Products for the Initial Indication.

10.2.15 To the Knowledge of CymaBay, all Clinical Studies and Nonclinical Studies sponsored by CymaBay relating to Licensed Products have been and are being conducted in material compliance with Applicable Law, including GCP requirements, and federal, national, state and local laws, rules, regulations and guidance restricting the use and disclosure of individually identifiable health information. CymaBay has not

received any written notices or other written correspondence from the FDA or any other Governmental Authority performing functions similar to those performed by the FDA with respect to any ongoing Clinical Studies and Nonclinical Studies relating to the Licensed Products requiring the termination, suspension or material modification of such Clinical Studies and Nonclinical Studies.

10.2.16 The inventions Covered by the owned CymaBay Licensed Patents: (1) were not conceived, discovered, developed or otherwise made, in whole or in part, using funds provided by the federal government of the U.S. or any agency thereof or any other Governmental Authority; (2) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e); and (3) are not otherwise subject to the provisions of the Bayh-Dole Act (35 U.S.C. §§ 200-212, as well as any regulations promulgated pursuant thereto, including 37 C.F.R. Part 401).

10.2.17 In connection with the Exploitation of the Licensed Products conducted by CymaBay, CymaBay has maintained as of the Effective Date internal procedures and policies that comply in all material respects with the U.S. Foreign Corrupt Practices Act (15 U.S.C. §§78dd-1, et seq.) and any other applicable anti-bribery or anti-corruption laws (collectively "**Anti-Corruption Laws**") and the Physicians' Payment Sunshine Act.

10.2.18 To the Knowledge of CymaBay, CymaBay has not (a) made an untrue statement of a material fact or fraudulent statement to the FDA or any Governmental Authority with respect to Licensed Products, (b) failed to disclose a material fact required to be disclosed to the FDA or any Governmental Authority with respect to Licensed Products, or (c) committed any other act, made any statement or failed to make any statement, that (in any such case) establishes a reasonable basis for the FDA to invoke its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Policy or for any other state or foreign Governmental Authority to invoke any similar policy with respect to Licensed Products. CymaBay is not the subject of any pending or, to the Knowledge of CymaBay, any threatened investigation by the FDA pursuant to its Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities Final Policy. Neither CymaBay, nor any of its Affiliates has been convicted of any crime or engaged in any conduct which has resulted in or, to the Knowledge of CymaBay, is reasonably likely to result in debarment, exclusion or disqualification by the FDA or any other Governmental Authority. To the Knowledge of CymaBay, none of its collaborators, agents or subcontractors it has used in the Development of the Licensed Products has been convicted of any crime or engaged in any conduct which has resulted in debarment, exclusion or disqualification by the FDA or any other Governmental Authority.

10.2.19 With respect to the Janssen License Agreement, Janssen has provided to CymaBay the technology transfer contemplated by Section 3.4 thereof requested by CymaBay and the transfer of the Materials (as defined therein) contemplated bySection 3.5 thereof, in each case in accordance with the terms of the Janssen License Agreement.

10.3 Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO THE OTHER PARTY WITH RESPECT TO ANY PATENTS, KNOW-HOW, MATERIALS, LICENSED PRODUCT, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT, AND EACH PARTY HEREBY DISCLAIMS ALL SUCH OTHER WARRANTIES AND ALL IMPLIED WARRANTIES OF MERCHANTABILITY, NONINFRINGEMENT, AND FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO ANY AND ALL OF THE FOREGOING. EACH PARTY HEREBY DISCLAIMS ANY REPRESENTATION OR WARRANTY THAT THE DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF ANY LICENSED PRODUCT PURSUANT TO THIS AGREEMENT WILL BE SUCCESSFUL.

10.4 Certain Covenants.

10.4.1 *Compliance*. Each Party and its Related Parties will conduct the Collaboration and the Development and Commercialization of the Licensed Products in accordance with all Applicable Law.

10.4.2 *No Debarment.* Each Party will use reasonable efforts to not use, in any capacity in connection with the Collaboration or the performance of its obligations under this Agreement, any Person that has been debarred pursuant to Section 306 of the FD&C Act, as amended, or that is the subject of a conviction described in such section, or, in the case of Kaken, such equivalent Applicable Law in the Kaken Territory. Each Party agrees to inform the other Party in writing immediately if it or any Person that is performing activities in the Collaboration or under this Agreement, is debarred or is subject to debarment or is the subject of a conviction described in Section 306 of the FD&C Act or, in the case of Kaken, such equivalent Applicable Law in the Kaken Territory, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the notifying Party's knowledge, is threatened, relating to the debarment or conviction of the notifying Party or any Person or entity used in any capacity by such Party or any of its Affiliates in connection with the Collaboration or the performance of its other obligations under this Agreement.

10.4.3 *Conflicting Transactions.* During the Term, CymaBay will not, and will cause its Affiliates not to, enter into any agreement granting a license or other right or interest under the CymaBay Licensed Technology that is inconsistent with this Agreement or that would impair the licenses to Kaken as purported to be granted pursuant to this Agreement. During the Term, Kaken will not, and will cause its Affiliates not to, enter into any agreement granting a license or other right under the Kaken Licensed Technology that is inconsistent with this Agreement or that would impair the licenses or other rights granted to CymaBay by Kaken as purported to be granted pursuant to this Agreement.

10.4.4 *Internal Procedures and Policies*. CymaBay will maintain and enforce in all material respects throughout the Term appropriate internal procedures and policies that comply with the Anti-Corruption Laws and the Physicians' Payment Sunshine Act (and any equivalent Applicable Law in any other country or jurisdiction outside the United States), including: (A) an applicable code of conduct and (B) provisions for monitoring, training and obtaining certifications of compliance from all Third Parties involved with the Exploitation of the Licensed Products. CymaBay shall provide such reasonable assistance and documentation as may be reasonably necessary for Kaken and its Affiliates to comply with the Anti-Corruption Laws, the Physicians' Payment Sunshine Act (and any equivalent Applicable Law in any other country or jurisdiction outside the United States).

10.5 Exclusivity.

10.5.1 Subject to Section 10.5.3, [***].

10.5.2 Subject to Section 10.5.3, [***].

10.5.3 Notwithstanding the terms of Section 10.5.1 and Section 10.5.2, it is agreed that, if Kaken undergoes a Change of Control with an Acquirer that was (either directly or through an Affiliate) Developing, Manufacturing or Commercializing a Competing Product prior to the closing of such Change of Control transaction, and Kaken thereby becomes an Affiliate of such Acquirer, then such Acquirer [***].

10.6 Kaken Right of First Negotiation for Additional Indications in the Kaken Territory. CymaBay hereby grants to Kaken a right of first negotiation during the Term of this Agreement to obtain a license (an "**Additional Indication Japan License**") under the CymaBay Licensed Technology to Develop, Manufacture and Commercialize Licensed Products for use in any particular Additional Indication (or set of Additional Indications) in the Kaken Territory in the event that CymaBay intends to grant an Additional Indication Japan License to any Third Party with respect to one or more particular Additional Indications. Such right is as follows: If CymaBay intends to grant an Additional Indication Japan License to any Third Party with respect to one or more particular Additional Indications, then CymaBay will provide Kaken written notice of such intent (an "**Additional Indication Notice**"), [***]. Kaken will have [***] from its receipt of such a Notice to notify CymaBay in writing either of its desire to commence negotiations or its rejection of such proposal. If Kaken notifies CymaBay of its rejection of such proposal, or if Kaken fails to respond to CymaBay in writing during such [***] period, CymaBay will have no further obligations to Kaken under this Section 10.6 with respect to the Additional Indication Japan License that was the subject of the applicable Additional Indication Notice. If Kaken notifies CymaBay of its desire to commerce negotiations during such [***] period, then: (a)

Kaken will have a right of first negotiation to obtain an Additional Indication Japan License consistent with such Additional Indication Notice, such right continuing for a period of [***] after Kaken's receipt of such Additional Indication Notice from CymaBay (the "**Negotiation Period**"), and (b) the Parties will promptly commence such negotiations and shall reasonably negotiate the terms of the proposed Additional Indication Japan License during such Negotiation Period, and (c) CymaBay will not, and will ensure that its Affiliates will not, during the Negotiation Period engage in negotiations with any Third Party other than Kaken (and Kaken's designee(s) for such negotiations) with respect to the Additional Indication Japan License that is the subject of such Additional Indication Notice from CymaBay. During the Negotiation Period, each Party will negotiate with the other in good faith towards executing a license agreement for such Additional Indication Japan License [***] during the Negotiation Period. It is understood that such license agreement can instead be a written amendment to this Agreement if so mutually agreed by the Parties during the Negotiation Period. Upon the expiration of the Negotiation Period, unless Kaken and CymaBay have executed a license agreement (or an amendment to this Agreement) covering such Additional Indication Japan License, CymaBay will be free to enter into negotiations with any Third Party for such Additional Indication Japan License and enter into any agreement for the same; [***].

ARTICLE 11

INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

11.1 General Indemnification by Kaken. Kaken will indemnify, hold harmless and defend CymaBay, its Related Parties, and their respective directors, officers, employees and agents ("**CymaBay Indemnitees**") from and against any and all liabilities, damages, costs, fees and expenses (including reasonable attorneys' fees and litigation expenses) (collectively, "**Losses**") incurred in connection with Third Party claims, suits or other legal proceedings ("**Claims**") against any CymaBay Indemnitee to the extent arising out of or resulting from: (a) any breach of, or inaccuracy in, any representation or warranty made by Kaken in this Agreement, or any breach or violation of any covenant or agreement of Kaken in, or in the performance of, this Agreement, (b) the [***] by or of Kaken or any of its Related Parties, or any of their respective directors, officers, employees or agents in the performance of Kaken's obligations or exercise of its rights under this Agreement, or (c) the Development or Commercialization or other Exploitation of Licensed Products by or on behalf of Kaken or any of its Related Parties. Kaken will have no obligation to indemnify the CymaBay Indemnitees to the extent that the Losses arise out of or result from any matters for which CymaBay is obligated to indemnify Kaken under Section 11.2.

