Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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

Commission File Number: 001-38080

Biohaven Pharmaceutical Holding Company Ltd.

(Exact Name of Registrant as Specified in its Charter)

British Virgin Islands	**Not applicable**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

c/o Biohaven Pharmaceuticals, Inc.
215 Church Street , New Haven , Connecticut **06510**
(Address of principal executive offices) (Zip Code)

(203) 404-0410
(Registrant's telephone number, including area code)

N/A
(Former address)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Shares, without par value	BHVN	New York Stock Exchange

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 Exchange 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Small reporting company	☐
		Emerging growth company	☐

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

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

The aggregate market value of the registrant's common shares held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2019, based on the last reported sale price of the registrant's common stock on the New York Stock Exchange on June 28, 2019 of $43.79, was $1.882 billion. The calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose. As of February 21, 2020, there were 58,282,598 common shares, no par value per share, outstanding.

Documents Incorporated by Reference

Portions of the registrant's definitive Proxy Statement to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934 for its 2020 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

Cautionary Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, or this report, contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “could”, “would”, “target”, “goal”, “intends”, “plans”, “anticipates, “believes”, “estimates”, “predicts”, “potential”, “continue”, or the negative of these terms or other comparable terminology. Forward-looking statements are not guarantees of performance and are based on certain assumptions, discuss future expectations, describe plans and strategies or state other forward-looking information. These forward-looking statements include, but are not limited to, statements about:

- timing of and potential for U.S. Food and Drug Administration ("FDA") approval of, and our plans to develop and commercialize, our product candidates, including rimegepant and BHV-0223;
- our ongoing and planned clinical trials for our rimegepant, troriluzole, BHV-0223, vazegepant, BHV-5000 and verdiperstat development programs and the potential effectiveness of such product candidates;
- the timing of the availability of data from our clinical trials;
- the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the clinical utility of our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position; and
- our estimates regarding future revenues, expenses and needs for additional financing;.

Any forward-looking statements in this report reflect our current views with respect to future events and with respect to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part I, Item 1A. Risk Factors, Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations, and elsewhere in this report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward- looking statements for any reason, even if new information becomes available in the future.

This report contains estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, not prove to have been accurate.

TABLE OF CONTENTS

PART I

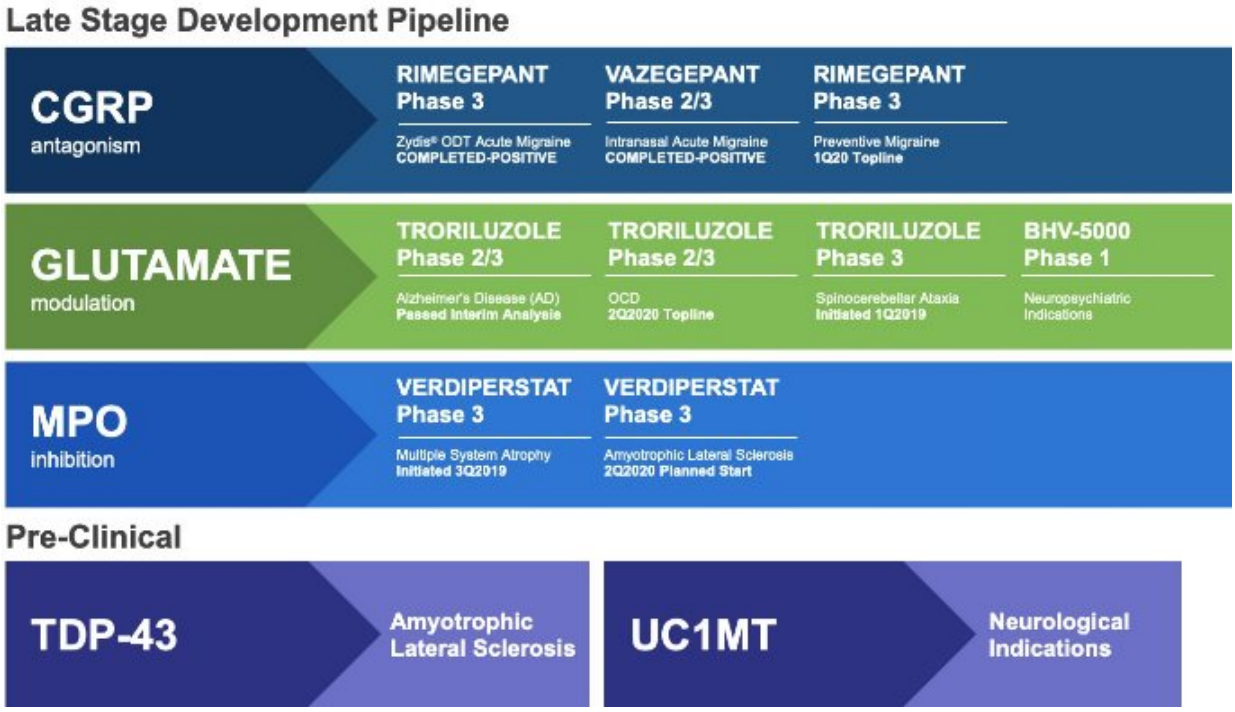
Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company with a portfolio of innovative, late-stage product candidates targeting central nervous system diseases, including neurological and rare disorders. Most of our product candidates are small molecules and based on three distinct mechanistic platforms—calcitonin gene-related peptide ("CGRP") receptor antagonists, glutamate modulators, and a myeloperoxidase inhibitor—which we believe have the potential to significantly alter existing treatment approaches across a diverse set of indications with high unmet need in both large and orphan indications.

Product Candidates

The following table summarizes our most advanced development programs. We hold the worldwide rights to all of our product candidates.



Our CGRP Receptor Antagonist Platform

Migraine Overview and Market Opportunity

Migraine is a chronic and debilitating disorder characterized by recurrent attacks lasting four to 72 hours with multiple symptoms, including typically one-sided, pulsating headaches of moderate to severe pain intensity that are associated with nausea or vomiting, and/or sensitivity to sound (phonophobia) and sensitivity to light (photophobia). Migraines are often preceded by transient neurological warning symptoms, known as auras, which typically involve visual disturbances such as flashing lights, but may also involve numbness or tingling in parts of the body. Migraine is both widespread and disabling. The Migraine Research Foundation ranks migraine as the world's third most prevalent illness, and the Global Burden of Disease Study 2015 rates migraine as the seventh highest specific cause of disability worldwide. According to the Migraine Research Foundation, in the United States, approximately 40 million individuals suffer from migraine attacks. While most sufferers experience migraine attacks once or twice per month, more than 4 million people have chronic migraine, defined as experiencing at least 15 headache days per month, of which at least eight are migraine, for more than three months. Others have episodic migraine, which is characterized by experiencing less than 15 migraine days per month. People with frequent episodes of migraine may progress to chronic migraine over time. Migraine attacks can last four hours or up to three days. More than 90% of individuals suffering from migraine attacks are unable to work or function normally during a migraine attack, with many experiencing comorbid conditions such as depression, anxiety and insomnia.

Triptans are the current first-line prescription therapy for the acute treatment of migraine, with over 13.9 million annual prescriptions in the United States. Despite the market for triptans being highly genericized, branded options continue to be popular. For example, even at a price of approximately $400-600/month, Maxalt is a commonly prescribed triptan. In addition, early in the first quarter of 2020, both Ubrelvy by Allergan and Reyvow by Eli Lilly and Company released the wholesaler acquisition costs for their respective medications to retailers at $850/month and $640/month, respectively.

Until recently, there has been minimal improvement in the standard treatment for migraine since the early 1990s. Reformulations of generic triptans or incremental improvements with new agents that target the same pathway are predicted to generate additional sales in the near term, but major sales growth for the migraine market are expected from novel therapeutics over the next several years. We believe that rimegepant will be a potential best-in-class small molecule CGRP receptor antagonist for the acute treatment of migraine and could achieve meaningful penetration of the market of migraine sufferers whose symptoms are not adequately addressed with current treatments. It is important to recognize that all migraine patients require acute treatment, including patients who take preventive medicine (as they typically do not eliminate all migraine attacks).

Of the 40 million migraine sufferers in the United States, nearly all require a treatment to address acute migraine attacks, while the migraine prevention market alone is a multi-billion dollar potential market. According to a report published by *Neuropsychiatric Disease and Treatment*, 38% to 50% of diagnosed migraine sufferers may be candidates for migraine prevention therapy. Currently, preventive medications approved for migraine included beta blockers, such as propranolol, topiramate, sodium valproate, and botulinum toxin ("Botox") (chronic migraine only), which generate nearly 10 million prescriptions annually. Three CGRP monoclonal antibodies ("mAbs") were approved in 2018 for the preventive treatment of migraine in adults. There has been rapid early uptake of this class, but utilization will continue to be defined over the first 24 months in the market.

In patients with high frequency and chronic migraine, beta blockers, topiramate and sodium valproate are commonly used to reduce the frequency of migraine. These medications are often not well tolerated by patients because of adverse events ("AEs") such as cognitive impairment, nausea, fatigue and sleep disturbance. In clinical trials with topiramate, the reduction in number of migraine days per month has been observed to be relatively small; for example, migraine days reduced by 2.5 days from six to seven days at baseline, or reduced by 3.5 days from 15 to 16 days at baseline. Migraine is twice as prevalent in women as compared to men. In the affected female patient population, predominantly women of child-bearing age, the association of these agents with poor pregnancy outcomes and fetal abnormalities can limit their use. Botox is only approved for the prevention of migraine in patients diagnosed with chronic migraine. Approximately 47% of Botox-treated patients experience a 50% reduction in either migraine days per month or migraine frequency per month within six months, which leaves more than half of patients inadequately treated. In addition, the Botox dosing regimen consists of approximately 31 subcutaneous injections at various sites on the head and neck, with recommended repetition every 12 weeks if the patient has a therapeutic response.

The CGRP mAbs have a similar profile across the agents approved to date. The three new FDA-approved drugs, Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), and Emgality (galcanezumab-gnlm), are all administered subcutaneously. The side effects from the new CGRP monoclonal antibody drugs are generally mild, including pain and redness at the site of injection, nasal congestion, and constipation. Studies show that the mAbs reduce the number of headache days by 50% or more in approximately half of the patients who take them. In only a small percentage of patients do these drugs eliminate migraine attacks, with the vast majority of patients also needing additional effective acute treatment.

CGRP's Role in Migraine

The CGRP receptor is located within pain-signaling pathways, intracranial arteries and mast cells and its activation is thought to play a causal role in migraine pathophysiology. For example, research and clinical studies have shown serum levels of CGRP are elevated during migraine attacks, infusion of intravenous CGRP produces persistent pain in migraine sufferers and non-migraine sufferers, and treatment with anti-migraine drugs normalizes CGRP activity. Additionally, multiple clinical studies show that small molecule CGRP receptor antagonists, which inhibit the binding of endogenous CGRP to CGRP receptors, are effective in the acute treatment of migraine attacks.

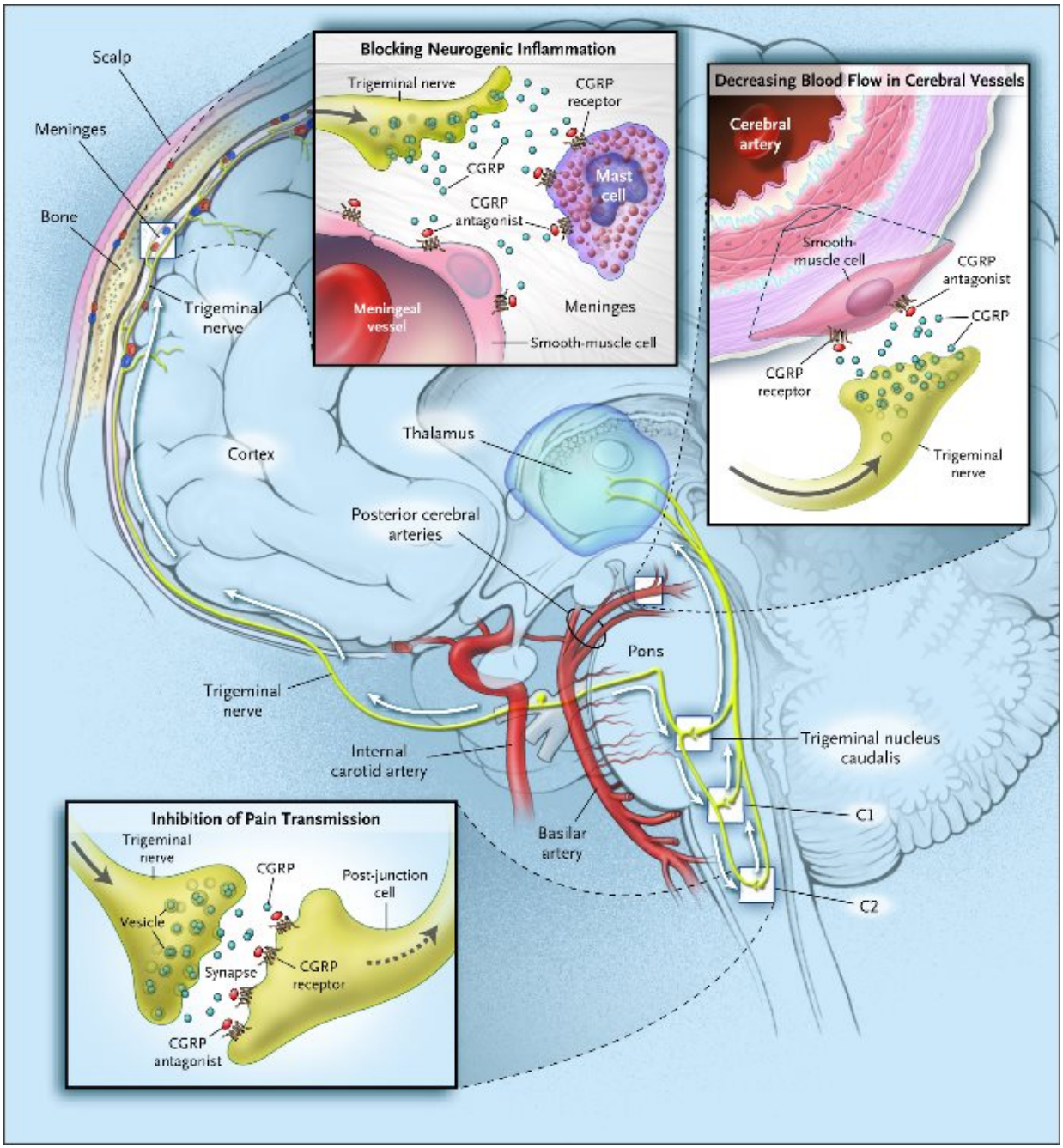
Treatment with a CGRP receptor antagonist is believed to relieve migraine through the following mechanisms:

- **Blocking Neurogenic Inflammation:** Binding of CGRP receptor antagonists to CGRP receptors located on mast cells inhibits inflammation caused by trigeminal nerve release of CGRP onto mast cells within the tough outer covering of the brain, or the meninges.