11.2 General Indemnification by CymaBay. CymaBay will indemnify, hold harmless, and defend Kaken, its Related Parties and their respective directors, officers, employees and agents ("**Kaken Indemnitees**") from and against any and all Losses incurred in connection with Third Party Claims against a Kaken Indemnitee to the extent arising out of or resulting from: (a) any breach of, or inaccuracy in, any representation or warranty made by CymaBay in this Agreement, or any breach or violation by CymaBay of any CymaBay covenant or agreement in this Agreement, (b) the [***] by or of CymaBay or any of its Related Parties, or any of their respective directors, officers, employees or agents in the performance of CymaBay's obligations under this Agreement, or (c) the Development or Commercialization or other Exploitation of Licensed Products by or on behalf of CymaBay or any of its Related Parties. CymaBay will have no obligation to indemnify the Kaken Indemnitees to the extent that the Losses or Claims arise out of or result from any matters for which Kaken is obligated to indemnify CymaBay under Section 11.1. For clarity, any such Third Party Claims against a Kaken Indemnity, and all Losses from such Claims, that arise out of or result from alleged manufacturing defects in License Product due to the Manufacture by CymaBay of Licensed Product supplied to Kaken are excluded from the obligations of CymaBay under this Section 11.2, as the indemnification for such Claims and Losses is addressed in the indemnification provisions of the Supply Agreements.

11.3 Indemnification Procedure. The Party entitled to indemnification under thisARTICLE 11 (an "**Indemnified Party**") will notify the Party potentially responsible for such indemnification (the "**Indemnifying Party**") in writing promptly upon being notified of or having actual knowledge of any claim or claims asserted or threatened against the Indemnified Party which could give rise to a right of indemnification under this Agreement; *provided*, that the failure to give such notice will not relieve the Indemnifying Party of its indemnity

obligation hereunder except to the extent that such failure materially prejudices the Indemnifying Party. If the Indemnifying Party has acknowledged in writing to the Indemnified Party the Indemnifying Party's responsibility for defending a claim, the Indemnifying Party will have the right to defend, at its sole cost and expense, such claim by all appropriate proceedings; *provided*, that the Indemnifying Party may not enter into any compromise or settlement unless (a) such compromise or settlement imposes only a monetary obligation on the Indemnifying Party and includes as an unconditional term thereof, the giving by each claimant or plaintiff to the Indemnified Party of a release from all liability in respect of such claim; or (b) the Indemnified Party consents to such compromise or settlement, which consent will not be unreasonably withheld, conditioned or delayed unless such compromise or settlement involves (i) any admission of legal wrongdoing by the Indemnified Party, (ii) any payment by the Indemnified Party that is not indemnified under this Agreement, or (iii) the imposition of any equitable relief against the Indemnified Party. The Indemnified Party will cooperate with the Indemnifying Party and may participate in, but not control, any defense or settlement of any claim controlled by the Indemnifying Party pursuant to this Section 11.3 and will bear its own costs and expenses with respect to such participation; *provided* that the Indemnifying Party will bear such costs and expenses if counsel for the Indemnifying Party will have reasonably determined that such counsel may not properly represent both the Indemnifying Party and the Indemnified Party. If the Indemnifying Party does not elect to assume control of the defense of a claim or if a good faith and diligent defense, in the Indemnified Party's reasonable opinion, is not being or ceases to be materially conducted by the Indemnifying Party, the Indemnified Party will have the right, at the expense of the Indemnifying Party, upon at least ten (10) Business Days' prior written notice to the Indemnifying Party of its intent to do so, to undertake the defense of such claim for the account of the Indemnifying Party (with counsel reasonably selected by the Indemnified Party and approved by the Indemnifying Party, such approval not to be unreasonably withheld, conditioned or delayed); *provided* that the Indemnified Party will keep the Indemnifying Party apprised of all material developments with respect to such claim. The Indemnified Party may not enter into any compromise or settlement without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld, conditioned or delayed.

11.4 Limitation of Liability. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES ARISING OUT OF THIS AGREEMENT, OR THE EXERCISE OF ITS RIGHTS OR THE PERFORMANCE OF ITS OBLIGATIONS HEREUNDER, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, EXCEPT AS A RESULT OF A BREACH OF ARTICLE 9. NOTHING IN THIS SECTION 11.4 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS ARTICLE 11.

11.5 Insurance. Each Party will obtain and maintain insurance during the Term and for a period of at least two (2) years after the last commercial sale of any Licensed Product for which it is responsible, with a reputable, solvent insurer in an amount appropriate for its business and products of the type that are the subject of this Agreement, and for its obligations under this Agreement. Specifically, each Party will maintain (i) product liability insurance and (ii) clinical trial liability insurance with limits of at least [***] and [***], respectively. Upon request, each Party will provide the other Party with evidence of the existence and maintenance of such insurance coverage.

ARTICLE 12

INTELLECTUAL PROPERTY

12.1 Inventorship.

12.1.1 *Determination of Inventorship*. Inventorship for inventions and discoveries (includingKnow-How) first made during the course of the performance of activities pursuant to the Collaboration will be determined in accordance with United States patent laws for determining inventorship.

12.1.2 *JRA Exception*. Notwithstanding anything to the contrary in this Agreement, each Party will have the right to invoke the America Invents Act Joint Research Agreement exception codified at 35 U.S.C. § 102(c) (the "**JRA Exception**") when exercising its rights under this Agreement, but only with prior written consent of the other Party in its sole discretion. If a Party intends to invoke the JRA Exception, once agreed to by the other Party if required by the preceding sentence, it will notify the other Party and the other Party will cooperate and coordinate its activities with such Party with respect to any filings or other activities in support thereof. The Parties acknowledge and agree that this Agreement is a "joint research agreement" as defined 35 U.S.C. § 100(h).

12.2 Ownership.

12.2.1 *CymaBay*. As between the Parties, CymaBay will own the entire right, title and interest in and to all Know-How (and Patents claiming inventions therein and all other Intellectual Property therein) first developed or conceived solely by CymaBay in the performance of the Collaboration ("**New CymaBay IP**"); for clarity, all Kaken Program IP and the Joint Program IP are not included in New CymaBay IP.

12.2.2 *Kaken.* As between the Parties, Kaken will own the entire right, title and interest in and to [***], (collectively, the "**Kaken Program IP**"); for clarity, all New CymaBay IP and all Joint Program IP, and all PPARd-related Know-How (and Patents claiming inventions therein and all other Intellectual Property therein) developed or conceived by Kaken independent of the Collaboration, are not included in Kaken Program IP.

12.2.3 *Joint Ownership*. The Parties will jointly own all Know-How (and Patents claiming inventions therein and all other Intellectual Property therein) developed or conceived in the performance of the Collaboration that is first developed or conceived jointly by (i) Kaken or any of its Related Parties and (ii) CymaBay or any of its Related Parties (the "**Joint Program IP**"); for clarity, New CymaBay IP and Kaken Program IP are not included in Joint Program IP.

12.3 Covenants in Support of IP Ownership Allocation

12.3.1 Each Party will have an equal and undivided joint ownership interest in and to the Joint Program IP. Each Party will have the right to exercise its ownership in and to such Joint Program IP, including: (a) the right to license and sublicense, and (b) otherwise to exploit, transfer or encumber its ownership interest, in each case without any accounting or obligation to, or consent required from, the other Party, but subject to the licenses under this Agreement and the other terms and conditions of this Agreement. A Party will give reasonable written notice to the other Party of any such license or other exploitation or transfer that is material. At the reasonable written request of a Party, the other Party will in writing grant such consents and confirm that no such accounting is required to effect the foregoing regarding Joint Program IP. Each Party, for itself and on behalf of its Affiliates, licensees and sublicensees, and employees, subcontractors, consultants and agents of any of the foregoing, hereby assigns (and to the extent such assignment can only be made in the future hereby agrees to assign), to the other Party an equal and undivided joint ownership interest in and to all Joint Program IP.

12.3.2 Each Party will provide the other Party (at such other Party's cost and expense) with such additional reasonable cooperation as needed to give effect to the allocation of ownership, as between the Parties, of the New CymaBay IP, Kaken Program IP and Joint Program IP (including with respect to rights of priority), in each case, as contemplated by Section 12.2, including executing and delivering needed further assignments, consents, releases and other commercially reasonable documentation, and providing good faith testimony by affidavit, declaration, deposition, in person or other proper means and otherwise assisting such other Party in support of its efforts to establish, perfect, defend, or enforce its rights in its respective intellectual property.

12.4 Disclosure of Inventions and IP. The Parties will promptly disclose to each other any New CymaBay IP, Kaken Program IP or Joint Program IP developed or conceived during the Term, but no later than [***] after the applicable Party's intellectual property department receives notice of such development or conception.

12.5 Prosecution and Maintenance of Patents.

12.5.1 *Kaken*.

12.5.1.1 *General.* Subject to the remainder of this Section 12.5.1, as between the Parties, Kaken will have sole control of and responsibility for the Prosecution and Maintenance of (and all applicable Patent Costs therefor), in Kaken's name, all Joint Program IP Patents within the Kaken Territory and Kaken Program IP Patents (collectively, the "**Kaken Controlled Patents**"). Kaken will furnish to CymaBay, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and material documents sent to or received from patent counsel in the course of Prosecuting and Maintaining the Kaken Controlled Patents in the CymaBay Territory, and copies of material documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to the Kaken Controlled Patents in the CymaBay Territory, and such other material documents related to the Prosecution and Maintenance of the Kaken Controlled Patents in the CymaBay Territory, in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by CymaBay. Kaken will consider in good faith timely comments and recommendations made by CymaBay in connection with such review.