- **Decreasing Artery Dilation:** By blocking the CGRP receptors located in smooth muscle cells within vessel walls, CGRP receptor antagonists inhibit the pathologic dilation of intracranial arteries without the unwanted effect of active vasoconstriction.

- **Inhibiting Pain Transmission:** Binding of CGRP receptor antagonists to CGRP receptors suppress the transmission of pain by inhibiting the central relay of exaggerated pain signals from the trigeminal nerve to the caudal trigeminal nucleus.

The graphic below depicts the mechanism of action by which CGRP receptor antagonism is thought to alleviate migraine.



From N Engl J Med, Durham PL, CGRP-Receptor Antagonists — A Fresh Approach to Migraine Therapy? 350:1073-1075, Copyright © 2018 Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

Our Lead Product Candidate: Rimegepant, an Oral CGRP Receptor Antagonist for the Acute and Preventive Treatment of Migraine

We are developing rimegepant as an orally available, selective and potent small molecule CGRP receptor antagonist for the acute and preventive treatment of migraine. The first indication being pursued is the acute treatment of migraine. We believe that rimegepant has the potential to be the best-in-class CGRP receptor antagonist for the acute treatment of migraine with the ability to address important unmet needs, such as early onset of pain relief, durable efficacy of pain relief and relief from the most bothersome symptoms ("MBS") and rapid return to normal function (decreased disability). Importantly, these benefits are noted without the cardiovascular contraindications of triptan therapy and/or the bothersome side effects that impact utilization. Additionally, oral small molecule CGRP receptor antagonists with high receptor affinity and long half-lives, such as rimegepant, may possess dual-therapy action with ability to provide both acute relief and preventive effects. We believe that rimegepant is the only oral CGRP receptor antagonist currently being developed for both acute and preventive treatment of migraine.

In July 2017, we initiated two Phase 3 clinical trials of rimegepant, and we completed enrollment in these trials in November 2017. Topline results from both of these Phase 3 trials were reported in March 2018. The co-primary endpoints (pain freedom at 2 hours and reduction of the MBS) were both met as well as key secondary endpoints (return to function, pain relief). These results are described in greater detail below under "—Our Clinical Program for Rimegepant in Acute Treatment of Migraine—Phase 3 Clinical Trials: Studies 301 and 302."

Those suffering from migraine often have accompanying nausea and have an aversion to consuming food or liquids during an attack. We are also developing an oral solid dosage formulation of rimegepant that disperses almost instantly in the mouth, without the need for water. The Zydis® oral dissolving tablet ("ODT") formulation being utilized uniquely addresses this issue. We have exclusive worldwide rights to the Zydis ODT fast-dissolving formulation for the development of rimegepant pursuant to a January 2018 license agreement with Catalent U.K. Swindon Zydis Limited, a subsidiary of Catalent, Inc. ("Catalent"). The agreement also provides exclusivity with respect to other small molecule CGRP receptor antagonists with the Zydis ODT technology. In February 2018, a bioequivalence study was conducted to compare this new ODT formulation to the tablet formulation we are concurrently developing and provided evidence of equivalence. A third Phase 3 clinical trial evaluating the Zydis ODT formulation of rimegepant commenced in February 2018 and the results from this trial were reported in December 2018.

Consistent with the prior Phase 3 studies, the ODT formulation met the co-primary endpoints of pain freedom and freedom from the MBS. Importantly the Zydis ODT formulation had a faster onset of action with rapid onset of pain relief beginning to show an effect as early as 15 minutes and becoming statistically significant by 60 minutes. Furthermore, this study met 21 consecutive pre-specified, hierarchically tested outcome measures including durability of effect out to 48 hours post-dose without the use of rescue medication. Importantly, consistent with the other trials, placebo-level tolerability was also noted. These results are described in greater detail below under "—Our Clinical Program for Rimegepant in Acute Treatment of Migraine— Phase 3 Clinical Trials: Study 303."

In December 2018 and September 2019, we reported interim and expanded data, respectively, from our rimegepant long-term safety study. The positive results from these analyses of this trial included over 111,000 doses of rimegepant 75 mg across over 1,700 patients with migraine. The favorable safety and tolerability profile of rimegepant with up to one year of dosing in patients with migraine was consistent with the profile previously seen in clinical trials with rimegepant. No liver safety signal was detected, including in a subset of patients with near-daily dosing (≥14 doses/month). This study concluded in the third quarter of 2019 and we expect to present results from the study at scientific meetings in 2020.

Overall, safety and tolerability data from this interim analysis and ongoing data from this study were sufficient to support new drug application ("NDA") submissions for the Zydis ODT and tablet formulations in the second quarter of 2019. The NDA submission of the Zydis ODT formulation of rimegepant was submitted using a FDA priority review voucher, purchased in March 2019, providing for an expedited 6-month review.

During the third quarter of 2019, we received communication from the FDA that our Zydis ODT and tablet formulation of rimegepant NDA submissions were accepted and we were given a Prescription Drug User Fee Act ("PDUFA") date in the first quarter of 2020 for our Zydis ODT submission. In December 2019, we also received a late-cycle communication update from the FDA in which no major issues were identified by the FDA. All comments from the FDA are preliminary and do not reflect a final decision on the review or approval of our NDA.

In 2019, we quickly and efficiently built what we believe is a world-class commercial organization prepared to diligently serve the migraine community, with resources and capabilities commensurate with a best-in-class medication. We are prepared to fully market rimegepant to clinicians and patients in need as of the PDUFA date, if the FDA approves. We intend to begin distribution to retail wholesalers shortly thereafter.

Based on emerging data from repeat dosing of rimegepant in the long-term safety trial, a Phase 3 trial to evaluate rimegepant as a preventative treatment of migraine was initiated in November 2018. We anticipate receiving topline results in the first quarter of 2020.

In November 2017, we received agreement from the FDA on an initial acute Pediatric Study Plan and, in June 2019, the FDA agreed to an amended Pediatric Study Plan.

In June and December 2018, we received scientific advice for rimegepant from the Committee for Medicinal Products for Human Use ("CHMP") a committee of the European Medicines Agency ("EMA") and feedback suggests there are several options for pursuing indications for rimegepant in Europe which are currently under consideration.

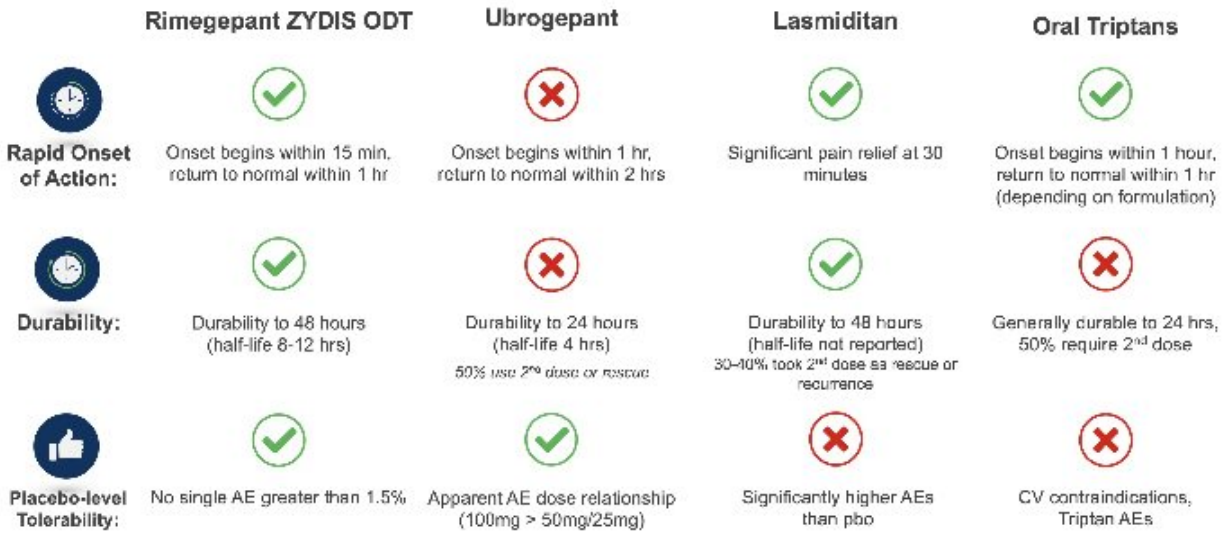
Additionally, in January 2019, we announced with our wholly-owned subsidiary, BioShin, that the National Medical Products Administration (formerly, the China FDA) ("NMPA") has accepted the investigation new drug ("IND") application for rimegepant for the treatment of migraine. We had previously announced the formation of BioShin in November 2018; the subsidiary was established to develop and potentially commercialize our late-stage migraine and neurological disorder product development portfolio in China and other Asia-Pacific markets. Following the results of the randomized, controlled Phase 3 clinical trial evaluating the efficacy and safety of our Zydis ODT formulation of rimegepant for the acute treatment of migraine, we submitted a second IND application to the NMPA for the Zydis ODT formulation of rimegepant for the acute treatment of migraine. The IND application for the Zydis ODT formulation of rimegepant was accepted by the NMPA in the fourth quarter of 2019.

Acute Treatment of Migraine and Limitation of Current Treatments

Clinicians use a number of pharmacologic agents for the acute treatment of migraine. A study published by the American Headache Society in 2015 concluded that the medications deemed effective for the acute treatment of migraine fell into the following classes: triptans, ergotamine derivatives, non-steroidal anti-inflammatory drugs ("NSAIDs"), opioids and combination medications. Lasmiditan, sold under the brand name Reyvow, a first-in-class serotonin 5-HT$_{1F}$ antagonist, was approved by the FDA in October 2019. The current standard of care for the acute treatment of migraine continues to be prescription of triptans, which are serotonin 5-HT$_{1B/1D}$ receptor agonists. Triptans have been developed and approved for the acute treatment of migraine over the past two decades. The initial introduction of triptans represented a shift toward drugs more selectively targeting the suspected pathophysiology of migraine. While triptans account for almost 80% of anti-migraine therapies prescribed at office visits by healthcare providers, issues such as an incomplete effect or headache recurrence remain important clinical limitations. In fact, for any given attack, almost 50% of patients take a second dose in search of pain relief. In addition, triptans are contraindicated in patients with cardiovascular disease, cerebrovascular disease, or significant risk factors for either because of potential systemic and cerebrovascular vasoconstriction from the 5-HT$_{1B}$-mediated effects. The package insert for triptans includes warnings and precautions for migraine patients with risk factors for cardiovascular disease and states that high risk patients, including those with increased age, diabetes, hypertension, smoking, obesity or a strong family history of coronary artery disease, should be evaluated prior to receiving the first dose of a triptan. Triptans are contraindicated in patients with a history of ischemic heart disease, coronary artery vasospasm, history of stroke, peripheral vascular disease or uncontrolled hypertension. Even in patients who have a negative cardiovascular evaluation, product labeling for triptans recommends that consideration be given to administration of the first dose in a medically-supervised setting and performing an electrocardiogram immediately following administration. Additionally, periodic cardiovascular evaluation should be considered for long-term users of triptans who have cardiovascular risk factors. According to a January 2017 study published in the journal *Headache,* an estimated 2.6 million migraine sufferers in the United States have a cardiovascular event, condition or procedure that limits the potential of triptans as a treatment option. Thus, we believe there remains a significant unmet medical need for a novel migraine-specific medication that does not increase the risk of cardiovascular liability.

The Potential Benefits of Rimegepant Compared to Other Treatments

The table below compares what we believe are key features of rimegepant contrasted to other product candidates and standard of care treatments for the acute treatment of migraine.*



*These are cross-trial comparisons and no comparative head-to-head studies between rimegepant and competitors have been conducted.

Based on the results from the rimegepant clinical trials to date, we believe rimegepant offers the following clinical and product benefits for the acute treatment of migraine:

- **Oral Availability.** Rimegepant is the only oral CGRP currently formulated in a Zydis ODT that can be administered sublingually for the potential for rapid onset of action. In our Phase 3 clinical trial, the rimegepant Zydis ODT formulation demonstrated pain relief beginning as early as 15 minutes (becoming statistically significant by 60 minutes), with patients returning to normal functioning by 60 minutes. We have an exclusive worldwide agreement with Catalent for the use of rimegepant in the Zydis ODT fast-dissolving formulation (which also provides exclusivity with respect to other small molecule CGRP receptor antagonists with the Zydis ODT technology). We believe oral availability in an easy to use formulation will provide advantages over injectable migraine treatments.

- **Comprehensive Treatment Effect.** Rimegepant has demonstrated consistent comprehensive treatment effect across 3 large Phase 3 trials and a Phase 2b trial with significant pain freedom, pain relief and relief from the MBS. These effects were all noted with a single dose of the 75 mg tablet or ODT. Approximately 85% of patients treated with a single dose of rimegepant 75 mg did not require the use of additional rescue medications after treating their migraine.

- **Durable Improvement.** In the Phase 3 trials, rimegepant demonstrated durable impact on pain freedom and pain relief through 48 hours compared to placebo. We believe that this durability of effect is related to the half-life of rimegepant and is an important differentiator from other products that have a shorter half-life and require additional doses of medications or rescue medications.

- **Favorable Safety Profile.** In three Phase 3 studies of over 3500 patients, rimegepant demonstrated a safety profile similar to placebo. There were no AEs greater than 1.6%. Consistent with the preclinical data, there was no clinical evidence suggesting that rimegepant has vasoconstrictor activity or other undesirable cardiovascular side effects, such as changes in the blood pressure or heart rate, that are commonly associated with triptans.

- **Potency.** Rimegepant is highly potent with subnanomolar affinity for the human CGRP receptor, which allows for a relatively low dose to provide maximal treatment effect with a single 75 mg dose.

- **Lower Expected Cost.** We expect that as a small molecule, rimegepant will have a lower cost of goods than CGRP antibodies, which are biologics.

The Potential of CGRP Antagonists: Novel mechanism of action without causing vasoconstriction

The release of the neuropeptide CGRP from pain nerves is believed to play a causal role in the underlying pathophysiology of migraine and is also a potent dilator of intracranial arteries. Unlike triptans, which possess potent vasoconstrictive properties that could worsen cardiovascular or cerebrovascular disease, blocking the CGRP receptor reverses pathologic dilation of blood vessels without constricting them past their normal resting state size and without active vasoconstriction. The absence of cardiovascular effects may prove to be one of the major advantages in the use of CGRP receptor antagonists for the treatment of migraine. Preclinical and clinical evidence suggests that the use of CGRP receptor antagonists may be effective in treating migraine by blocking the pathophysiological processes associated with CGRP release, specifically by: (1) inhibiting pain transmission; (2) decreasing artery dilation without any active vasoconstriction; and (3) halting neurogenic inflammation. To date, the preclinical and clinical evidence indicates that CGRP receptor antagonists have an absence of vasoconstrictor activity and lack other undesirable cardiovascular side effects, such as changes in the blood pressure or heart rate. Studies of numerous drugs in development have provided proof of concept of the effects of CGRP targeting agents in humans.

Our Clinical Program for Rimegepant in Acute Treatment of Migraine

We licensed rimegepant from Bristol-Myers Squibb ("BMS") in July 2016. BMS selected rimegepant as a lead CGRP receptor antagonist compound for its potential best-in-class chemical profile after 10 years of research on this drug target.

Phase 3 Clinical Trials: Studies 301 and 302

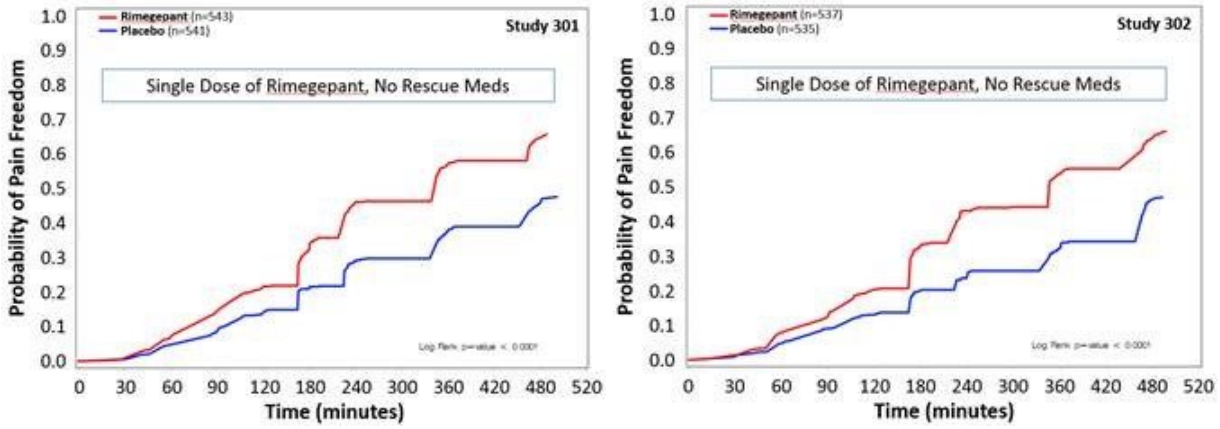
We commenced two Phase 3 clinical trials ("Study 301" and "Study 302") in July 2017 with the oral tablet. We completed enrollment in these trials in November 2017. Approximately 3,000 patients were enrolled and 2,300 patients randomized across these two Phase 3 trials.

We believe that our Phase 3 trials of rimegepant 75 mg conform to the FDA guidance for approval in acute treatment of migraine. The trials were double-blinded, randomized, and placebo-controlled. The first two Phase 3 trials treated subjects with the tablet version of rimegepant and recruited male and female patients 18-65 years of age with at least a one year history of migraine, including an age of onset prior to 50, migraine attacks that last about four to 72 hours, not more than eight attacks of moderate to severe intensity per month within the last three months and not less than two attacks per month. Our goal was to enroll patients who represent the spectrum of real-world migraine patients, including those who have previously been non-responsive to triptans, as the FDA stated to us at our end of Phase 2 meeting in March 2017 that triptan-resistant patients may benefit from rimegepant treatment. We also enrolled patients who had cardiovascular risk factors and/or vascular disease. The primary objective of the trials was to evaluate the efficacy of 75 mg of rimegepant compared with placebo in the acute treatment of migraine as measured by two co-primary endpoints: (1) pain freedom (headache pain intensity level reported as "no pain") at two hours after dosing using a four-point numeric rating scale (no pain, mild pain, moderate pain, severe pain) and (2) freedom from the MBS at two hours after dosing. The three other important migraine symptoms (nausea, photophobia and phonophobia) were assessed as secondary endpoints, consistent with FDA guidance.

In March 2018, we announced positive topline data from our first two Phase 3 clinical trials of rimegepant. In each trial, treatment with a single 75 mg tablet dose of rimegepant met the co-primary efficacy endpoints of the trial, which were superior to placebo, at two hours post-dose, on measures of pain freedom and freedom from the patient’s MBS, selected as either nausea, photophobia or phonophobia.

The figures below show, for each trial, Kaplan-Meier curves depicting the effect of rimegepant on pain freedom as compared to placebo over the course of eight hours after dosing. A Kaplan-Meier curve is a method of statistical analysis used to show estimates of data over time even though data was only collected at intervals throughout that time period.

Kaplan-Meier Curve Showing Pain Freedom 0-8 Hours Post-Dosing



Rimegepant showed a numerical improvement in pain freedom as compared to placebo as early as 45-60 minutes post-dosing, with continued improvement over the course of eight hours post-dosing. The magnitude of the treatment effect over placebo at two hours post-dosing or later, as shown in the figures above, ranged from 5% to 19% in Study 301 and 7% to 22% in Study 302. This continued improvement in pain freedom was observed in patients who received a single dose of rimegepant and did not use rescue medications. Rescue medications are additional medications that patients in clinical trials may take concurrently with the study drug or placebo after the 2 hour endpoint has been registered when the patient experiences inadequate relief. Each of the figures above excludes patients who took rescue medication or who were lost to follow-up during the specified interval.

Pain freedom at two hours post-dosing, one of the co-primary endpoints of these trials, was 19.2% and 19.6% for rimegepant-treated patients in Study 301 and 302, respectively, as compared to 14.2% and 12.0% for patients receiving placebo, with corresponding p-values of <0.03 and <0.001, respectively. P-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of 0.05 or less represents statistical significance, meaning that there is a less than 1-in-20 likelihood that the observed results occurred by chance. The table below summarizes these results.

Rimegepant also achieved statistically significant results on a second co-primary endpoint, freedom from MBS, selected from photophobia, phonophobia or nausea, at two hours post-dosing. As shown in the table below, freedom from MBS for patients treated with rimegepant were 36.6% and 37.6% in Study 301 and Study 302, respectively, as compared to 27.7% and 25.2% for patients receiving placebo, with corresponding p-values of <0.002 and <0.0001, respectively.

Co-Primary Regulatory Endpoints in Study 301 and 302

Study 302

2 Hour Endpoint	**Rimegepant** (N=537)	**Placebo** (N=535)	**p-value**
Pain Freedom	19.6 %	12.0 %	< 0.001
Freedom from MBS[(1)]	37.6 %	25.2 %	< 0.0001

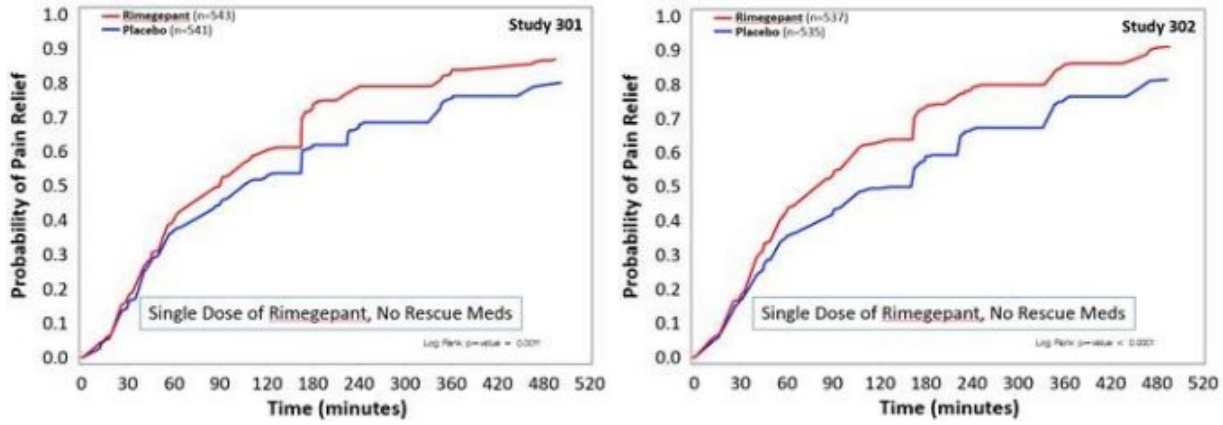
Study 301

2 Hour Endpoint	**Rimegepant** (N=543)	**Placebo** (N=541)	**p-value**
Pain Freedom	19.2 %	14.2 %	< 0.03
Freedom from MBS[(1)]	36.6 %	27.7 %	< 0.002

(1) MBS: Most Bothersome Symptom of Photophobia, Phonophobia or Nausea.

We also evaluated rimegepant' s effect on pain relief, which is the transition from experiencing moderate-to-severe pain to either no pain or mild pain, as a secondary endpoint in both trials. Although pain relief does not always indicate that a patient has no pain, unlike pain freedom, it is a clinically important endpoint because it often is associated with reduced disability due to migraine attacks. In each of the Phase 3 trials, onset of pain relief in patients treated with rimegepant was observed early after dosing, with separation between rimegepant and placebo evident between 30 and 45 minutes post-dosing. In both trials, by two hours post-dosing, over 55% of patients receiving only a single dose of rimegepant achieved pain relief (p-values of 0.0006 in Study 301 and <0.0001 in Study 302). The figures below show, for each trial, Kaplan-Meier curves depicting the effect of rimegepant on pain relief as compared to placebo over the course of eight hours after dosing.

Kaplan-Meier Curve Showing of Time to Pain Relief Up to 8 Hours Post Single Dose



Each of the figures above excludes patients who took rescue medication or who were lost to follow-up during the specified interval.

In addition to achieving both co-primary endpoints in each of the trials, rimegepant also was observed to be generally well-tolerated in the trials, with a safety profile similar to placebo. In particular, pooled liver function test ("LFT") results showed that rimegepant was no more likely than placebo to increase ALT or AST levels above the upper limit of normal, or ULN. An LFT is a blood test that gives an indication of whether the liver is functioning properly. Across both trials, one patient treated with placebo and one patient treated with rimegepant showed LFTs above 3x ULN.

In both trials, no single adverse event, or AE, occurred with an incidence higher than 2% and the overall AE rates in the rimegepant groups were similar to those in the placebo groups. The most common AEs seen in patients treated with rimegepant were similar to placebo in a pooled analysis of both trials. There were no serious adverse events ("SAE"), determined by the study investigators to be drug related.

The co-primary endpoints achieved in the Phase 3 trials are consistent with regulatory guidance from the FDA and provided the basis for the submission of an NDA to the FDA in the second quarter of 2019.

Phase 3 Clinical Trials: Study 303

Our third Phase 3 trial was a randomized, controlled Phase 3 clinical trial ("Study 303") evaluating the efficacy and safety of rimegepant 75 mg Zydis ODT conducted with the rimegepant 75 mg Zydis ODT and was initiated after bioequivalence between the tablet and ODT were established. This Phase 3 Zydis ODT sStudy 303 was conducted to further characterize the ODT formulation and was designed in keeping with the previous Phase 3 studies.

In December 2018, we announced positive topline data from Study 303. In Study 303, rimegepant Zydis ODT statistically differentiated from placebo on the two co-primary endpoints as well as the first 21 consecutive primary and secondary outcome measures that were pre-specified in hierarchical testing. Consistent with the two previous Phase 3 clinical trials, Study 303 met its co-primary endpoints of pain freedom and freedom from the MBS at 2 hours using a single dose (Table 1). Importantly, patients treated with the rimegepant Zydis ODT formulation began to numerically separate from placebo on pain relief as early as 15 minutes, and this difference was statistically significant at 60 minutes ($p < 0.0001$) (Figure 1). Additionally, a significantly greater percentage of patients treated with rimegepant Zydis ODT returned to normal functioning by 60 minutes as compared to placebo ($p < 0.002$). Lasting clinical benefit was observed through 48 hours after a single dose of rimegepant on freedom from pain ($p < 0.001$), pain relief ($p < 0.001$), freedom from the MBS ($p < 0.001$), and freedom from functional

disability ($p < 0.003$). Superiority over placebo was also demonstrated in multiple other secondary endpoints. The vast majority of rimegepant Zydis ODT treated patients (85%) did not use any rescue medications.