12.5.1.2 *Kaken Controlled Patents Abandonment.* In the event that Kaken elects not to Prosecute and Maintain (or continue to Prosecute and Maintain, including filing a Patent claiming priority to a Patent prior to its issuance), any Kaken Controlled Patent, Kaken will notify CymaBay at least [***] before any such Kaken Controlled Patent would become abandoned, no longer available or otherwise forfeited, whereupon, at the written request of CymaBay, the Parties will meet to discuss any such decision by Kaken. Subject to, if applicable, the provisions of any in-license agreement of Kaken applicable to such Kaken Controlled Patent, CymaBay will have the right (but not the obligation), at its sole discretion, to assume the Prosecution and Maintenance (and all applicable Patent Costs therefor) of such Kaken Controlled Patent in the name of Kaken (which right will include the right to file additional Patents claiming priority to such Patent). CymaBay will consult reasonably with Kaken on its strategy for the Prosecution and Maintenance of all such assumed Kaken Controlled Patents. CymaBay will furnish to Kaken, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and material documents sent to or received from patent counsel in the course of Prosecuting and Maintaining such assumed Kaken Controlled Patents, and copies of material documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to such assumed Kaken Controlled Patents, and such other material documents related to the Prosecution and Maintenance of such assumed Kaken Controlled Patents, in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by Kaken. CymaBay will consider in good faith timely comments and recommendations made by Kaken in connection with such review. Kaken will sign, or will use Commercially Reasonable Efforts to have signed, all legal documents as are reasonably necessary for CymaBay to assume the Prosecution and Maintenance of such assumed Kaken Controlled Patent.

12.5.2 *CymaBay*.

12.5.2.1 *General.* Subject to remainder of this Section 12.5.2, as between the Parties, CymaBay will have sole control of and responsibility for the Prosecution and Maintenance [***], in CymaBay's name, of all Patents within the New CymaBay IP, all Joint Program IP Patents in the CymaBay Territory, and all other CymaBay Licensed Patents. CymaBay will furnish to Kaken, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and material documents sent to or received from patent counsel in the course of Prosecuting and Maintaining the CymaBay Licensed Patents, and copies of material documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to such foregoing Patents in the Kaken Territory, and such other material documents related to the Prosecution and Maintenance of such foregoing Patents in the Kaken Territory, in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by Kaken. CymaBay will consider in good faith timely comments and recommendations made by Kaken in connection with such review.

12.5.2.2 *CymaBay Licensed Patents Abandonment.* In the event that CymaBay elects not to Prosecute and Maintain (or continue to Prosecute and Maintain, including filing a Patent claiming priority to a Patent prior to its issuance), any CymaBay Licensed Patent, CymaBay will notify Kaken at least [***] before any such CymaBay Licensed Patent would become abandoned, no longer available or otherwise

forfeited, whereupon, at the written request of Kaken, the Parties will meet to discuss any such decision by CymaBay. Subject to, if applicable, the provisions of any in-license agreement of CymaBay applicable to such CymaBay Licensed Patent, Kaken will have the right (but not the obligation), at Kaken's sole discretion, to assume the Prosecution and Maintenance (and all applicable Patent Costs therefor) of such foregoing Patent in the name of CymaBay (which right will include the right to file additional Patents claiming priority to such Patent). Kaken will consult with CymaBay on its strategy for the Prosecution and Maintenance of all such assumed foregoing Patents. Kaken will furnish to CymaBay, via electronic mail or such other method as mutually agreed by the Parties, copies of proposed filings and material documents sent to or received from patent counsel in the course of Prosecuting and Maintaining such assumed foregoing Patents, and copies of material documents filed with or received from the relevant national patent offices or other Governmental Authorities with respect to such assumed foregoing Patents, and such other material documents related to the Prosecution and Maintenance of such assumed foregoing Patents, in sufficient time prior to filing such document or making any payment due thereunder to allow for review and comment by CymaBay. Kaken will consider in good faith timely comments and recommendations made by CymaBay in connection with such review. CymaBay will sign, or will use reasonable efforts to have signed, all legal documents as are reasonably necessary for Kaken to assume the Prosecution and Maintenance of such assumed foregoing Patents. If Kaken, in its sole discretion, elects to assume the Prosecution and Maintenance of such CymaBay Licensed Patent that CymaBay has notified Kaken of its intention to abandon the Prosecution and Maintenance of, such CymaBay Licensed Patent shall remain a CymaBay Licensed Patent, but shall not be Royalty Patent.

12.5.2.3 *Notice of CymaBay Licensed Patent Abandonment after Expiration.* In the event that CymaBay elects not to Prosecute and Maintain (or continue to Prosecute and Maintain, including filing a Patent claiming priority to a Patent prior to its issuance), any CymaBay Licensed Patent after expiration of this Agreement under Section 13.1, CymaBay will notify Kaken at least [***] before any such CymaBay Licensed Patent would become abandoned, no longer available or otherwise forfeited, whereupon, at the written request of Kaken, the Parties will meet to discuss any such decision by CymaBay and the Parties will negotiate in good faith to agree upon any appropriate action in regard to such CymaBay Licensed Patent.

12.5.3 *Patent Miscellaneous*. Each Party hereby agrees: (a) to use Commercially Reasonable Efforts to make its employees, agents and consultants reasonably available to the other Party (or to the other Party's authorized attorneys, agents or representatives), to the extent reasonably necessary to enable such Party to undertake any Prosecution and Maintenance described in this Section 12.5; and (b) to reasonably cooperate in any such Prosecution and Maintenance by the other Party to the extent requested.

12.6 Third Party Infringement and Defense.

12.6.1 *Notices*. Each Party will promptly report in writing to the other Party any Competitive Infringement of which such Party (or any of its Affiliates or Sublicensees) becomes aware, and will provide the other Party with all available material evidence of such Competitive Infringement in such Party's control; *provided*, *however*, that (a) for cases of Competitive Infringement under Section 12.6.2.3, such written notice will be given within [***], and (b) for cases of infringement as described in Section 12.6.2.4, such written notice will be given as specified in Section 12.6.2.4. Without limiting the last sentence of the definition of "Competitive Infringement," a notice under 21 U.S.C. § 355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) (however those sections may be amended) or any equivalent provision under Applicable Law outside of the United States with respect to any Patents that are the subject of this Agreement will be deemed to describe an act of Competitive Infringement, regardless of its content. Subject to the rest of this Section 12.6, the JSC will discuss in good faith strategies for abating such Competitive Infringement of any Licensed Product within each of the Party's respective Territory. For clarity, it is agreed that any discussion between the Parties (including the JSC) under this Section 12.6 shall not require either Party to disclose any information if such disclosure would likely act as a waiver of the attorney-client privilege, protections under the work product doctrine, or any similar privilege.

12.6.2 *Rights to Enforce.*

12.6.2.1 *Competitive (Kaken) Infringement.* As between the Parties, Kaken will have the first right (but not the obligation), at Kaken's sole discretion, through counsel of its choosing reasonably acceptable to CymaBay (solely if Kaken is enforcing a CymaBay Licensed Patent), to seek to abate any Competitive (Kaken) Infringement by enforcing any CymaBay Licensed Patents or any Kaken Controlled Patents, in each case, solely in the Kaken Territory. Kaken will pay all Patent Costs incurred by Kaken for such enforcement. If Kaken does not take steps to abate such Competitive (Kaken) Infringement, within [***] of becoming aware, or receiving written notice from CymaBay, of such Competitive (Kaken) Infringement (or such shorter period of time as is required to comply with Applicable Law to not waive any statutory rights), Kaken will provide CymaBay with written notice of such decision, and CymaBay will have the rights set forth in Section 12.6.5.1 with respect to enforcing the CymaBay Licensed Patents and the Kaken Controlled Patents in the Kaken Territory to abate such Competitive (Kaken) Infringement.

12.6.2.2 *Competitive (CymaBay) Infringement.* As between the Parties, CymaBay will have the first right (but not the obligation), at CymaBay's sole discretion, through counsel of its choosing reasonably acceptable to Kaken (solely if CymaBay is enforcing a Kaken Controlled Patent), to seek to abate any Competitive (CymaBay) Infringement by, as applicable, (a) enforcing any Patents within the New CymaBay IP that are not also CymaBay Licensed Patents anywhere in the world and (b) enforcing any Kaken Controlled Patent or any CymaBay Licensed Patents solely in the CymaBay Territory. CymaBay will pay all Patent Costs incurred by CymaBay for such enforcement. If CymaBay does not take steps to abate such Competitive (CymaBay) Infringement, within [***] of becoming aware, or receiving written notice from Kaken, of such Competitive (CymaBay) Infringement (or such shorter period of time as is required to comply with Applicable Law to not waive any statutory rights), CymaBay will provide Kaken with written notice of such decision, and Kaken will have the rights set forth in Section 12.6.5.1 with respect to enforcing the Kaken Controlled Patents in the CymaBay Territory (but not, for clarity, the right to enforce any CymaBay Licensed Patents) to abate such Competitive (CymaBay) Infringement in the CymaBay Territory.

12.6.2.3 *35 U.S.C. § 271(e)(2) Infringement.* Notwithstanding anything to the contrary in this Section 12.6.2, for a Competitive Infringement under 35 U.S.C. § 271(e)(2), the time period set forth in Section 12.6.2.1 or 12.6.2.2, as applicable, during which a Party will have the initial right to bring a Proceeding will be shortened to [***], so that, to the extent the other Party has the right, pursuant to such Section 12.6.2.1 or 12.6.2.2, as applicable, to initiate a Proceeding, if the first Party does not initiate a Proceeding, then such other Party will have such right if the first Party does not initiate a Proceeding within such twenty-five (25) days after such first Party's receipt of written notice of such Competitive Infringement.