Table 1: Met Co-Primary Endpoints of Pain Freedom & Freedom from Most Bothersome Symptom

2 Hour Endpoint	Rimegepant (N=669)		Placebo (N=682)		Difference		p-value
Pain Freedom	21	%	11	%	10	%	< 0.0001
Freedom from MBS(1)	35	%	27	%	8	%	0.0009

(1) Most Bothersome Symptom of Photophobia, Phonophobia or Nausea

Figure 1: Kaplan-Meier Pain Relief Curve Through 2 Hours after Single Dose of Rimegepant 75 Mg Zydis ODT

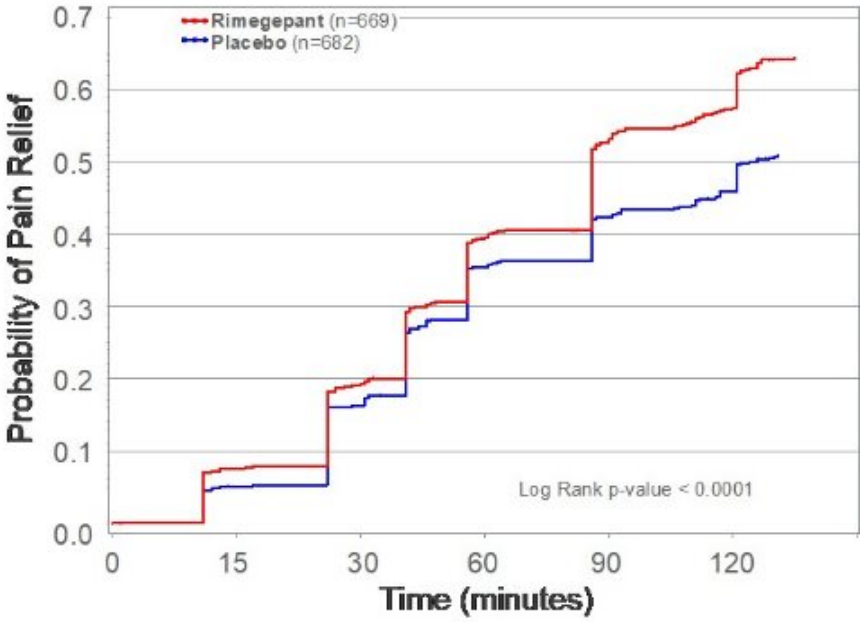


Figure 1 shows the percentage of patients reporting pain relief between 0 and 2 hours after dosing for patients who took a single dose of rimegepant Zydis ODT 75 mg or placebo. Data are Kaplan-Meier estimates of the time to first report of pain relief (report of no pain, or mild pain). Subjects were censored who took rescue medication or were lost to follow-up.

The safety and tolerability observations of rimegepant in Study 303 were consistent with the profile previously observed in Studies 301 and 302. Table 2 shows the pooled safety data across all three trials. In study 303, no single adverse event (AE) occurred in the rimegepant group with an incidence higher than 1.6% and overall rates of AEs were similar to placebo. With regard to LFTs, one patient treated with placebo and one patient treated with rimegepant showed LFTs > 3x ULN in Study 303. Pooled LFT results across the three pivotal trials (n=3,556) performed to date showed that rimegepant was similar to placebo with regard to aminotransferase (ALT or AST) levels above the upper limit of normal ("ULN") and no patients experienced elevations in bilirubin > 2x ULN (Table 3).

Table 2: Pooled AE Safety Data: Rimegepant was Similar to Placebo Across Studies

AEs from Studies 301, 302 and 303 with an incidence ≥ 1%

Adverse Event	Rimegepant N=1,771	Placebo N=1,785
≥ 1 On-Study AE[1]	252 (14.2)%	209 (13.2)%
Nausea	26 (1.5)%	15 (0.8)%
UTI	21 (1.2)%	12 (0.7)%
SAEs[2]	3 (0.2)%	3 (0.2)%

(1) No other individual AEs ≥ 1% in rimegepant treated subjects than those listed in table. Includes all AEs without attribution to drug relatedness.
(2) No drug-related Serious Adverse Events (SAEs). Two of the subjects with SAE in rimegepant group and one in placebo group had not been dosed before onset of SAE.

Table 3: Pooled Liver Function Test (LFT) Profile: Rimegepant was Similar to Placebo Across Studies

Pooled LFT Results from Studies 301, 302, and 303*

ALT or AST	Rimegepant N=1,771	Placebo N=1,785
> ULN[1]	48 (2.7%)	52 (2.9%)
> 3x ULN	2 (0.1%)	2 (0.1%)
> 5x ULN	1 (0.06%)[2]	0
> 10x ULN	0	0
> 20x ULN	0	0

(1) Upper limit of normal; ALT alanine aminotransferase; AST aspartate aminotransferase
(2) AST elevation, Not Drug-Related as deemed by the investigator: subject newly initiated weight-lifting with laboratory results consistent with muscle injury
* AST/ALT Categories are not mutually exclusive; No bilirubin elevations > 2x ULN across Studies 301, 302 and 303

The efficacy and safety profile of rimegepant has now been observed across three randomized controlled trials to date. The co-primary endpoints achieved in the Phase 3 trials (Study 301, 302 and 303) are consistent with regulatory guidance from the FDA. We continue to advance the rimegepant Zydis ODT and tablet formulation development programs towards potential commercialization for the acute treatment of migraine.

Phase 3 Clinical Trials: Long-term Safety Study (Study 201)

In August 2017, we commenced a long-term safety study ("Study 201") to meet FDA requirements for approval. On December 10, 2018, we announced the results from an interim analysis from our ongoing long-term safety study.

On May 8, 2019, we announced updated interim results from the long-term safety study. As of February 20, 2019 (the database cutoff date of the interim assessment), 105,192 doses of rimegepant 75 mg had been administered across 1,784 patients with migraine. As of February 20, 2019, approximately 527 patients have received near daily dosing (14 or more doses in 4 weeks) of rimegepant 75 mg to date for a duration ranging between 4 and 52 weeks. Interim hepatic data as of February 21, 2019 were reviewed by an external independent panel of liver experts who concluded that there was no liver safety signal detected through the data analysis cut-off date and, compared to placebo arms of other migraine treatments, there was a very low incidence of overall elevations of liver laboratory abnormalities (1% incidence of serum ALT or AST > 3x the upper limit of normal ("ULN") through the data analysis cut-off date). Based on this interim analysis, there are indications that rimegepant may be safe and well tolerated with long-term dosing in patients with migraine.

On May 8, 2019, we also reported the safety and preliminary exploratory efficacy data from the scheduled dosing cohort in the study. In this cohort of patients with a history of 4 to 14 moderate to severe migraine attacks per month, patients were treated with rimegepant 75 mg every other day for up to 12 consecutive weeks. Patients in this cohort could also supplement their scheduled rimegepant dosing with additional as-needed dosing on nonscheduled dosing days. In this cohort, 286 patients received a total of 11,296 doses of rimegepant 75 mg tablets at least every other day, with a median number of 14.2 tablets per 4 week period. During the on-treatment period, no rimegepant-treated patients (n=281) experienced ALT or AST levels >3x the ULN. There were also no rimegepant-treated patients who experienced alkaline phosphatase or bilirubin >2x the ULN. With

regard to efficacy, 48.4% of subjects in the scheduled dosing cohort experienced a ≥50% reduction in the frequency of monthly migraine days with moderate-to-severe pain intensity during the third month of treatment. This preliminary exploratory open-label efficacy data from Study 201 suggest that rimegepant may be associated with a reduction in migraine days per month (30 days) compared to the observational lead-in period, suggesting a potential preventive effect that warrants further study.

Study 201 concluded during the third quarter of 2019 with additional data analyses submitted to the FDA in connection with the NDA submissions, including the required 120-day safety update. We expect to present results from the study at scientific meetings in 2020. Additionally, this program for the acute treatment of migraine is supported by results of 20 Phase 1/2 trials.

Our Clinical Program for Rimegepant in Preventative Treatment of Migraine

A Phase 3 clinical trial in the preventive treatment of migraine was initiated in November 2018 to examine the efficacy and safety of rimegepant 75 mg dosed on 747 adult subjects who have suffered from migraine for at least one year and who have a frequency of 4 to 14 migraine attacks of moderate to severe pain intensity per month over the three months prior to enrollment. The primary outcome measure is the change from baseline at week 12 in the mean number of migraine days per month. Secondary outcome measures include the achievement of at least a 50% reduction from baseline in mean monthly migraine days across the double-blind treatment phase, and the mean number of rescue medication days per month, each as measured over the course of the double-blind, treatment phase. We expect to report topline results from this trial in the first quarter of 2020.

Our Clinical Program for Rimegepant in Treatment of Trigeminal Neuralgia

In the second quarter of 2019, we initiated a Phase 2 proof of concept trial to evaluate the safety and efficacy of rimegepant in patients with treatment refractory trigeminal neuralgia. Trigeminal neuralgia is a chronic facial pain syndrome characterized by paroxysmal, severe, and lancinating episodes of pain in the distribution of one or more branches of the trigeminal nerve. The trigeminal nerve, or fifth cranial nerve, is the largest of the 12 cranial nerves and provides sensory innervation to the head and neck, as well as motor innervation to the muscles of mastication. These episodic bouts of severe facial pain can last seconds to minutes, occur several times per day, and often result in significant disability. Over the long-term course of the disease, symptoms often become refractory to medical therapy and current treatment options remain suboptimal.

Clinical Trials with Rimegepant

As of February 2020, twenty-nine clinical trials have been completed (enrollment and treatment completed) in healthy volunteers and patients with migraine that inform pharmacokinetic, metabolic interactions, safety, tolerability and efficacy of rimegepant. Rimegepant has been observed to be generally well tolerated in humans when given as single oral doses up to the maximum dose of 1500 mg and multiple oral doses up to the maximum daily dose of 600 mg for 14 days. No deaths have occurred in clinical trials to date. Currently, we are continuing to conduct one Phase 3 clinical trial in preventive treatment of migraine, and results are expected in the first quarter of 2020. The long-term safety study concluded during the third quarter of 2019 with additional data analyses submitted to the FDA in connection with the NDA submissions, including the required 120-day safety update. The final report is expected in the first quarter of 2020.

In addition, we commenced four Phase 1 clinical trials during 2019. These Phase 1 trials included a drug-drug interaction study looking at the effects of administering metformin and rimegepant concurrently. A study to evaluate the pharmacokinetics ("PK") in breast milk and plasma in lactating women was initiated. Additionally, a Phase 1 study to evaluate the PK with lower doses of rimegepant ODT was conducted to support the future pediatric program and a food effect study of sublingual rimegepant ODT with a low-fat meal was initiated. All of these Phase 1 PK clinical trials completed enrollment in the fourth quarter of 2019, with the exception of the Phase 1 study in lactating women which is expected to complete enrollment in 2020.

As of February 2020, over 3,500 patients have been administered rimegepant across all studies. In completed Phase 2 and Phase 3 rimegepant clinical trials, for which all subjects have completed treatment, SAEs have been reported with none of these SAEs considered to be related to study drug. In total, we believe the current data suggests a favorable benefit-risk profile for rimegepant in the acute treatment of migraine attacks. The clinical experience with rimegepant to date has allowed the characterization of safety and tolerability at substantial multiples of the intended therapeutic dose and intended frequency of use. Rimegepant has been assessed in single doses up to 1500 mg and in multiple doses from 75 mg to 600 mg with 14 days of dosing (including 300 mg twice daily), where the higher doses yielded exposures more than 54 times greater in area under the curve ("AUC"), which is a measure of drug exposure, and 23 times higher in C_{max}, which is the peak concentration that a drug achieves after dosing, as compared to the mean therapeutic exposure of a single 75 mg dose. These high exposure multiples were observed to be generally well tolerated.

Since no data are available regarding the effects of rimegepant on human fetuses or newborns, women of childbearing potential must use adequate birth control and have a negative serum or urine pregnancy test to be eligible to receive rimegepant.

Female subjects are instructed to avoid attempts at pregnancy in the month prior to exposure to rimegepant and eight weeks after exposure to rimegepant. All urine pregnancy testing results must be confirmed by serum pregnancy testing. Drug interaction studies with oral contraceptives demonstrated modest increase in exposure to estrogen and norelgestromin upon multiple doses of rimegepant 75 mg. Co-administration of rimegepant with oral contraceptives was safe and well tolerated. These results enabled enrollment of women of childbearing potential receiving oral contraceptives to be enrolled in the Phase 3 studies.

Nonclinical Toxicology

Rimegepant at oral doses of 30, 100 or 300 mg/kg/day for 26 weeks was not carcinogenic in male and female transgenic mice. Additionally, there was no evidence of carcinogenicity in rats administered oral doses of 5, 20, or 45 mg/kg/day rimegepant for up to 2 years. Exposures at the no observable effect level ("NOEL") doses for neoplastic findings were at least 331X (mice) and 28X (rats) the anticipated human AUC at a 75 mg/day clinical dose.

Rimegepant is not genotoxic or phototoxic and has a low potential for off-target receptor interactions or effects on the cardiovascular, respiratory, and central nervous systems ("CNS"). With repeated dosing up to three months, rimegepant was clinically tolerated at up to 150 mg/kg/day in rats and 100 mg/kg/day in monkeys. No histopathologic liver findings were noted in monkeys treated for 3 months at all doses (the highest dose yielded an AUC exposure that was 120× the anticipated human AUC at a therapeutic dose of 75 mg/day). The liver was the primary target organ in mice at levels of 100 mg/kg/day and greater and in rats at levels of 60 mg/kg/day and greater. These dosing levels were not associated with hepatocellular degeneration/necrosis, inflammation, or fibrosis. In monkeys treated for 3 months, target organ effects were limited to minimal to moderate macrophage accumulation (histiocytosis) in mandibular and mesenteric lymph nodes (considered to be a marginal exacerbation of a common spontaneous change in this species) at 100 mg/kg/day. Hepatic lipidosis identified in mouse and rat studies was determined to be rodent specific as it was not observed at rimegepant exposures in monkeys which overlapped those producing lipid effects in rats in the three-month pivotal studies. At the NOEL and no observable adverse effect level ("NOAEL") doses in rats (30 mg/kg/day) and monkeys (50 mg/kg/day) in the three-month studies, mean (male and female combined) AUC exposures were at least 23× (for rats) and 56× (for monkeys) the anticipated human AUC at a 75 mg/day clinical dose. Since fetal effects in rats were observed only at doses that produced maternal toxicity (300 mg/kg/day) and there were no fetal findings in rabbits at any dose level, rimegepant is not considered to be a selective developmental toxicant.