12.6.2.4 *Notification of Patent Certification.* If either Party becomes aware of any allegations of alleged patent invalidity, unenforceability or non-infringement of any Patent licensed under this Agreement Covering a Licensed Product (including methods of use thereof) pursuant to a Paragraph IV Patent Certification by a Third Party filing an Abbreviated New Drug Application, or other similar patent certification by a Third Party, and any foreign equivalent thereof, for a Generic Product, such Party will notify and provide the other Party with copies of such allegations. Such notification and copies will be provided to such other Party as soon as practicable and at least within [***] after such Party receives such certification, and will be sent by overnight courier to the address set forth in Section 14.10.

12.6.3 *Defense of Patent Challenges.* As between the Parties, the Party controlling the Prosecution and Maintenance of any Patent under Section 12.5 will have the right (but not the obligation), at its sole discretion, to defend against a declaratory judgment action or other action (such as a revocation proceeding or an opposition) challenging any such Patent (a "**Third Party Action**"), other than with respect to (a) any counter-claims in any enforcement action brought by the other Party pursuant to Section 12.6.2 or (b) any action by a Third Party in response to an enforcement action brought by the other Party, which in both cases ((a) and (b)) will be controlled by such other Party. If the Party controlling such Prosecution and Maintenance of Patents under Section 12.5 does not provide notice to the other Party of such Party's intent to defend such Patent under this Section 12.6.3 within [***] (or such shorter period of time as is required to not waive any statutory rights), or elects not to initiate or continue any such defense (in which case it will promptly provide notice thereof to the other Party), then (i) in the case of any of the foregoing done by CymaBay with respect to any Patent under this Agreement for which CymaBay is responsible for the Prosecution and Maintenance thereof at such time in

the Kaken Territory, Kaken will have the right (but not the obligation), at its sole discretion, to defend any CymaBay Licensed Patent against any such Third Party Action in the Kaken Territory, and (ii) in the case of any of the foregoing done by Kaken with respect to any Patent under this Agreement for which Kaken is responsible for the Prosecution and Maintenance thereof at such time in the CymaBay Territory, CymaBay will have the right (but not the obligation), at its sole discretion, to defend any Kaken Controlled Patent against any such Third Party Action in the CymaBay Territory, in each case of (i) and (ii), as further set forth in Section 12.6.5.

12.6.4 *Cooperation Regarding Enforcement or Defense.* With respect to any Competitive Infringement action brought by a Party under Section 12.6.2 or defense of any Third Party Action identified above in Section 12.6.3, and subject to the terms and conditions of this Section 12.6.4, the Party controlling any such Competitive Infringement action or Third Party Action (the "**Controlling Party**") will keep the other Party (the "**Non-Controlling Party**") reasonably informed of the status and progress of such enforcement or defense efforts, and will reasonably consider the Non-Controlling Party's comments on any such efforts, and will reasonably seek to achieve both the interests of such Party and those of the other Party in any such efforts. The Non-Controlling Party will provide the Controlling Party with all reasonable assistance in the enforcement or defense of the applicable Patents, as the Controlling Party may request, at such Controlling Party's expense, including by signing or executing any necessary documents and consenting to it being named a party to any applicable Proceedings. Where the Non-Controlling Party is named a party or joins any applicable Proceeding, the Non-Controlling Party will have the right to be represented by counsel of its choice at the Non-Controlling Party's expense.

12.6.5 *Withdrawal, Cooperation and Participation*. With respect to any Competitive Infringement action or Third-Party Action identified above in Sections 12.6.2 and 12.6.3 and subject to the terms and conditions of this Section 12.6.5:

12.6.5.1 If the Controlling Party does not pursue or ceases to pursue or withdraws from such action (the "**Withdrawing Party**"), it will promptly notify the other Party (in sufficient time to enable such other Party to meet any deadlines by which any action must be taken to preserve any rights in such infringement or defensive action) and (a) if CymaBay is the Withdrawing Party, then Kaken will have the right (but not the obligation) to substitute itself for CymaBay in any Competitive Infringement action or Third Party Action identified above in Section 12.6.2.2 or 12.6.3 solely to the extent involving the Kaken Controlled Patents in the CymaBay Territory and proceed under the terms and conditions of this Section 12.6.5, and (b) if Kaken is the Withdrawing Party, then CymaBay will have the right (but not the obligation) to substitute itself for Kaken in any Competitive Infringement action identified above in Section 12.6.2.1 or 12.6.3 solely to the extent involving or relating to the CymaBay Licensed Patents or the Program IP Patents in the Kaken Territory, and proceed under the terms and conditions of this Section 12.6.5 (Kaken or CymaBay, as applicable, under (a) or (b), the "**New-Controlling Party**").

12.6.5.2 The Withdrawing Party will cooperate with the New-Controlling Party controlling any such action (as may be reasonably requested by the New-Controlling Party), including, at the New-Controlling Party's sole cost and expense, (a) providing access to relevant documents and other evidence, (b) using reasonable efforts to make its Affiliates and its and its Affiliates' licensees and Sublicensees and all of their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (c) if reasonably necessary, by being joined as a party, subject to, for this clause (c), the New-Controlling Party agreeing to indemnify such Withdrawing Party for its involvement as a named party in such action and paying those Patent Costs incurred by such Withdrawing Party in connection with such joinder. The New-Controlling Party controlling any such action will keep the Withdrawing Party reasonably updated with respect to any such action, including providing copies of all materials documents received or filed in connection with any such action.

12.6.5.3 The Withdrawing Party will have the right to consult with the New-Controlling Party regarding any such action controlled by such New-Controlling Party, in each case at such Withdrawing Party's sole cost and expense. If the Withdrawing Party elects to so be involved, the New-Controlling Party will provide such Withdrawing Party and its counsel with an opportunity to consult with the

New-Controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any material correspondence, legal papers or other documents related thereto), and the New-Controlling Party will take into account reasonable and timely requests and comments of the Withdrawing Party regarding such enforcement or defense. However, nothing in this Section 12.6.5.3 will limit the New-Controlling Party's ability to prosecute any such action.

12.6.6 *Settlement.* With respect to any Competitive Infringement or Third Party Action identified above in thisSection 12.6, the Controlling Party of such action will have the right to settle or otherwise dispose of such action on such terms and conditions as such Party will determine in its sole discretion, including by granting a license or sublicense (such sublicense must comply with the terms of Section 7.1.4, as applicable) to a Third Party under the rights granted to such Party in ARTICLE 7; *provided* that, notwithstanding the foregoing, no such settlement or other disposition will (a) impose any monetary restriction or obligation on or admit fault of the other Party, or (b) adversely affect the other Party's rights under this Agreement to any such Patent then being enforced or defended, in each case ((a) and (b)) without the prior written consent of the other Party, not to be unreasonably withheld, conditioned or delayed.

12.6.7 *Allocation of Recovery.* Unless otherwise agreed by the Parties, all monies and amounts recovered upon the final judgment or settlement of any action described in this Section 12.6 will be used first to reimburse the Controlling Party for its Patent Costs incurred in conducting the action, with the balance of any such recovery (the "**Net Recovery**") to be retained or divided as follows:

[***]

12.7 Patent Extensions. With respect to any election for patent term restoration or extension, supplemental protection certificate or any of their equivalents, (a) Kaken will have the sole and exclusive right to make any such decision relating to any Kaken Controlled Patents that are not Joint Program IP Patents, (b) CymaBay will have the sole and exclusive right to make any such decision relating to any Patents within the CymaBay Licensed Technology that are not Joint Program IP Patents, and (c) Kaken and CymaBay together will make such decision relating to any Joint Program IP Patents, in each case of (a), (b) and (c) with respect to any Licensed Product, *provided* that notwithstanding the foregoing clauses (a) and (b), each Party will use reasonable efforts to obtain any such patent term restoration or extension, supplemental protection certificate or any of their equivalents available for the Patents subject to the enforcement rights specified in Section 12.6.2 with respect to any Licensed Product; and further *provided, however*, that no Party will be required to use any such reasonable efforts in a manner inconsistent with any term or condition of this Section 12.7 if any such item could impair the applicable Patent (including its enforcement potential) or the ability to obtain any such patent term restoration or extension, supplemental protection certificate or any of their equivalents for any other pharmaceutical product. Upon the written request by a Party, the other Party will reasonably cooperate with the implementation of such requesting Party's decisions made in a manner consistent with this Section 12.7.

12.8 Patent Listings. With respect to any filings of Patents made with Regulatory Authorities for any Licensed Product, including as required or allowed in connection with, in the United States, the FDA's Orange Book, or, outside of the United States, other international equivalents, but subject to Section 12.6.2.3, (a) each of the Parties will list any such Patents as may be required by Applicable Law with respect to any such filings for Licensed Products made with Regulatory Authorities in their respective Territory, and (b) otherwise (i) Kaken will have the sole and exclusive right to make any such decision whether to list any Kaken Program IP Patents and Joint Program IP Patents with respect to any Licensed Product in filings made with Regulatory Authorities in the Kaken Territory, and (ii) CymaBay will have the sole and exclusive right to make any such decision whether to list any Joint Program IP Patents and any CymaBay Licensed Patents that are not Joint Program IP Patents with respect to any Licensed Product in filings made with Regulatory Authorities in the CymaBay Territory, *provided* that notwithstanding the foregoing clauses (b)(i) and (ii), each Party will use Commercially Reasonable Efforts to make any such listing if available for the Patents subject to the enforcement rights specified in Section 12.6.2 with respect to any Licensed Product; and further *provided, however*, that no Party will be required to use any such Commercially Reasonable Efforts in a manner inconsistent with any term or condition of this Section 12.8 if any such item could impair the applicable Patent (including its enforcement potential) or the ability to list such Patent for any other pharmaceutical product. Upon the request by a Party, such other Party will reasonably cooperate in the implementation of such requesting Party's decisions made in a manner consistent with this Section 12.8.