In a 6-month rat study, animals were administered rimegepant orally at daily doses of 0, 20, or 45 mg/kg/day. The NOAEL was the high dose, 45 mg/kg/day with no evidence of toxicity at any dose. In a 9-month cynomolgus monkey study, animals were administered rimegepant orally at daily doses of 0, 15 or 50 mg/kg/day. The NOAEL was the high dose, 50 mg/kg/day with no evidence of toxicity at any dose level. Chronic administration to rats (6 months) and monkeys (9 months) demonstrated NOAEL values at doses of 45 and 50 mg/kg/day, respectively. Exposures were at least 29X (rat) and 17X (monkey) the anticipated human AUC at a 75 mg/day clinical dose.

Our Product Candidate Vazegepant (previously BHV-3500), a CGRP Receptor Antagonist for Acute and Preventive Treatment of Migraine

Vazegepant is the second compound from our CGRP receptor antagonist platform and represents a novel chemical structure compared to other small molecule CGRP receptor antagonists in development (including rimegepant). We are developing vazegepant for the acute and preventive treatment of migraine, with initial studies being conducted in acute treatment, and we believe it has the potential to improve the existing standard of care based on the following benefits:

- **Multiple Potential Routes of Delivery**—Vazegepant may be used by nasal, subcutaneous, inhalation or potential oral routes of administration with rapid onset of treatment effect, compared to the anti-CGRP mAbs that are currently available which have a more cumbersome route of administration to patients in the form of intravenous or subcutaneous use. The first formulation of vazegepant in clinical trials is for intranasal delivery that will be assessed for rapid onset of action in the acute treatment of migraine.

- **Favorable Safety Profile**—Like rimegepant, we believe vazegepant will have a favorable safety and tolerability profile in the clinic, attributable to multiple properties such as its high selectivity for the CGRP receptor, low propensity to aggregate in lipids, and its expected excretion from the body in a largely unchanged state. Unlike other small molecule CGRP receptor antagonists that show potential for liver effects at high exposures, vazegepant has not demonstrated any propensity for liver abnormalities in preclinical studies to date, even at very high dose levels. Because preventative treatments involve chronic dosing on a daily basis, any potential target organ effects on the liver could be problematic. Therefore, based on these observations from nonclinical toxicology studies, we believe that vazegepant may provide a substantial benefit over other agents with such propensities. In addition, in preclinical studies of vazegepant, no significant cardiovascular safety or systemic toxicity issues were observed, in contrast to sumatriptan, which displays dose-dependent vasoconstriction.

- **Superior Chemical Attributes**—Vazegepant is a highly soluble, potent antagonist at the human CGRP receptor. Because vazegepant exhibits an *in vitro* and *in vivo* efficacy profile similar to rimegepant, we believe that vazegepant will also have a comprehensive (pain, nausea, photophobia and phonophobia) and durable efficacy profile. The chemical attributes of vazegepant also allow for a variety of formulations that may provide a more rapid onset of efficacy. Unlike mAbs, which are large biologic molecules, vazegepant is a small molecule that directly binds with high potency to the human CGRP receptor.

- **Higher Value to Patients and Payors with Lower Expected Cost Compared to Biologics**—We expect that as a small molecule, vazegepant will have a lower cost of goods than mAbs, which are biologics.

- **Potential for Multiple Indications**—Although its nonclinical safety and efficacy profile suggests vazegepant's potential for daily administration and development for prevention of migraine, we believe this compound also has the potential to be developed in the acute treatment of migraine. vazegepant adds flexibility to our CGRP development program as a stand-alone agent for prevention therapy or a complementary intranasal formulation for rapid onset of action in the acute treatment of migraine.

We believe vazegepant has the potential to address a significant unmet need in the acute treatment of migraine in patients by delivering a faster onset of action and relief of migraine. This profile will enable it to compete effectively with current and future migraine therapies. Vazegepant may afford multiple routes of delivery including intranasal delivery and daily oral administration for acute and preventative treatment of migraine, potential for enhanced safety profile, superior chemical attributes and a higher value to patients and payors with lower expected costs compared to large molecule biologics in current development.

Clinical Development Plans

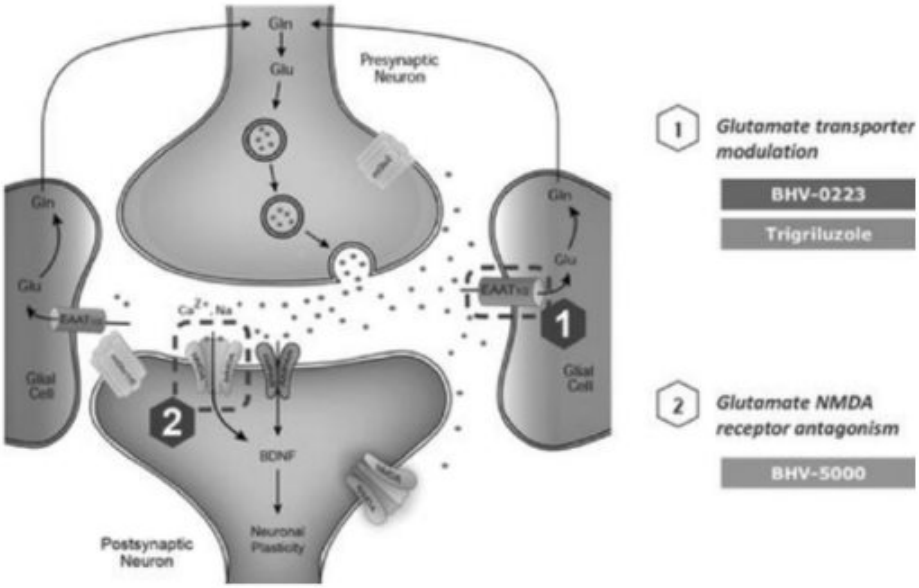
Administration of intranasal vazegepant in a Phase 1 clinical trial was initiated in October 2018 and has achieved targeted therapeutic exposures. We advanced vazegepant into a Phase 2/3 trial to evaluate efficacy for the acute treatment of migraine in the first quarter of 2019. In December 2019, we announced positive topline results from the Phase 2/3 trial. Vazegepant 10 mg and 20 mg were statistically superior to placebo on the co-primary endpoints of pain freedom and freedom from most bothersome symptom at two hours using a single dose. Additional results from this study are anticipated to be presented at upcoming scientific meetings in 2020, and a Phase 3 replicative study and Phase 2/3 long term safety study is planned for mid-2020. We believe that intranasal vazegepant may provide an ultra-rapid onset of action that could be used in a complementary fashion with other migraine treatment when the speed of onset is critical to a patient.

Our Glutamate Platform

We are developing three product candidates, troriluzole (previously referred to as trigriluzole and BHV-4157), BHV-0223 and BHV-5000, that modulate the glutamate system via two distinct mechanisms which form the basis of our glutamate platform—glutamate transporter modulators (troriluzole and BHV-0223) and glutamate N-methyl-D-aspartate ("NMDA") receptor antagonists (BHV-5000).

Glutamate is an important neurotransmitter present in over 90% of all brain synapses and is a naturally occurring molecule that nerve cells use to send signals to other cells in the central nervous system. Glutamate plays an essential role in normal brain functioning and its levels must be tightly regulated. Abnormalities in glutamate function can disrupt nerve health and communication, and in extreme cases may lead to nerve cell death. Nerve cell dysfunction and death leads to devastating diseases, including ataxia, ALS and other neurodegenerative disorders. Glutamate clearance is necessary for proper synaptic activation and to prevent neuronal damage from excessive activation of glutamate receptors. Excitatory amino-acid transporters ("EAATs"), help regulate glutamate clearance, and are responsible for most of the glutamate uptake within the brain.

The mechanism of action of our glutamate platform is depicted below. Glutamate must be tightly regulated once released from a pre-synaptic neuron and acts as a signaling neurotransmitter to stimulate the post-synaptic neuron via stimulation of glutamate receptors (e.g., NMDA, AMPA or Kainate receptors). Glial cells surrounding the synaptic junction are predominantly responsible for clearing glutamate through transporters, the EAATs. There are five distinct types of glutamate transporters. (1) As depicted in the glial cell to the right of the figure below, BHV-0223 and troriluzole increase the activity of the EAATs to increase the clearance of glutamate and decrease glutamate release from the pre-synaptic neuron. Troriluzole and BHV-0223 also inhibit presynaptic ion channels that may inhibit the release of glutamate from presynaptic neurons. (2) As depicted in the postsynaptic neuron to the bottom of the figure below, BHV-5000 blocks glutamate signaling that is mediated by post-synaptic NMDA receptors. Modulating glutamate also has the potential to be neuroprotective and increase the release of neurotrophic factors, including brain derived neurotrophic factor ("BDNF") which are endogenous molecules that help to support the survival of existing neurons, and encourage the growth and differentiation of new neurons and synapses.



Glutamate Transporter Modulation

Abnormal glutamate release or dysfunction of glutamate clearance can cause overstimulation of glutamate receptors which can lead to a dangerous neural injury called excitotoxicity, which has been associated with a wide range of neurodegenerative diseases. The FDA has approved anti-excitotoxicity drugs that act on the glutamatergic system by blocking NMDA receptors, such as memantine ("Namenda") for Alzheimer's disease, lamotrigine ("Lamictal") for epilepsy and bipolar disorder and riluzole ("Rilutek") for ALS. Although these drugs show the therapeutic potential of glutamate receptor antagonists in the treatment of a range of neurological diseases, many of these approved drugs have serious side effects and other drawbacks that we have attempted to solve with our development of BHV-0223 and troriluzole.

We are currently developing troriluzole as a potential FDA-approved drug treatment option for patients suffering from obsessive compulsive disorder ("OCD"), Alzheimer's disease and ataxia (initially focusing on SCA). We commenced a Phase 2/3 double-blind, randomized controlled trial on the use of troriluzole in OCD in December 2017, which is expected to complete enrollment in the first quarter of 2020. In addition, a Phase 2/3 double-blind, randomized controlled trial of troriluzole in the treatment of mild-to-moderate Alzheimer's disease has advanced with the Alzheimer's Disease Cooperative Study, a consortium of sites funded by the National Institutes of Health. In the fourth quarter of 2019, we completed enrollment in the study and announced that the study passed the interim futility analysis. The 48-week extension phase of the SCA Phase 2/3 trial is complete and the extension phase has been expanded to 96-weeks. We believe that the non-statistically significant clinical observations from our first Phase 2/3 trial and open-label extension phase in SCA support our decision to advance troriluzole into a Phase 3 trial that could provide the data needed to serve as the basis for an NDA. A Phase 3 trial began enrollment in the first quarter of 2019 to evaluate the efficacy of troriluzole in SCA. We expect to complete enrollment in the Phase 3 trial of troriluzole in SCA in the second quarter of 2020.

OCD is a chronic neuropsychiatric disorder characterized by symptoms of obsessions (intrusive thoughts) and compulsions (repetitive behaviors) that can interfere with patients' functional abilities. According to the National Institute of Mental Health, the 12-month prevalence of OCD is 1% of the U.S. adult population, and approximately half of these cases are characterized as severe. First-line treatment for OCD includes cognitive behavior therapy, selective serotonin reuptake inhibitors ("SSRIs") and adjunctive use of atypical antipsychotics. Nonetheless, up to 60% of patients have an inadequate response to conventional intervention strategies. While SSRIs and atypical antipsychotics have been approved for OCD, the majority of patients do not have an adequate response to pharmacologic treatment, and some seek invasive neurosurgical procedures to ameliorate symptoms. Despite the significant public health burden, no novel mechanisms of action have been approved by the FDA for OCD in over two decades. The rationale for use of troriluzole in OCD is supported by clinical data with its active metabolite, riluzole, in populations with OCD in open-label and placebo-controlled clinical trials as well as in preclinical, genetic and neuroimaging studies implicating the glutamatergic hyperactivity in the pathogenesis of OCD.

Alzheimer's disease is the most common form of dementia, characterized by symptoms of progressive memory loss and impairment in other areas of cognition. According to the Alzheimer's Association, approximately 5.5 million people in the United States are affected by the disease and, with the aging population, that number is expected to triple by 2050. We believe the rationale for the study of troriluzole in Alzheimer's disease is supported by preclinical studies on the active metabolite,

riluzole, in multiple relevant preclinical models and our own clinical data from the Phase 2/3 clinical trial on the potential of troriluzole to overcome limitations of administering riluzole.

SCA represents an orphan disease. According to a 2016 report by Orphanet cataloging the prevalence and incidence of rare diseases, SCA affects approximately 22,000 individuals in the United States. We have received both orphan drug designation and fast track designation from the FDA for troriluzole for the treatment of SCA. In October 2017, we reported topline data from the 8-week randomization period from the Phase 2/3 clinical trial in SCA. At the eight week time point, troriluzole did not statistically differentiate from placebo. Post-hoc analyses suggested the potential for favorable therapeutic effects of troriluzole, based on numerically superior treatment effects compared to placebo in groups of subjects with less inherent pre-randomization variability on the primary endpoint and also in those, who based on baseline characteristics, would be expected to have greater drug exposures. In the trial, we observed a favorable safety and tolerability profile. For example, no subjects demonstrated an elevation of liver transaminases of 3-fold or greater than the upper limit of normal; whereas, a similar exposure of the active metabolite, riluzole, is associated with about an 8% rate of such elevations, based on the Rilutek Prescribing Information. The 96-week extension phase of the SCA trial is ongoing, and we are continuing to assess the data from the trial. Based on post-hoc analyses we are in active dialogue with the FDA to discuss the potential for further development of troriluzole in ataxias and the FDA has expressed willingness to accept a modification of our trial's primary endpoint, the Scale for Assessment and Rating of Ataxia ("SARA"), as an acceptable registrational endpoint.

In addition, preclinical and small-scale pilot studies are underway to explore troriluzole's use in the treatment of a pipeline of other indications such as some cancers whose spread is thought mediated by glutamate transmission, such as melanoma and glioblastoma. We are also developing analogs of troriluzole and other related prodrugs for potential use in these indications.

An NDA for ALS was filed for BHV-0223 with the FDA in September 2018 with the PDUFA date of July 2019. In July 2019, we announced that we received a Complete Response Letter ("CRL") from the FDA for the 505(b)2 application seeking approval for BHV-0223 (riluzole) for the treatment of ALS. The sole issue identified in the CRL relates to an FDA concern regarding the use of an active pharmaceutical ingredient (“API”) manufactured by Apotex Pharmachem India Private Limited (“Apotex”) and used in the drug product supplies for the bioequivalence study in 2017. In the CRL, the FDA stated that it provided recommendations to Apotex regarding the information needed to qualify previous API batches manufactured at Apotex during the time period in question. We have been subsequently informed by the manufacturer that the manufacturer had an exemption from the FDA to supply riluzole to the U.S. market during that time period. We have been in contact with the FDA’s Chemistry, Manufacturing, and Controls (“CMC”) group and Apotex to resolve the matter and we have already submitted additional information to the FDA regarding this issue. We note that the API for commercial supply of BHV-0223 is currently sourced from another supplier, with whom no CMC issues have been identified. The FDA did not cite any other concerns in their CRL regarding BHV-0223.

BHV-5000 is an orally available, first-in-class, low-trapping, NMDA receptor antagonist prodrug that we are developing for the treatment of neuropsychiatric indications. One of these indications may include Rett syndrome. Rett syndrome is a rare and severe genetic neurodevelopmental disorder. After six to 18 months of apparently normal post-natal development, patients with Rett syndrome develop global deceleration of psychomotor function, loss of acquired cognitive skills and brain-mediated episodes of transient respiratory suppression. With intensive care, patients may survive into adulthood, yet they are severely physically and cognitively impaired. Rett syndrome affects approximately 15,000 individuals in the United States. No approved drug therapies for Rett syndrome are currently available and care is supportive. The rationale for the study of BHV-5000 in Rett syndrome is based on results of studies with BHV-5000, its active metabolite and ketamine in preclinical mouse models, in which improvement in key clinical features of the disease have been observed, including a reduction in the frequency of episodes of respiratory suppression. These preclinical findings are supported by anecdotal clinical reports regarding the use of ketamine, another NMDA receptor antagonist, in patients with Rett syndrome that have been reported to also show clinical improvements. Other potential indications include neuropathic pain and major depression.

Our Product Candidate Troriluzole for Ataxias, OCD and Alzheimer's Disease

Troriluzole is a new chemical entity ("NCE") and tripeptide prodrug of the active metabolite, riluzole. Based on its mechanism of action, preclinical data and clinical studies, troriluzole has potential for therapeutic benefit in a range of neurological and neuropsychiatric illnesses. Initial development has focused on its use in treating SCA, an orphan neurological indication that currently has no approved drug therapies and for which the active metabolite, riluzole, has demonstrated preliminary efficacy in two prior randomized controlled trials conducted by third parties. We acquired troriluzole from ALS Biopharma, LLC ("ALS Biopharma"), and Fox Chase Chemical Diversity Center, Inc. ("FCCDC"), along with an estate of over 300 prodrugs. A prodrug is a compound that, after administration, is metabolized in the body into an active drug. Troriluzole is actively transported by virtue of recognition of its tripeptide moiety by the PepT1 transporter in the gut, and is responsible for the increased bioavailability of the drug. Once inside the body, the prodrug, troriluzole is cleaved by enzymes in the blood to the active metabolite riluzole. To mitigate the limitations of riluzole, several classes of prodrugs were designed, synthesized, and evaluated in multiple *in vitro* stability assays that predict *in vivo* drug levels. Troriluzole is a third generation of prodrug development and the product of six years of intensive chemistry efforts.

Riluzole is currently only indicated for ALS and has a number of non-desirable attributes that have limited its clinical use. Key limitations of riluzole include:

- **Poor oral bioavailability**—When riluzole is administered in a tablet form, approximately 40% is either not absorbed or is metabolized in the liver before reaching systemic circulation. The fraction that does not reach systemic circulation and does not contribute to efficacy only increases the drug burden to the liver. This is thought to contribute to its negative safety effects, such as the liver effects described below.

- **Negative food effect**—Riluzole must be taken on an empty stomach, at least one hour before or two hours after a meal, and failure to adhere to these guidelines results in lower drug levels and potentially decreased therapeutic effects. This can be particularly challenging for late-stage ALS patients who require a feeding tube for nutrition.

- **Negative effect on liver**—Riluzole has been shown to have dose-dependent liver effects that include elevations on LFTs. Taking riluzole necessitates regular laboratory monitoring of liver function. In addition, according to the FDA's warnings and precautions for Rilutek in its U.S. prescribing information, cases of clinical hepatitis, one of which has been fatal, have been reported in patients taking riluzole.

- **Pharmacokinetic variability**—Due to extensive first-pass metabolism and CYP1A2 metabolism, which is heterogeneously expressed and thought to be responsible for the marked pharmacokinetic variability between individuals, riluzole has been observed to have marked pharmacokinetic variability, an attribute that manifests as a wide range of systemic drug exposure in populations administered the same dose.

- **Oral numbness**—Patients have reported oral numbness associated with the active pharmaceutical ingredient riluzole, which makes development of alternate formulations challenging.

The prodrug design and selected administration pathway that was pursued with troriluzole is intended to address all of these limitations of riluzole. In addition, a prodrug can be engineered to enhance absorption and protect from diminished absorption when taken with meals. The troriluzole preclinical development strategy was based on optimizing *in vivo* and *in vitro* features, such as stability in gastrointestinal and stomach fluids; stability in liver microsomes; favorable safety pharmacology with respect to off-target effects (particularly liver effects); metabolic cleavage in the plasma to release the active moiety; and enhanced gastrointestinal absorption properties. In *in vivo* studies in rodents, the intended benefits of this optimization program were observed, including delayed peak concentrations and greater exposure.

After six years of chemistry development and preclinical testing, the resulting lead prodrug from the chemistry program was troriluzole. Troriluzole is chemically comprised of riluzole linked via an amide bond to a tripeptide that is a substrate for gut transporters (PepT1) and which contributes to its improved bioavailability. The tripeptide moiety is cleaved by plasma aminopeptidases, releasing riluzole and naturally occurring amino acids, which we believe are readily managed by endogenous metabolic routes. We believe that the estate of compounds we acquired, combined with our internally developed intellectual property, will provide a significant protection for our innovations. Troriluzole is stable in fluids from the gastrointestinal tract and expected to have a differentiated profile with regard to any liability for hepatic effects.

SCA was chosen as the lead indication based on a strong preclinical rationale as well as demonstration of preliminary efficacy of troriluzole's active metabolite, riluzole, in two randomized controlled trials in patients with SCA and other ataxias conducted by third parties (Ristori 2010; Romano 2015). We continue to develop troriluzole for the treatment of ataxias, with an initial focus on SCA.

The Potential Benefits of Troriluzole Compared to Riluzole

We believe troriluzole offers the following potential advantages, compared to orally dosed riluzole:

- **Improved Bioavailability**—Troriluzole is a substrate for the gut transporters (PepT1). This is thought to increase the bioavailability of the drug as compared to orally dosed riluzole, meaning that more of the compound is absorbed by the body into the blood stream and can have an active effect. Studies have shown that administration of agents through peptide transporters significantly increases the absorption of drugs with otherwise poor oral bioavailability.

- **No Negative Food Effect**—Troriluzole shows no food effect in human studies, meaning that the drug will not be associated with special meal restrictions, a phenomenon potentially attributable to enhanced uptake by intestinal transporters specific to the peptide-containing moiety of troriluzole. This is in contrast to oral riluzole tablets, which require a period of fasting around dosing in order to reach therapeutic levels, currently a dose-limiting factor of riluzole.

- **Lower Overall Drug Burden to the Liver**—As a prodrug that mitigates first-pass liver metabolism and enhances bioavailability, therapeutic concentrations of the active metabolite riluzole can be achieved with a lower drug dose as compared to riluzole tablets. In addition, release of the active metabolite over time will result in a reduced bolus hepatic concentration as compared to that associated with riluzole tablets. Taken together, we believe these attributes of troriluzole will reduce the potential for adverse liver effects.

- **Optimized Dosing Regimen and Compliance**—Troriluzole has been developed as a convenient once-daily dose, which could improve regimen compliance for patients. We believe these are important features to optimize long-term health outcomes in the treatment of patients with chronic diseases.

- **Potential for Developing Multiple Formulations**—Troriluzole is highly soluble and does not exhibit the profound oral numbness associated with riluzole tablets. As such, we believe troriluzole has the potential to be developed in multiple formulations including intranasal, subcutaneous, intravenous, sublingual and other forms.

Overview of Ataxias and Limitations of Current Treatment

Ataxias are a group of degenerative diseases of the nervous system, including hereditary ataxias and sporadic ataxias. According to the National Ataxia Foundation, the word "ataxia" originates from a Greek word meaning "without order" or "incoordination" and aptly describes many of the symptoms that are experienced by people who suffer from the many forms of ataxia, including problems with coordination, balance and movement which can affect a person's fingers, hands, arms, legs, body, speech and eye movements. Ataxias are generally classified as being either hereditary or sporadic. Hereditary ataxias are degenerative disorders that progress over a number of years. The hereditary ataxias include autosomal dominant forms, such as SCA, episodic ataxias and dentratorubral-pallidoluysian atrophy, and autosomal recessive forms, such as Friedreich's ataxia, fragile X-associated tremor/ataxia syndrome and ataxia-telangiectasia. Sporadic ataxias are generally idiopathic, do not run in families and have an onset later in life. Sporadic ataxias share many clinical features of the hereditary forms, which is thought to be attributable to similar underlying cerebellar dysfunction.

Although symptoms may vary, the typical clinical course of SCA might be described as follows. Balance and coordination are affected first. Incoordination of hands, arms, and legs, and slurring of speech are other common, early symptoms. Over time, individuals with SCA may develop numbness, tingling, or pain in the arms and legs (sensory neuropathy), uncontrolled muscle tensing (dystonia), muscle wasting (atrophy), and muscle twitches (fasciculations). Walking becomes difficult and is characterized by walking with feet placed further apart to compensate for poor balance. Impaired coordination of the arms and hands affects the ability to perform tasks requiring fine motor control such as writing and eating. Rarely, rigidity, tremors, and involuntary jerking movements (chorea) have been reported in people who have been affected for many years. As time goes on, ataxia can affect speech and swallowing. Finally, individuals with SCA may also have difficulty processing, learning, and remembering information (cognitive impairment). Notably, there can also be significant clinical variation in the order and extent of symptom expression between mutations, within a common mutation, and even within a kindred that shares the same genotype. Non-cerebellar involvement may also occur in many SCA subtypes (such as cognition, pyramidal, extrapyramidal, motor neuron, peripheral nerve or macular involvement). Signs and symptoms of SCA typically begin in early adulthood, but can appear anytime from childhood to late adulthood; SCA is degenerative and progresses over a number of years. The neurodegeneration is attributed to the production of abnormal proteins that cause the affected nerve cells, predominantly cerebellar purkinje fibers, to eventually function poorly and ultimately degenerate. As SCA progresses, coordination problems become more pronounced. Atrophy of the cerebellum and sometimes brainstem may be apparent on brain imaging. The diagnosis of SCA requires the exclusion of acquired, non-genetic causes of ataxia, such as alcoholism, vitamin deficiencies, multiple sclerosis, vascular disease, tumors, and paraneoplastic disease. A definitive diagnosis requires genetic testing or occurrence within a kindred that has an identified mutation. Lifespan is significantly shortened due to complications related to neurological deficits.

There are currently no FDA-approved medications for the treatment of SCA or any other cerebellar ataxia, and treatment is supportive. In general, multidisciplinary care provides supportive measures and the goal of this treatment is to improve quality of life and survival.

Our Clinical Program for Troriluzole in Spinocerebellar Ataxia

Phase 2/3 Trials with Troriluzole

The Phase 2/3 trial for SCA had two periods: an 8-week randomized, double-blind, placebo-controlled phase followed by a 96-week open-label treatment. The study is being conducted at approximately 15 sites in the United States. The design of the trial was informed predominantly by an advisory panel of the leading ataxia experts that we hosted in February 2016 as well as the observations from peer-reviewed publications in the scientific literature. 141 subjects were randomized to receive a once-daily dose of either placebo or 140 mg troriluzole. Patients were stratified by diagnosis (genotype) and baseline severity (as

measured by the patient's gait SARA score). The primary outcome measure of the trial is the change from baseline in patient SARA score after eight weeks of treatment. The choice of the SARA, a validated scale, as the primary outcome measure was based on the consensus of a panel of national experts, based largely on the validation of the instrument in multiple populations, its effective use in demonstrating efficacy in a trial with riluzole (as shown in the Romano study discussed above), favorable psychometric properties, and its ability to assess a broad spectrum of ataxia-related symptoms. A secondary outcome measure is the patient time to perform an eight-meter walk test. Exploratory outcome measures include improvement as measured using the Unified Huntington's Disease Rating Scale Part IV on functional assessment, Clinical Global Impression of Improvement and the Patient Global Impression of Change. Qualifying subjects have genotypically confirmed diagnosis of the most common SCA subtypes. They must have moderate symptom severity (i.e., SARA scores of 8 to 30 inclusive and be able to walk eight meters without assistance). Almost all subjects who completed the eight-week treatment phase elected to participate in the 96-week open-label extension phase.

In October 2017, we reported topline data from the 8-week randomization period from the Phase 2/3 clinical trial in SCA. At the eight week time point, troriluzole did not statistically differentiate from placebo. After eight weeks of treatment, troriluzole treated subjects demonstrated an improvement of –0.81 points [95% CI: –1.4 to –0.2] on the SARA versus –1.05 points [95% CI: –1.6 to –0.4] improvement in placebo, p-value = 0.52. Placebo response in this genetically defined disorder was higher than expected based upon prior European randomized controlled trials in SCA (Romano et al 2015; Ristori et al 2010). Post-hoc analyses suggested the potential for favorable therapeutic effects of troriluzole, based on numerically superior treatment effects compared to placebo in groups of subjects with less inherent pre-randomization variability on the primary endpoint and also in those, who based on baseline characteristics, would be expected to have greater drug exposures.