12.9 Third Party Rights. Notwithstanding the foregoing provisions of this ARTICLE 12, each Party's rights and obligations with respect to any Patent under this ARTICLE 12 will be subject to any Third-Party rights and obligations that such Party is subject to (including under anyin-license of a Party applicable to such Party's licensed intellectual property rights hereunder).

12.10 Common Interest. All information exchanged between the Parties regarding the Prosecution and Maintenance, and enforcement and defense, of Patents under this ARTICLE 12 will be deemed Confidential Information of the disclosing Party. In addition, the Parties acknowledge and agree that, with regard to such Prosecution and Maintenance, and enforcement and defense, the interests of the Parties as collaborators and licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The Parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Patents under this ARTICLE 12, including privilege under the common interest doctrine and similar or related doctrines. Notwithstanding anything to the contrary contained herein, to the extent a Party has a good faith belief that any information required to be disclosed by such Party to the other Party under this ARTICLE 12 is protected by attorney-client privilege or any other applicable legal privilege or immunity, such Party will not be required to disclose such information, and the Parties will in good faith cooperate to agree upon a procedure (including entering into a specific common interest agreement, disclosing such information on a "for counsel eyes only" basis or similar procedure) under which such information may be disclosed without waiving or breaching such privilege or immunity.

12.11 Trademarks.

12.11.1 *Licensed Products Trademarks.* Kaken will have the right to determine the branding for the Licensed Product in the Field of Use in the Kaken Territory using those trademarks, logos, and trade names that it determines appropriate for such Licensed Product. In consultation with the JSC, Kaken shall determine the Trademark for the Commercialization of the Licensed Products in the Field of Use in the Kaken Territory (the "**Japanese Trademark**"). The Japanese Trademark may not include other Trademarks Controlled by CymaBay. As between the Parties, Kaken will own all right, title, and interest (including all applications for registration and registrations) in and to the Japanese Trademark. Kaken shall be responsible for the registration, maintenance and defense of the Japanese Trademark for use in connection with the sale or marketing of Licensed Products in the Field of Use in the Kaken Territory, and the fees and expenses incurred in connection therewith for the Japanese Trademark applicable to Licensed Products in the Kaken Territory shall be the responsibility of Kaken. Kaken will own also all rights to any Internet domain names incorporating the Japanese Trademark or any variation or part thereof used as its URL address or any part of such address.

12.11.2 *Trademark Infringement*. In the event either Party becomes aware of any infringement of the Japanese Trademark, by a Third Party, such Party will promptly notify the other Party, and the Parties will consult with each other and discuss the best way to prevent such infringement, including by the institution of legal proceedings against such Third Party. Notwithstanding the foregoing, Kaken retains the sole and exclusive right (but not obligation) to seek to abate any such infringement.

12.11.3 *No Other Trademark Rights.* For the avoidance of doubt, except as expressly permitted by this Agreement or as otherwise agreed in writing by the Parties, neither Party will have any right to use the other Party's or the other Party's Affiliates' Trademarks, corporate names or logos in connection with Development, Manufacturing, or Commercialization of Licensed Products.

12.12 Third Party Claims of Infringement.

12.12.1 *Notice*. In the event that a Party receives any claim by a Third Party alleging infringement and/or misappropriation of Patent or any other Intellectual Property owned or controlled by such Third Party (each, an "**Infringement Claim**") that is provided in Section 12.12.2 or 12.12.3, such Party shall promptly, but in any event no later than [***] after receipt thereof, notify the other Party in writing.

12.12.2 *Claims Based on Exploitation in Kaken Territory.* If a Third Party brings any Infringement Claim in the Kaken Territory against Kaken, or its Related Party, or CymaBay or its Affiliate, based upon any activities by Kaken or its Related Party in Exploiting Licensed Product in the Kaken Territory, then Kaken shall have the sole right and responsibility (except as otherwise provided below), at its expense, to conduct and control the defense of such claim or action. Kaken shall keep CymaBay fully informed of such defense, and will provide CymaBay and its counsel with an opportunity to consult with Kaken and its counsel regarding the defense of such claim or action (including reviewing the contents of any material correspondence, legal papers or other documents related thereto), and Kaken will take into account reasonable and timely requests and comments of CymaBay regarding such defense. However, if CymaBay (or its Affiliate) is a defendant in any such Third-Party claim or action, CymaBay shall retain the right to conduct its own defense of its interests as affected by such action or claim, notwithstanding anything else in this Section. If Kaken pays to such Third Party that brought the Infringement Claim any damages or royalty payments as a result of the final judgment or settlement of any such Infringement Claim under this Section 12.12.2, [***].

12.12.3 *Claims Based on CymaBay Manufacturing*. If a Third Party brings any Infringement Claim (a) against CymaBay or its Affiliate, or against Kaken or its Related Party, and (b) such claim or action is based primarily upon any activities by CymaBay or its contract manufacturer in the manufacture of Licensed Compound and/or the Licensed Product by or on behalf of CymaBay for supply to Kaken for use and sale in the Kaken Territory, then CymaBay shall have the sole right and responsibility (except as otherwise provided below), at its expense, to conduct and control the defense of such claim or action. CymaBay shall keep Kaken reasonably informed of such defense, and will provide Kaken and its counsel with an opportunity to consult with CymaBay and its counsel regarding the defense of such claim or action to the extent relevant to Kaken or its rights hereunder (including reviewing the contents of any material and relevant correspondence, legal papers or other documents related thereto), and CymaBay will take into account reasonable and timely requests and comments of Kaken regarding such defense. If Kaken (or its Affiliate) is a defendant in any such Third-Party claim or action, Kaken shall retain the right to conduct its own defense of its interests as affected by such action or claim. If CymaBay concludes an in-license agreement under any Intellectual Properties owned or controlled by Third Party to resolve an Infringement Claim under this Section 12.12.3, then CymaBay shall use Commercially Reasonable Efforts to secure the right to grant a sublicense under such Intellectual Properties to Kaken to manufacture the Licensed Compound and Licensed Products for supply, use and Commercialization in the Field of Use in the Kaken Territory, and any payments under such in-license agreement shall be CymaBay's responsibility. Section 7.3.1.2 shall apply *mutatis mutandis* to in-license agreements that CymaBay concludes with a Third Party under this Section 12.12.3.

ARTICLE 13

TERM AND TERMINATION

13.1 Term. This Agreement will be effective as of the Effective Date and will continue until the date upon which (a) the Royalty Term has expired in the Kaken Territory for the final Licensed Product, in which case the Agreement will expire if not renewed, or (b) the Agreement is earlier terminated (the "**Initial Term**"). After the Initial Term (except in the case of early termination), this Agreement will be automatically renewed for two (2) year periods, unless either Party has given the other Party a written notice not to renew the Agreement no later than twelve (12) months prior to the expiration of the Initial Term or any subsequent renewal term, in which case the Agreement shall expire (and thus terminate) at the end of the then-existing term or, if applicable, shall earlier terminate upon an early termination (with the time period from the Effective Date to (i) the end of the later of (x) the Initial Term and (y) any subsequent renewal term, or (ii) if applicable, the date of an earlier termination of the Agreement, being the "**Term**"). Upon expiration of the Royalty Term for a Licensed Product in the Kaken Territory or upon expiration of this Agreement, all licenses granted from one Party to the other Party in ARTICLE 7 with respect to such Licensed Product will become fully paid (subject to any continuing Kaken payment obligations as set forth in the Agreement or the Commercial Supply Agreement, including Kaken's continuing obligation to pay for the supply of Licensed Product to Kaken as provided in Section 8.4), irrevocable and perpetual.

13.2 Termination by Kaken for Convenience. Kaken may terminate this Agreement upon prior written notice to CymaBay, provided such notice is given at least [***] prior to the date of termination if the date of termination is prior to achieving the first Regulatory Approval of the first Licensed Product in the Kaken Territory, and [***] prior to the date of termination if the date of termination is after achieving the first Regulatory Approval of the first Licensed Product in the Kaken Territory. Such termination may be for any reason or no reason.

13.3 Termination by Kaken due to Termination of Janssen License Agreement. Kaken may terminate this Agreement immediately upon termination of the Janssen License Agreement by providing written notice thereof to CymaBay.

13.4 Termination by Kaken for Safety Concern or Clinical Failure. At any time, Kaken will have the right to terminate this Agreement in its entirety in the event of (a) a Safety Concern or (b) a Clinical Failure, in each case of (a) or (b), upon [***] prior written notice to CymaBay, *provided* that, during such [***] period, Kaken will consult with CymaBay in respect of measures to overcome the Safety Concern or Clinical Failure, as applicable, and avoid termination of this Agreement.

13.5 Termination for Material Breach.

13.5.1 *Material Breach.*

13.5.1.1 Subject to Section 13.5.2, CymaBay will have the right to terminate this Agreement in its entirety upon delivery of written notice to Kaken in the event of any material breach by Kaken of this Agreement, *provided* that such termination will not be effective if such breach has been cured within thirty (30) days after written notice thereof is given by CymaBay to Kaken specifying the nature of the alleged breach (or, if such default cannot be cured within such thirty (30) day period, within ninety (90) days after such notice if Kaken commences actions to cure such default within such thirty (30) day period and thereafter diligently continues such actions, but fails to cure the default by the end of such ninety (90) days); *provided, however*, that if such material breach involves the failure to make a payment when due, such breach must be cured within [***] after written notice thereof is given by CymaBay to Kaken.