In this trial, we observed a favorable safety and tolerability profile of troriluzole, with no drug-related SAEs and low discontinuation rates due to AEs. No randomized subjects demonstrated an elevation of liver transaminases of three-fold or greater than the upper limit of normal; whereas, a similar exposure of the active metabolite, riluzole, is associated with about an 8% rate of such elevations. We believe that the reduced effects on the liver may be attributable to a higher bioavailability that in part reflects mitigated first-pass liver metabolism and enhanced PepT1-mediated absorption. Troriluzole has shown absence of a negative food effect, optimized oral bioavailability and no pattern of clinically significant effects on liver function, presenting a profile that appears distinct from what is described for riluzole in its U.S. prescribing information. This profile, in context of recent Phase 1 data assessing higher doses, will allow for exploration of higher exposures of the active metabolite than allowed by the current Rilutek label.

Post-hoc analyses of the data have led to our continued interest in developing troriluzole in SCA and is also founded on two academic randomized controlled trials studying the active metabolite or troriluzole in diverse populations with cerebellar ataxia. In these two publications, the authors conducted studies of riluzole compared to placebo to assess improvement in patients with ataxias using two different ataxia rating scales. In each study, the authors observed statistically significant improvements in the riluzole treatment groups compared to the placebo groups.

- Ristori et al 2010 demonstrated statistically significant improvement in patients with a variety of cerebellar ataxias: In a paper published in *Neurology* in 2010, Ristori and colleagues reported results from a randomized, double-blind, placebo-controlled trial of patients presenting with cerebellar ataxias of diverse etiologies. Forty subjects were randomized to receive eight weeks of treatment with either placebo or 100 mg riluzole (50 mg riluzole tablets, dosed twice daily). The primary endpoint of the trial was the proportion of patients with a decrease of at least 5 points in the International Cooperative Ataxia Rating Scale (ICARS) after four and eight weeks of treatment, compared with the baseline score. The ICARS quantifies severity of ataxia-related symptoms on a scale of zero to 100, with a higher score indicating greater impairment. The total score is the sum of four subscores which measure a patient's posture and gait (static subscore), limb coordination (kinetic subscore), speech (dysarthria subscore) and oculomotor function (ocular movement subscore). The number of patients with a five-point ICARS drop (the primary outcome measure) was significantly higher in the riluzole treatment group than in the placebo group after four weeks (9 out of 19 versus 1 out of 19; p-value = 0.003) and at eight weeks (13 out of 19 versus 1 out of 19; p-value = 0.001). The patient group treated with riluzole demonstrated superior mean changes on the ICARS scores over eight weeks of treatment as compared to the placebo group (–7.05 versus 0.16; p-value < 0.001). The table below shows the changes in ICARS from baseline in each treatment group after eight weeks of treatment, as well as the change in each subscore category. Only sporadic, mild AEs were reported in the trial. Results from this study suggest that riluzole, which is the active metabolite of troriluzole, may confer acute therapeutic effects after eight weeks of dosing in diverse forms of cerebellar ataxia.

Patients, n (%)	Riluzole Group n = 19	Placebo Group n = 19	P-value
Total ICARS scores	-7.05(4.96%)	0.16 (2.65%)	**<0.001**
Static subscores	-2.11 (2.75%)	0.68 (1.94%)	**<0.001**
Kinetic subscores	-4.11 (2.96%)	0.37 (2.0%)	**<0.001**
Dysarthria subscores	-0.74 (0.81%)	0.05 (0.4%)	**<0.001**
Ocular movement subscores	-0.16 (0.9%)	0.11 (0.66%)	0.838

Bold: Statistical significant over placebo treatment

- Romano et al 2015 demonstrated statistically significant improvement in patients with hereditary cerebellar ataxia (both SCA and Friedreich's ataxia): In an article published in *The Lancet* in 2015, Romano and colleagues described results of a study on the use of riluzole in patients with hereditary cerebellar ataxias over a 12-month period. In this multi-center, double-blind, placebo-controlled trial, sixty subjects diagnosed with either SCA or Friedreich's ataxia (enrolled in a 2:1 ratio) were randomized to receive 12 months of treatment with either placebo or 100 mg riluzole (50 mg tablets of riluzole, twice daily). The primary endpoint was the proportion of patients with a minimum one-point improvement on the Scale for the Assessment and Rating of Ataxia (SARA) after 12 months. The SARA is a validated scale consisting of an eight-item, semi-quantitative performance-based assessment of cerebellar ataxia symptoms that measures impairment on a scale of zero to 40, with a higher score indicating more severe ataxia. This scale was developed to address limitations of the ICARS and has been broadly adopted over the ICARS based on superior practicability, reliability and psychometric properties. Twenty-eight patients were treated with riluzole (19 with SA and 9 with Friedreich's ataxia) and 27 patients were in the placebo group (19 with SA and 8 with Friedreich's ataxia). The proportion of patients in the riluzole treatment group with a decreased SARA score was 14 (50%) versus three (11%) in the placebo group (p-value = 0.002). No severe AEs were reported. Primary and secondary outcome measures are shown in the table below. Mean changes in the SARA scores were reported at three and 12 months of treatment, with riluzole associated with reductions in SARA ratings (1.00 and 1.02 points improvement, respectively) and placebo associated with increases (0.50 and 1.67 points, respectively) and resulting in differences between treatment groups that were statistically significant (p-values of 0.008 and 0.001, respectively). Results from this study suggest the potential efficacy of riluzole, which is the active metabolite of troriluzole, in the treatment of cerebellar ataxia.

Patients, n (%)		Riluzole Group n = 28	Placebo Group n = 19	OR 95% or Mean Difference (95% CI)	P-value
Primary Endpoint: Proportion of patients with improved SARA score at month 12	**Yes**	14 (50%)	3 (11%)	8.00 (1.95 to 32.83)	**0.002**
	No	14 (50%)	24 (50%)		
Proportion of patients with improved SARA score at month 3	**Yes**	14 (50%)	7 (26%)	2.86 (0.92 to 8.89)	0.066
	No	14 (50%)	20 (74%)		
Changes in SARA score from baseline	**Month 3**	-1.00 (1.75)	0.50 (2.28)	-1.50 (-2.59 to 0.40)	**0.008**
	Month 12	-1.02 (2.15)	1.67 (2.63)	-2.68 (-3.98 to 1.39)	**0.001**

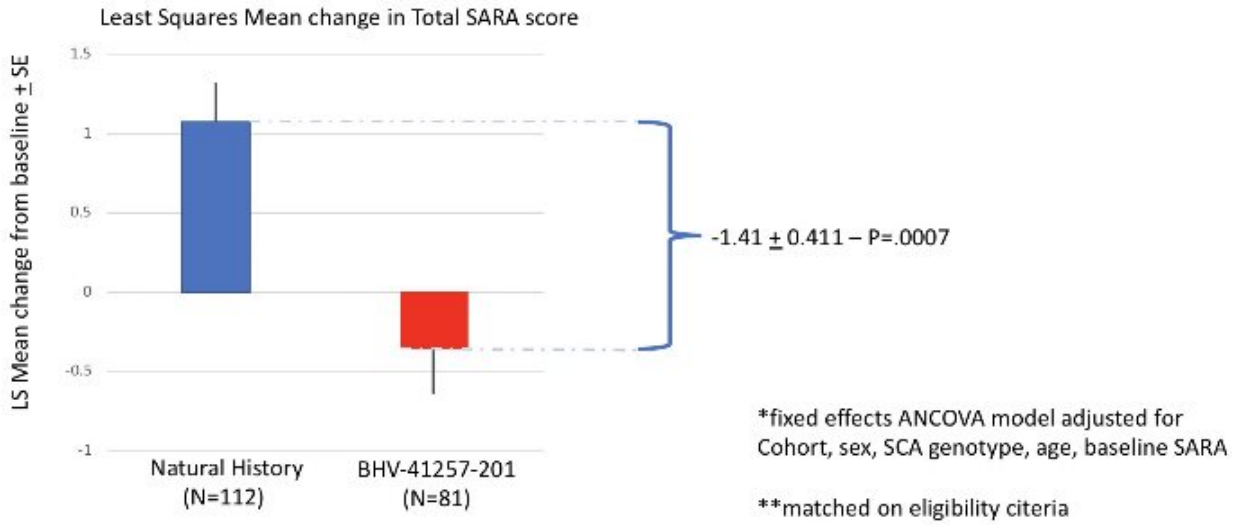
Bold: Statistical significant over placebo treatment

Subsequent to our announcement of the topline results from this trial, we engaged in discussions with the FDA regarding the potential for further development of troriluzole in ataxias, and the FDA expressed willingness to consider a modification of our trial's primary endpoint, the SARA, as an acceptable registrational endpoint. The SARA is a scale consisting of an eight-item, semi-quantitative performance-based assessment of cerebellar ataxia symptoms that measures impairment on a scale of zero to 40, with a higher score indicating more severe ataxia. Subsequent post-hoc analyses of the data from the Phase 2/3 trial has shown trends for therapeutic benefit in certain patient subgroups (for example, those who are projected to have higher drug exposures, those with certain genotypes, and those with SARA assessments with more consistent scores prior to randomization). Further, item-specific analyses of the SARA scale data suggest that certain of the eight items measured by SARA were strongly susceptible to a placebo effect. Based upon our analysis of this data, we proposed the use of a modified SARA scale in future clinical evaluation of troriluzole to the FDA. In November 2018 and February 2019, the FDA provided feedback on the use of the SARA scale and definitive guidance on the use of a modified version of the SARA scale, including a reduction in the number of domains measured and simplified scoring categories.

In March 2019, we announced results of a post-hoc analysis of patients enrolled in the short-term randomization and long-term extension phase of the initial Phase 2b/3 randomized controlled trial of troriluzole in patients with SCA, compared to patients selected from a natural history cohort of SCA patients who were matched on multiple eligibility criteria. The primary efficacy endpoint for this analysis was the change from baseline in the SARA total score after 48 weeks of follow up. Patients from the natural history cohort were matched to patients from the BHV4157-201 trial on SCA Genotype (SCA1, SCA2, SCA3, SCA6), age at baseline (18 to 75 years of age), gender, SARA Score at baseline (≥ 8 and ≤ 30), and initial score on gait item of the SARA ≥ 2.

Based on analysis of covariance least square mean changes after one year were -0.34 points (representing numerical improvement with a 95% confidence interval of -0.94 to 0.26) for 81 troriluzole-treated patients versus +1.07 points (representing numerical decline with a 95% confidence interval of 0.56 to 1.58) for 112 natural history cohort patients (increasing score indicates worsening disease status). The Least Squares Mean difference between cohorts was -1.41 points (95% confidence interval of -2.22 to -0.60) suggesting therapeutic benefits of troriluzole (p=0.0007).

Figure 1: SCA patients treated for 1 year with troriluzole exhibit no disease progression* versus Ashizawa natural history cohort**



The figure above shows an attenuation of disease progression at one year among patients treated with troriluzole versus the natural history cohort in this post-hoc analysis. The difference in progression rates (-1.41) exceeds the minimum clinically important difference of 1.0 on the total SARA score at one year.

The natural history cohort was derived from a prospective study, conducted by the Clinical Research Consortium for Spinocerebellar Ataxias (Ashizawa, et al. 2013) and recruited from 12 ataxia clinics throughout the United States. Patients in Study BHV4157-201 were treated with 140 mg of troriluzole administered daily for one year.

A Phase 3 trial began enrollment in the first quarter of 2019 to evaluate the efficacy of troriluzole in SCA. We believe that the non-statistically significant clinical observations from our first Phase 2/3 trial and open-label extension phase in SCA support our decision to advance troriluzole into a Phase 3 trial that could provide the data needed to serve as the basis for an NDA. We expect to complete enrollment in the Phase 3 trial of troriluzole in SCA in the second quarter of 2020.

Development and Regulatory Pathway

Our clinical program for troriluzole is based on a regulatory pathway under section 505(b)(2) of the U.S. Food Drug and Cosmetic Act that allows reference to data on riluzole for the purpose of safety assessments. In addition, under current FDA interpretations, we believe troriluzole also qualifies as an NCE and thereby is eligible for conventional regulatory data exclusivities.

We are in active dialogue with the FDA to discuss the potential for further development of troriluzole in ataxias and the FDA has expressed willingness to accept a modification of our study's primary endpoint, the SARA, as an acceptable registrational endpoint. Future directions in ataxia will be based on this interaction and results from the extension phase of the ongoing study.

In the fourth quarter 2017, we completed a study demonstrating the bioequivalence of a commercial formulation of 140 mg troriluzole with the Phase 2/3 formulation that is being used in ongoing studies. An additional Phase 1 study has been conducted to assess the safety, tolerability and PK of higher doses of troriluzole (280 mg daily) in healthy young and elderly

adults. We believe the preliminary results suggest an acceptable safety and tolerability profile of this dose and support its exploration in clinical populations.

Overview of Troriluzole in OCD

OCD is a chronic neuropsychiatric disorder characterized by symptoms of obsessions (intrusive thoughts) and compulsions (repetitive behaviors) that can interfere with patients' functional abilities. According to the National Institute of Mental Health, the 12-month prevalence of OCD is 1% of the U.S. adult population, and approximately half of these cases are characterized as severe. First-line treatment for OCD includes cognitive behavior therapy, SSRIs and adjunctive use of atypical antipsychotics. Nonetheless, up to 60% of patients have an inadequate response to conventional intervention strategies. While SSRIs and atypical antipsychotics have been approved for OCD, the majority of patients do not have an adequate response to pharmacologic treatment, and some seek invasive neurosurgical procedures to ameliorate symptoms. Despite the significant public health burden, no novel mechanisms of action have been approved by the FDA for OCD in over two decades.