13.5.1.2 Subject to Section 13.5.2, and to Kaken's election of the alternative remedy under Section 13.8, Kaken will have the right to terminate this Agreement in its entirety upon delivery of written notice to CymaBay in the event of any material breach by CymaBay of this Agreement, *provided* that such termination will not be effective if such breach has been cured within thirty (30) days after written notice thereof is given by Kaken to CymaBay specifying the nature of the alleged breach (or, if such default cannot be cured within such thirty (30) day period, within ninety (90) days after such notice if CymaBay commences actions to cure such default within such thirty (30) day period and thereafter diligently continues such actions, but fails to cure the default by the end of such ninety (90) days); *provided, however*, that to the extent such material breach involves the failure to make a payment when due, such breach must be cured within [***] after written notice thereof is given by Kaken to CymaBay.

13.5.2 *Disputed Breach*. If the alleged breaching Party disputes in good faith (a) the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section 13.5.1, or (b) the lack of cure of such breach, and such alleged breaching Party provides the other Party notice of such dispute prior to the end of the applicable cure period above, then the non-breaching Party will not have the right to terminate this Agreement under Section 13.5.1 unless and until the dispute resolution process set forth in Section 14.3 has been completed (including the tolling and cure periods set forth therein) and such completed resolution process has determined that the asserted material breach did occur and has not been cured.

13.6 Termination for Bankruptcy. If, at any time during the Term (a) a case is commenced by or against either Party under Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States (the "**Bankruptcy Code**") and, in the event of an involuntary case under the Bankruptcy Code, such case is not dismissed within sixty (60) days after the commencement thereof, (b) either Party files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (c) either Party assigns all or a substantial portion of its assets for the benefit of creditors, (d) a receiver or custodian is appointed for either Party's business, or (e) a substantial portion of either Party's business is subject to attachment or similar process; then, in any such case ((a), (b), (c), (d) or (e)), the other Party may terminate this Agreement upon written notice to the extent permitted under Applicable Law.

13.7 Patent Challenge. A Party has the right to terminate this Agreement upon written notice to the other Party in the event that the other Party or any of its Affiliates or Sublicensees directly or indirectly challenges in a legal or administrative proceeding the patentability, enforceability or validity of any Patents within the CymaBay Licensed Technology (with respect to a challenge brought by Kaken), any Patents within the Kaken Licensed Technology (with respect to a challenge brought by CymaBay), or any Joint Program IP Patents (with respect to a challenge brought by either Party), as the case may be (each, a "**Patent Challenge**"); *provided* that (a) with respect to any Third Party that becomes an Affiliate of a Party during the Term as a result of a Change of Control of such Party or acquisition by such Party, this Section 13.7 will not apply to any Patent Challenge involving such Third Party if such proceeding was initiated before the signing of the definitive document(s) whereby such Third Party becomes such an Affiliate, and (b) with respect to any non-Affiliate Sublicensee, a Party will not have the right to terminate this Agreement under this Section 13.7 if the other Party (i) causes such Patent Challenge to be terminated or dismissed (or in the case of *ex-parte* proceedings, multi-party proceedings, or other Patent Challenges in which the challenging party does not have the power to unilaterally cause the Patent Challenge to be withdrawn, causes such Sublicensee to withdraw as a party from such Patent Challenge and to cease actively assisting any other party to such Patent Challenge), or (ii) terminates such Sublicensee's sublicense to the Patents being challenged by the Sublicensee, in each case, [***] of the terminating Party's notice to the other Party under this Section 13.7.

13.8 Kaken Alternative Remedy for Intentional or Willful CymaBay Breach or Janssen Agreement Termination If (a) CymaBay materially breaches this Agreement and such breach is intentional or willful, and CymaBay does not cure such breach in accordance with Section 13.5.2, or (b) the Janssen License Agreement is terminated, [***]:

13.8.1 Upon such election, this Agreement will remain in full force and effect, including each Party retaining all of its licenses and other rights granted under this Agreement, subject to all of its payment and other obligations hereunder; [***]; and

13.8.2 [***]; and

13.8.3 Kaken may (if it so elects) terminate CymaBay's participation in the JSC, *provided that* after any such termination, Kaken would provide to CymaBay written reporting, every six (6) months, summarizing the progress and results of its and its Related Parties' Development and Commercialization activities for Licensed Product in the Kaken Territory, such reporting in reasonable detail.

If Kaken exercises its alternative remedy under this Section 13.8, then the above alternate remedy will be the sole monetary remedy available to Kaken for the uncured material breach by CymaBay, but Kaken will retain the right to seek any applicable equitable remedies for such breach. For the avoidance of doubt, if Kaken exercises the alternative remedy set forth above in this Section 13.8, then all rights and obligations of both Parties under this Agreement will continue unaffected, *except* as otherwise set forth in this Section 13.8, and unless and until this Agreement is subsequently terminated by either Party pursuant to this ARTICLE 13.

13.9 General Consequences of Termination or Expiration. Upon expiration or early termination of this Agreement, the following shall apply (in addition to any other applicable rights and obligations under this ARTICLE 13 or otherwise under this Agreement with respect to such termination or expiration):

13.9.1 *Winding Down of Activities.* If there are any on-going Development or Commercialization activities at termination or expiration of this Agreement, the Parties shall negotiate in good faith and adopt a plan to wind-down such activities in an orderly fashion or, at the continuing Party's election, promptly transition such activities from the non-continuing Party to the continuing Party or its designee, with due regard for patient safety and the rights of any subjects that are participants in any Clinical Studies of the Licensed Products, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all Applicable Law. Further, unless this Agreement is terminated pursuant to Section 13.3, Kaken will conduct all reasonable actions, as reasonably requested by CymaBay, to ensure the smooth and prompt transition to CymaBay of the entire Licensed Product program in Japan.

13.9.2 *Return of Confidential Information.* Except to the extent that the applicable Party retains a license or other rights to use the applicable information under the surviving terms of this Agreement, each Party will promptly return all records and materials in its possession or control containing or comprising the other Party's Confidential Information. Each Party shall have the right to maintain one copy of such records in its files for archive purposes; any such copy shall be maintained by the retaining Party in accordance with the surviving confidentiality and non-use obligations of this Agreement.

13.9.3 *Dissolution of Committees.* All Committees will be dissolved as of the effective date of such termination or expiration, provided that, for any surviving terms or conditions of the Agreement that would require action or decision by any of the Committees or an Executive Officer, each Party will appoint representatives to act as its Committee members or Executive Officer, as applicable, solely to effect such required action or decision.

13.9.4 *Right of Reference.* Any Right of Reference granted by one Party to the other Party in Section 5.4 will terminate, except to the extent such other Party has a reasonable need for such Right of Reference to exercise its rights under the surviving terms of this Agreement;

13.9.5 *Termination of Rights and Obligations.* Except as otherwise set forth in this Section 13.9 or in Sections 13.10 or 13.12, all rights and obligations of the Parties under this Agreement will terminate as of the effective date of such termination or expiration.

13.10 Rights Arising on Early Termination. In the event this Agreement is early terminated by either Party pursuant to Sections 13.2, 13.3, 13.4, 13.5, 13.6 or 13.7, then:

13.10.1 *Termination/Survival of License Rights.* Except for license rights that expressly survive the expiration or termination (pursuant to applicable survival provisions hereunder), any and all license rights granted by one Party to the other Party under this Agreement will terminate, provided that such licenses will continue solely as necessary for the Parties to complete the orderly wind-down of their activities under this Agreement in accordance with Applicable Law and as otherwise required in accordance this Agreement;

13.10.2 *Kaken Regulatory Materials.* To the extent permitted by Applicable Law, Kaken shall transfer to CymaBay copies of and its entire right, title and interest in all Regulatory Materials in the Kaken Territory, but subject to Section 13.11 if such termination is by Kaken under Section 13.5 for CymaBay's uncured material breach;

13.10.3 *Japanese Trademark.* If CymaBay so requests, Kaken shall assign to CymaBay all right title and interest in and to any Japanese Trademark and any other trademarks used exclusively with Licensed Products in the Kaken Territory (excluding any such trademarks that include, in whole or in part, any corporate name or logo of Kaken or its Affiliates or Sublicensees), but subject to Section 13.11 if such termination is by Kaken under Section 13.5 for CymaBay's uncured material breach;

13.10.4 *Third Party Agreements.* If CymaBay so requests, and to the extent permitted under Kaken's or such Affiliate's obligations to such Third-Party counterparties, Kaken will transfer and assign to CymaBay any Third-Party agreements relating to the Development, Manufacture or Commercialization of the Licensed Products to which Kaken or any of its Affiliates is a party, subject to any required consents of such Third Party (if such consent is required, Kaken shall use good faith, reasonable efforts to obtain such needed consents);

13.10.5 *Product Inventory.* If CymaBay so requests, Kaken will transfer to CymaBay any inventory of the Licensed Products owned by Kaken or its Affiliates as of the effective date of termination at the actual price paid by Kaken for such supply;

13.10.6 *Grant Back License.* Kaken will grant, and is deemed automatically to grant upon such termination, to CymaBay, with immediate effect from the effective date of the termination, a non-exclusive, fully paid up, royalty-free sublicensable (through multiple tiers) license under the Kaken Program IP solely for the Exploitation of Licensed Compounds and Licensed Products worldwide. At CymaBay's written request promptly after such termination, Kaken will use reasonable efforts to disclose to CymaBay promptly thereafter all applicable Kaken Program IP (reports, data, documents, etc.) that are included in the reversion license grant under this Section.

13.11 Certain Compensation for Rights After Termination by Kaken for Breach. In the event this Agreement is early terminated by Kaken pursuant to Section 13.5 for uncured material breach by CymaBay, then in consideration of the rights granted or documents transferred by Kaken pursuant to Sections 13.10.2 or 13.10.3, CymaBay shall pay to Kaken [***], but solely to the extent that CymaBay or its Affiliate or licensee actually used or practiced the rights or documents granted or transferred by Kaken under such Sections in connection with Developing or Commercializing such Licensed Product in Japan.

13.12 Remedies Survive Termination. Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Termination or expiration of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect, any rights, remedies or claims, whether for damages or otherwise, that a Party may have hereunder based on the other Party's performance under this Agreement prior to such termination or expiration.

13.13 Effect of Expiration or Termination; Survival

13.13.1 Expiration or termination of this Agreement for any reason will not preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity, with respect to any breach of this Agreement occurring prior to such expiration or termination. For the avoidance of doubt, termination of this Agreement will not affect any SDEA, which will continue to survive so long as any Licensed Products thereunder are being Commercialized.

13.13.2 Subject to the expiration and termination consequences set forth inSections 13.1, 13.9 and 13.10 (and any Sections or Articles referenced therein), the following provisions will survive expiration or termination of this Agreement for any reason: ARTICLE 1 (to the extent the applicable defined terms therein are used in the Articles or Sections that survive hereunder), ARTICLE 9, ARTICLE 11 and ARTICLE 14, and Sections 4.7, 5.4 (to the extent the applicable Party retains the applicable right of reference under the surviving terms of this Agreement),5.5 (as applicable with respect to Licensed Product sold or otherwise commercially transferred during the Term), 7.1.3 (solely after expiration of the Term), 7.3.1.2 (solely after expiration of the Term), 7.7, 8.4.2, 8.5.4 (as to supply after the Term), 8.6 through 8.10 (with respect to all payment obligations that accrue during the Term, and payment obligations that accrue pursuant to Section 8.4.2 after the Term, [***], 10.3, 12.1, 12.2, 12.3, 12.4, 12.5.2.3, 12.9, 12.10, 12.12 (to the extent the applicable Infringement Claims arise from actions during the Term), 13.1, 13.9, 13.10, 13.11, 13.12 and 13.13.

ARTICLE 14

MISCELLANEOUS

14.1 Assignment.

14.1.1 *General*. Except as provided in this Section 14.1.1 or Section 14.1.2, this Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by either Party without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed. Notwithstanding anything in this Section 14.1.1 to the contrary, each Party may, without the other Party's prior written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to an Affiliate or to a party that acquires, by or otherwise in connection with, a merger, sale of assets, reorganization or other similar transaction, all or substantially all of the assets of the Party relating to its pharmaceutical business. Any permitted successor or assignee of any rights or obligation under this Agreement must expressly assume the performance thereof in a writing delivered to the non-assigning Party; provided that the assigning Party shall provide notice of such permitted assignment to the non-assigning Party promptly following the occurrence thereof. Notwithstanding any permitted assignment, the assigning Party, in the case of an assignment to the Party's Affiliate, will remain responsible for the performance by such Affiliate assignee of any obligation hereunder so assigned. Any purported assignment in violation of this Section 14.1.1 will be void.

14.1.2 *Securitization*. Notwithstanding anything to the contrary in Section 14.1.1 or elsewhere in this Agreement, CymaBay may assign to a Third Party its right to receive any of the milestone payments or royalty payments owed to CymaBay under ARTICLE 8 (such assignment, a "**Securitization Transaction**") without the prior written consent of Kaken. Further, in connection with a contemplated Securitization Transaction, CymaBay may disclose to such Third Party the Confidential Information of Kaken (including the royalty reports contemplated under Section 8.6.2), without the prior written consent of Kaken, to the extent reasonably necessary to enable such Third Party to evaluate the Securitization Transaction opportunity (*provided* that such Third Party is under obligations of confidentiality and non-use with respect to such Confidential Information that are no less stringent than the terms of Section 9.1), and to allow such Third Party to exercise its rights under this Section 14.1.2. As part of any consummated Securitization Transaction, CymaBay may assign, without the prior written consent of Kaken, its right to receive the royalty reports and to conduct audits under Section 8.7 to the counterparty in such Securitization Transaction, and to allow such counterparty to exercise its rights under such Sections.

14.2 Governing Law. The Agreement will be construed, and the respective rights of the Parties determined, in accordance with the substantive laws of the State of New York, United States, notwithstanding any provisions of New York law or any other Applicable Law governing conflicts of laws to the contrary.

14.3 Dispute Resolution; Arbitration.

14.3.1 *Disputes*. Except as otherwise expressly set forth in this Agreement, including Section 2.3.1, any dispute of any nature between the Parties arising under, relating to, or in connection with this Agreement (a "**Dispute**") will be resolved pursuant to this Section 14.3.

14.3.2 *Dispute Escalation*. In the event of a Dispute, the Parties will first attempt to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within [***] from receipt by a Party of written notice of such Dispute from the other Party, any Party may, by written notice to the other, have such Dispute referred to the Executive Officers (or their designee, which designee is required to have decision-making authority on behalf of such Party), who will attempt to resolve such Dispute by good faith, reasonable negotiation and consultation for a [***] period following receipt of such written notice of referral.

14.3.3 *Full Arbitration*. Except as otherwise expressly set forth in this Agreement, in the event the Parties have not resolved such Dispute within [***] of receipt of the written notice referring such Dispute to the Executive Officers, either Party may at any time after the end of such [***] period submit such Dispute to be finally settled by arbitration administered in accordance with the procedural rules of the International Chamber of Commerce (the "**ICC**") in effect at the time of submission, as such rules are modified by this Section 14.3. The arbitration will be governed by the laws of the State of New York. The arbitration will be heard and determined by three (3) arbitrators who are retired judges or attorneys, each of whom will be impartial and independent of each Party and its Affiliates. Each Party will appoint one (1) arbitrator and the third (3rd) arbitrator will be selected by the two (2) Party-appointed arbitrators, or, failing agreement within [***] following appointment of the second (2nd) arbitrator, by the ICC; each such appointed arbitrator must meet

the criteria set forth above for arbitrators. Such arbitration will take place in Honolulu, HI, United States. The arbitration award so given will, absent manifest error, be a final and binding determination of the Dispute, will be fully enforceable in any court of competent jurisdiction, and will not include any damages expressly prohibited by Section 11.4. Fees, costs and expenses of arbitration are to be divided by the Parties in the following manner: Kaken will pay for the arbitrator it chooses, CymaBay will pay for the arbitrator it chooses, and the Parties will share payment for the third (3rd) arbitrator. Except in a proceeding to enforce the results of the arbitration or as otherwise required by Applicable Law, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties.

14.3.4 *Expedited Arbitration.*

14.3.4.1 If, as to a Dispute that is subject to ICC arbitration under the terms of Section 14.3.3, a Party exercises its right under this Agreement to refer such dispute to arbitration and in such referral such Party elects expedited arbitration (an "**Expedited Dispute**"), then the Parties will follow the expedited dispute resolution process in this Section 14.3.4 (and not the dispute resolution process in Section 14.3.3 of this Agreement) ("**Expedited Arbitration**"). The Parties agree and acknowledge that any good faith dispute under Expedited Arbitration will not be deemed to be a material breach of this Agreement.

14.3.4.2 The Expedited Dispute will be submitted to fast-track, binding arbitration in accordance with the following:

(a) Arbitration will be conducted in Honolulu, HI, United States, under the rules of the ICC for the resolution of commercial disputes in the most expedited manner permitted by such rules. The Parties will appoint a single arbitrator to be selected by mutual agreement. If the Parties are unable to agree on an arbitrator, the Parties will request that the ICC select the arbitrator. The arbitrator will be a professional in business or licensing experienced in the valuation of biopharmaceutical products with at least ten (10) years of experience in the pharmaceutical and life sciences industries, including the conduct of development and commercialization collaborations. The cost of the arbitration will be borne equally by the Parties. Except in a proceeding to enforce the results of the arbitration or as otherwise required by Applicable Law, neither Kaken nor CymaBay nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written agreement of Kaken and CymaBay.

(b) Within thirty (30) days after such matter is referred to arbitration, each Party will provide the arbitrator with a proposal and written memorandum in support of its position regarding the Expedited Dispute, as well as any documentary evidence it wishes to provide in support thereof (each a "**Brief**") and the arbitrator will provide each Party's Brief to the other Party after it receives it from both Parties. The Parties agree and acknowledge that the Harmonization Principle will serve as a guiding principle for each Party's Brief and for the arbitrator's determination.

(c) [***] after a Party submits its Brief, the other Party will have the right to respond thereto. The response and any material in support thereof will be provided to the arbitrator and the other Party.

(d) The arbitrator will have the right to meet with the Parties as necessary to inform the arbitrator's determination and to perform independent research and analysis. Within thirty (30) days of the receipt by the arbitrator of both Parties' responses (or expiration of the thirty (30) day period if any Party fails to submit a response), the arbitrator will deliver his/her decision regarding the Expedited Dispute in writing; *provided* that the arbitrator will select one of the resolutions proposed by the Parties.

14.3.5 *Injunctive Relief.* Notwithstanding the dispute resolution procedures set forth in this Section 14.3, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief), without first submitting to any dispute resolution procedures under this ARTICLE 14. Any claim for such equitable relief shall be submitted to the United States District Court for the Southern District of New York or any New York State court sitting in New York City so long as one of such courts has subject matter jurisdiction

over such claim, and each Party hereby irrevocably consents to the exclusive jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any proceeding with respect to any such equitable claim and irrevocably waives, to the fullest extent permitted by Applicable Law, any objection that it may now or hereafter have to the laying of the venue of any such proceeding in any such court or that any such proceeding brought in any such court has been brought in an inconvenient forum. Process in any such proceeding may be served on either Party anywhere in the world, whether within or without the jurisdiction of any such court. Without limiting the foregoing, each Party agrees that service of process on such Party in accordance with Section 14.10 shall be deemed effective service of process on such Party with respect to any such equitable claim and proceeding under this Section 14.3.5. Each of the Parties hereby irrevocably waives any and all right to trial by jury in any such equitable proceeding.

14.3.6 *Tolling*. The Parties agree that, with respect to any particular Dispute, all applicable statutes of limitation and time-based defenses (such as estoppel and laches), as well as all time periods in which a Party must exercise rights with hereunder with respect to such Dispute, will be tolled once the dispute resolution procedures set forth in this Section 14.3 have been initiated as to such Dispute and for so long as they are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such results. In addition, during the pendency of any such dispute resolution procedures for a Dispute under this Agreement initiated before the end of any applicable cure period, including under Section 13.5, (a) this Agreement will remain in full force and effect, (b) the provisions of this Agreement relating to termination for material breach with respect to such Dispute will not be effective, (c) the time periods for cure under Section 13.5 as to any termination notice given prior to the initiation of arbitration will be tolled, (d) any time periods to exercise rights or perform obligations will be tolled, and (e) neither Party will issue a notice of termination pursuant to this Agreement based on the subject matter of the arbitration, until in each case the arbitral tribunal has confirmed that the alleged material breach did occur, based on the existence of the facts claimed by a Party to be the basis for the asserted material breach, and was not cured; *provided*, that if such breach can be cured (i) by the payment of money, the defaulting Party will have an additional ten (10) days within its receipt of the arbitral tribunal's decision to pay such amount, or (ii) by the taking of specific remedial actions, the defaulting Party will have a reasonably necessary period to diligently undertake and complete such remedial actions within such period (not in any event to exceed ninety (90) days after the date of the decision), such period as established by such arbitral tribunal's decision, before any such notice of termination can be issued. Further, with respect to any time periods that have run during the pendency of the dispute, the applicable Party will have a reasonable period of time or any specific timeframe established by such arbitral tribunal's decision to exercise any rights or perform any obligations affected by the running of such time periods.

14.4 Entire Agreement; Amendments. This Agreement, together with any applicable supply agreement (and related quality agreements) between the Parties, and SDEA, contains the entire understanding of the Parties with respect to the subject matter hereof, and supersedes all previous arrangements with respect to the subject matter hereof, whether written or oral, including, effective as of the Effective Date, the Mutual Non-Disclosure Agreement between CymaBay and Kaken, dated as of February 24, 2022 (provided that all information disclosed or exchanged under such agreement will be treated as Confidential Information disclosed by the applicable Party hereunder). This Agreement (including all its Schedules) may be amended, or any term or condition hereof modified, only by a written instrument duly executed by authorized representatives of both Parties. Any term or condition of this Agreement may be waived if, but only if, such waiver is in writing and signed by an authorized representative of the Party against whom the waiver is to be effective. The Schedules attached hereto are part of the Agreement.

14.5 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any respect in any jurisdiction, the Parties will substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions, which valid provisions in their economic effect are sufficiently similar to the invalid, illegal or unenforceable provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such valid provisions. In case such valid provisions cannot be agreed upon, the invalid, illegal or unenforceable nature of one or several provisions of this Agreement will not affect the validity of this Agreement as a whole, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal or unenforceable provisions.

14.6 Headings. The captions to the Articles and Sections hereof are not a part of this Agreement but are merely for convenience to assist in locating and reading the several Articles and Sections hereof.

14.7 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

14.8 Interpretation. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa); (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation" and will not be interpreted to limit the provision to which it relates; (c) the word "shall" will be construed to have the same meaning and effect as the word "will"; (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (e) any reference herein to any Person will be construed to include the Person's successors and assigns; (f) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof; (g) all references herein to Articles, Sections or Schedules will be construed to refer to Articles, Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto and any capitalized terms used but not defined in any Schedules shall have their respective meanings as defined in this Agreement; (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement; (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging); (j) references to any specific law or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law thereof; and (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or".

14.9 No Implied Waivers; Rights Cumulative. No failure on the part of CymaBay or Kaken to exercise, and no delay in exercising, any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

14.10 Notices. All notices that are required or permitted hereunder will be in writing and sufficient if delivered personally, sent by nationally recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to CymaBay, to:	CymaBay Therapeutics, Inc. 7575 Gateway Blvd., Suite 110 Newark, CA 94560, USA Attention: General Counsel
With a copy to (which will not constitute notice):	Cooley LLP 3175 Hanover St. Palo Alto, CA 94304, USA Attention: Barclay James Kamb

If to Kaken, to:	Kaken Pharmaceutical Co., Ltd. 20th Floor, Bunkyo Green Court 28-8, Honkomagome 2-chome, Bunkyo-ku Tokyo 113-8650, Japan Attention: Head of Business Development
With a copy to (which will not constitute notice):	Jones Day The Okura Prestige Tower 2-10-4 Toranomon, Minato-ku Tokyo 105-0001, Japan Attention: Benjamin Lang

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) when delivered if personally delivered on a Business Day (or if delivered or sent on a non-Business Day, then on the next Business Day); (b) on the Business Day of receipt if sent by overnight courier; or (c) on the Business Day of receipt if sent by mail.

14.11 Compliance with Export Regulations. Neither Party will export any technology licensed to it by the other Party under this Agreement except in compliance with U.S. export laws and regulations.

14.12 Force Majeure. Neither Party will be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any particular obligation under this Agreement to the extent that such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, earthquakes, floods, or other acts of God, *provided that* such affected Party (a) provides written notice to the other Party of such force majeure circumstances as soon as reasonably practical, and (b) promptly undertakes all reasonable efforts necessary to cure or avoid the effects of such force majeure circumstances, resumes performance of the applicable obligations hereunder as soon as practicable after such force majeure effects cease or can be avoided, and continues in full its performance of all its other obligations hereunder. If such a force majeure event occurs and causes failure or delay in performance by a Party of a material obligation of such Party under this Agreement, then the other Party may terminate this Agreement on written notice if such obligation is not performed within one hundred eighty (180) days of the start of such event, except as otherwise agreed by the Parties in writing.

14.13 Independent Parties. It is expressly agreed that CymaBay and Kaken will be independent contractors and that the relationship between CymaBay and Kaken will not constitute a partnership, joint venture or agency. CymaBay will not have the authority to make any statements, representations or commitments of any kind, or to take any action, that will be binding on Kaken, without the prior written consent of Kaken, and Kaken will not have the authority to make any statements, representations or commitments of any kind, or to take any action, that will be binding on CymaBay, without the prior written consent of CymaBay.

14.14 Expenses. Except as otherwise provided herein, all fees, costs and expenses (including any legal, accounting and banking fees) incurred in connection with the preparation, negotiation, execution and delivery of this Agreement and to consummate the transactions contemplated hereby will be paid by the Party incurring such fees, costs and expenses.

14.15 Counterparts/Execution. The Agreement may be executed in two or more counterparts, including by facsimile or PDF signature pages, each of which will be deemed an original, but all of which together will constitute one and the same instrument. This Agreement may also be executed using any electronic signature complying with the U.S. federal ESIGN Act of 2000 (such as DocuSign), the Uniform Electronic Transactions Act or other Applicable Law.

14.16 Binding Effect; No Third-Party Beneficiaries. As of the Effective Date, this Agreement will be binding upon and inure to the benefit of the Parties and their respective permitted successors and permitted assigns. Except as expressly set forth in this Agreement, no Person other than the Parties and their respective Affiliates and permitted assignees hereunder will be deemed an intended beneficiary hereunder or have any right to enforce any obligation of this Agreement.

14.17 Further Assurances. The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken in furtherance of their respective obligations under this Agreement, including (a) furnishing to each other such further information; (b) executing and delivering to each other such other documents; and (c) doing such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

[THE REMAINDER OF THIS PAGE HAS BEEN LEFT INTENTIONALLY BLANK]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

CymaBay Therapeutics, Inc.

By: /s/ Sujal Shah
Name: Sujal Shah
Title: CEO

Kaken Pharmaceutical Co., Ltd.

By: /s/ Hiroyuki Horiuchi
Name: Hiroyuki Horiuchi
Title: President and Representative Director

[Signature Page to the Collaboration and License Agreement]

List of Schedules

Schedule 1.33	Kaken's Existing Pharmaceutical Products
Schedule 1.45	CymaBay's Licensed Patents
Schedule 1.157	Seladelpar
Schedule 3.4.1	Global Development Plan
Schedule 6.2.1	Form of Clinical Supply Agreement
Schedule 9.3.1	Press Release
Schedule 10.2	Disclosure Schedule
Schedule 10.2.8	INDs filed in Japan
Schedule 10.2.13	Material Contracts

Exhibit 21.1

List of Subsidiaries

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

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

(1) Registration Statement (Form S-3 No. 333-239670) 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, 333-229953, 333-254697 and 333-263644) pertaining to the Metabolex, Inc. 2003 Equity Incentive Plan, the CymaBay Therapeutics, Inc. 2013 Equity Incentive Plan, and the CymaBay Therapeutics, Inc. 2020 New Hire Plan;

of our report dated March 23, 2023, 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, 2022.

/s/ Ernst & Young LLP

San Mateo, California
March 23, 2023

Exhibit 31.1

CERTIFICATIONS

I, Sujal Shah, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 23, 2023

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

Exhibit 31.2

CERTIFICATIONS

I, Daniel Menold, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 23, 2023

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

Exhibit 32.1

CERTIFICATION

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

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2022, to which this Certification is attached as Exhibit 32.1 (the "Annual Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In **Witness Whereof**, the undersigned have set their hands hereto as of the 23rd day of March, 2023.

/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.