In multiple case studies, the use of riluzole in patients with refractory OCD has commonly been associated with meaningful improvement of symptoms. A small-scale randomized controlled trial in adults with OCD conducted by a third party showed favorable trends for the use of riluzole in outpatient settings but not in inpatient settings, a difference possibly attributed to the intensive therapeutic interactions often available in an inpatient setting. Another randomized controlled third-party study in refractory OCD failed to demonstrate the efficacy of the adjunctive use of riluzole in 60 pediatric patients with refractory OCD. A third randomized controlled third party trial demonstrated statistically significant therapeutic effects with the adjunctive use of riluzole as compared to adjunctive placebo in 50 adults with refractory OCD. These clinical effects are consistent with findings such as genetic associations of glutamate transporter genes with OCD and increased glutamate concentrations in brain and cerebrospinal fluid of patients with OCD.

A Phase 2/3 double-blind, randomized controlled trial on the use of troriluzole in adults with OCD commenced in late 2017 and, based on learnings from the Phase 2/3 trial in SCA, employs a higher target dose (200 mg daily) than the study in SCA. Enrollment was completed in the first quarter of 2020 and we expect results from the trial in mid-2020. If the results are favorable, we anticipate beginning additional studies necessary to support an NDA.

Overview of Troriluzole in Alzheimer's Disease

Alzheimer's disease is a progressive, fatal neurodegenerative dementia. It accounts for up to 80% of dementias. According to the Alzheimer's Association, in 2016 there were approximately 5.5 million people in the United States with the disease, and that number is expected to escalate rapidly in the coming years as the population ages. Observations in multiple preclinical models, suggests the active metabolite of troriluzole protects from Alzheimer's-related pathology and cognitive dysfunction. Reduced glutamate uptake transporters have been reported in postmortem brain tissue of individuals with Alzheimer's disease and the level of glutamate transporter reduction correlates with cognitive impairment as well as markers of synaptic density and neurodegeneration. Preclinical studies also suggest that age-related memory impairment in rats correlates with decreased glutamate transporter expression and this impairment has been shown to be restored by three-weeks of daily treatment with troriluzole's active drug metabolite. These findings form our rationale for pursuing a Phase 2, proof-of-concept trial of troriluzole in patients with mild to moderate Alzheimer's disease, which we began in July 2018 in collaboration with the Alzheimer's Disease Cooperative Study ("ADCS").

The ADCS is a leading Alzheimer's disease clinical trials research consortium that receives major support from the U.S. National Institute on Aging, a part of the U.S. National Institutes of Health. The ADCS was developed to promote the discovery, development, and testing of new drugs for the treatment of Alzheimer's disease. The randomized controlled trial of troriluzole began in July 2018. In the fourth quarter of 2019, we completed enrollment in the study and announced that the study passed the interim futility analysis. In order to pass the interim futility analysis, troriluzole had to demonstrate numerically greater benefit over placebo on at least one of the two pre-specified criteria at 26 weeks: either (i) cognitive function as measured by the Alzheimer’s Disease Assessment Scale-Cognitive Subscale (“ADAS-cog”) or (ii) hippocampal volume as assessed by magnetic resonance imaging.

Overview of Troriluzole in Other Indications

Given the novel chemical properties of troriluzole and its unique mechanism of action, we believe troriluzole, or another optimized prodrug of riluzole, has the potential for broad applicability across several neurological indications where modulation of brain glutamate has been implicated in underlying disease states. A brief description of potential indications that we could pursue in the future with troriluzole or other optimized prodrugs from our pipeline is summarized below. We will determine the timing and prioritization of additional indications as warranted by emerging data.

Other Orphan Indications

If data from the ongoing extension phase of the SCA trial support the role of troriluzole in the treatment of SCA, then we will explore the role troriluzole in the treatment of other ataxias. Of note, preliminary data is also provided by the Ristori and

Romano randomized controlled trials, which showed improvement in some patients with Friedreich's ataxia, multisystem atrophy of the cerebellar type, sporadic ataxia, antibody-associated ataxia and fragile X-associated tremor/ataxia syndrome. We expect that the next wave of ataxia indications we would pursue, if warranted by data from the SCA trial, would include Friedreich's ataxia and sporadic ataxia.

- *Friedreich's Ataxia:* Friedreich's ataxia is an autosomal recessive disorder associated with progressive cerebellar degeneration with worsening ataxia, areflexia, which is the absence of reflexes, sensory loss, weakness, glucose dysregulation, and cardiomyopathy—often with onset in early childhood. According to the Friedreich's Ataxia Research Alliance, an estimated 6,400 individuals in the United States have Friedreich's ataxia. Treatment is supportive and no pharmacotherapies are approved by the FDA for the treatment of Friedreich's ataxia.

- *Sporadic Ataxia:* Sporadic ataxia, also called idiopathic ataxia, shares symptoms of SCA but is associated with an unknown cause, typically presenting after the age of 40 years and commonly associated with cerebellar degeneration. Sporadic ataxia comprises the majority of patients treated in specialty ataxia clinics. These patients typically have progressive balance difficulties with other features of cerebellar disease such as dysarthria (speech problems), dysphagia (swallowing difficulty), as well as visual symptoms such as double vision. According to Orphanet, the prevalence of sporadic ataxia is between 1 and 9 per 100,000 persons, suggesting that there are between 3,200 and 28,000 individuals with sporadic ataxia in the United States.

Other (Non-Orphan) Cerebellar Disorders

- *Essential Tremor:* Like SCA, the pathophysiology of essential tremor ("ET") reflects underlying cerebellar dysfunction. ET is the most common type of tremor, characterized by action and postural tremor in the upper extremities and/or head and voice tremor. The prevalence of ET is approximately four times that of the second most common tremor disorder, Parkinson's disease. ET can be highly disabling, as many ET patients cannot write, type, drink, or feed themselves due to tremor. ET is a progressive disease and with time, the tremor becomes more severe and disabling. Currently, only two medications, primidone and propranolol, are commonly employed as first-line symptomatic treatment of ET, but these are ineffective in 40% of ET patients and none of the available medications are FDA-approved for ET. Therefore, a novel symptomatic therapy for ET could serve an important unmet medical need for a substantial population. Preclinical studies with troriluzole in mouse genetic and toxicity models of ataxia have shown reductions in tremor. Supported by this data, we are developing a Phase 2 study of troriluzole in subjects with ET in collaboration with the Tremor Research Group, a national, independent, non-profit organization of scientific investigators.

Broader Neuropsychiatric Indications

Based upon preclinical and preliminary clinical work, we also believe there are several potential expansions for troriluzole, or another optimized prodrug of riluzole from our pipeline, including potential for therapeutic application in a broad range of neuropsychiatric conditions, such as anxiety disorders, mood disorders and neurodegenerative disorders.

Other Indications Being Pursued by our Collaborators

Our collaborators are exploring the potential applicability of troriluzole beyond cerebellar and neuropsychiatric indications, including in melanoma (Rutgers University and Dana Farber Cancer Institute) and glioblastoma (Johns Hopkins University). The oncology collaborations with Rutgers and Johns Hopkins are based upon the mechanistic rationale that some tumors overexpress glutamate receptors, the central role that glutamate may have in cancer metabolism and the effect of glutamate on the tumor microenvironment. Troriluzole is currently being assessed in a Phase 1 study (NCT03229278) to evaluate the safety in combination with nivolumab and pembrolizumab in patients with metastatic or unresectable cancer (including melanoma). The study is being conducted at Rutgers University.

Discontinuation of Development of Troriluzole for GAD

During 2019, we were in the process of developing troriluzole as a potential FDA-approved treatment option for patients suffering from Generalized Anxiety Disorder (GAD). In February 2020 we reported negative topline results from our Phase 2/3 clinical trial evaluating troriluzole compared to placebo. This eight-week trial randomized 402 adult patients equally at more than 45 centers in the United States. In this trial, troriluzole monotherapy at 100mg twice daily did not differentiate from placebo on the primary endpoint of the mean change from baseline on the Hamilton Anxiety Rating Scale (HAM-A) after eight weeks of treatment. The efficacy results do not support continued development of troriliuzole as a monotherapy in GAD.

Our Product Candidate BHV-0223 for ALS

Overview of Amyotrophic Lateral Sclerosis and Limitations of Current Treatments

ALS is a progressive neurodegenerative motor neuron disease that affects nerve cells in the brain and the spinal cord. The disease belongs to a group of disorders known as motor neuron diseases, which are characterized by the gradual degeneration and death of motor neurons. ALS affects up to 20,000 individuals in the United States and typically presents in patients with painless muscle weakness, trouble swallowing and muscle atrophy that ultimately progresses to paralysis, impaired breathing and death.

Since the FDA's approval of riluzole in 1995, only two agents have been approved by the FDA in ALS drug therapeutics and riluzole is the only agent indicated to enhance survival and/or time to tracheostomy. Several therapies are currently in clinical trials. Riluzole itself has pharmacokinetic and pharmaceutic limitations that have restricted its broader clinical application. Riluzole tablets have 60% bioavailability, attributed to high first-pass metabolism in the liver that is thought to be mediated via metabolism by the heterogeneously expressed CYP1A2 enzyme. This metabolic route is also thought to contribute to the high pharmacokinetic variability associated with riluzole. In addition, riluzole is associated with reduced exposure when taken with meals, or a negative food effect, resulting in the guidance to take riluzole within a period of fasting (one hour before or two hours after a meal) for each of two daily doses. In addition, riluzole has dose-dependent effects on LFTs that necessitate periodic LFT monitoring and is associated with transient liver transaminase elevations. At riluzole daily doses of 100 mg, drug discontinuation is required in 2% to 4% of subjects. However, this has not been observed with lower doses, an important observation as the planned commercial dose of BHV-0223 represents a lower drug load than the FDA-approved dose of riluzole while delivering similar exposures. The drug substance of riluzole itself has other intrinsic limitations that complicate the ability to produce non-tablet formulations, including very low solubility in water, poor oral palatability, pH dependent chemical stability and intense oral numbness if administered directly to the oral mucosa.

Our Clinical Program for BHV-0223 in ALS

BHV-0223 is a formulation of riluzole designed to advance beyond the limitations of riluzole tablets for application in ALS. BHV-0223 is a sublingual ODT of riluzole, that makes use of proprietary Zydis ODT technology that we have licensed from Catalent for use with riluzole. Catalent's ODT technology allows us to develop a form of riluzole that is fast-dissolving and which we expect will mitigate many of the shortcomings associated with the solid oral dosage form of riluzole. Based on over 20 years of global clinical experience with riluzole, we expect that BHV-0223 is likely to be well tolerated in chronic dosing. To date, we have conducted two Phase 1 trials of BHV-0223 in healthy volunteers.

We believe BHV-0223 offers the following potential advantages, compared to the solid oral dosage form of riluzole, in the treatment of ALS:

- **Ease of Administration**—An early symptom in many patients with ALS is difficulty swallowing, which makes it especially challenging for ALS patients to swallow traditional riluzole tablets. In contrast, using our licensed ODT technology, ALS patients will benefit from a fast-dissolving tablet that does not require swallowing or administration of liquids.

- **More Predictable Pharmacokinetic Performance**—Because some ALS patients experience difficulty swallowing, they often crush their solid riluzole tablets and take with food in order to ease administration, which, in addition to resulting in mucosal numbness, leads to uncertain pharmacokinetic performance as riluzole is supposed to be administered on an empty stomach. With BHV-0223, ALS patients will not have to crush or alter the form of administration, leading to more predictable pharmacokinetic performance. In our Phase 1 trials, we have observed that BHV-0223 is associated with less pharmacokinetic variability than 50 mg riluzole.

- **Lack of Food Effect on Overall Exposure (as assessed by AUC)**—Prescribing instructions for riluzole tablets state that it should be taken at least an hour before, or two hours after, a meal to avoid food-related decreases in bioavailability. Patients who do not strictly adhere to these fasting requirements or administer crushed riluzole in food may not be obtaining desired therapeutic levels of riluzole. BHV-0223 was designed to readily be absorbed sublingually and directly enter the blood stream without passing through the intestines. Since absorption of BHV-0223 occurs through the vasculature under the tongue, we do not anticipate fasting requirements. We believe this attribute will be particularly beneficial for late-stage ALS patients who require a continuous feeding tube for nutrition. Topline results from a food effect assessment with a Phase 1 study, demonstrated bioequivalent exposure (i.e., overall exposures as measured by AUC) for BHV-0223 40 mg when administered under fed or fasted states. C_{max} concentrations under fed and fasted conditions differed, as is commonly observed with sublingual formulations; however, it is generally thought that efficacy of riluzole is driven by overall extent of exposure (AUC).

- **Reduced Drug Load and Liver Exposure**—Riluzole is associated with dose-dependent liver function increases attributable to high dose loads and extensive liver metabolism. Since BHV-0223 is sublingually absorbed, first-pass liver metabolism is mitigated and lower doses of riluzole are needed to be administered, thereby reducing potential risk for hepatic enzyme elevations.

BHV-0223 has been dosed in approximately 150 healthy subjects in Phase 1 studies and in patients with ALS for the assessment of PKs, safety and tolerability. AEs have generally been mild and transient; no treatment-related SAEs have been observed. In January 2018, we announced topline results of a bioequivalence study. Topline results confirmed that sublingual BHV-0223 (40 mg) achieves bioequivalent exposures relative to Rilutek (50 mg). In the study, 138 healthy volunteers were administered BHV-0223 and Rilutek under fasted conditions. In the pre-specified primary analysis, BHV-0223 achieved area-under-the-curve and peak exposures of approximately 90% and 113%, respectively, compared to those generated by generic riluzole. The 90% confidence intervals were within the 80% to 125% range that is used to define bioequivalence. In this study, 67 of these 138 subjects were also assessed after being administered BHV-0223 (40mg) under fed conditions. Topline results from a food effect assessment with a Phase 1 study, demonstrated bioequivalent AUC exposures for BHV-0223 40 mg when administered under fed or fasted states. C_{max} concentrations under fed and fasted conditions differed, as is commonly observed with sublingual formulations; however, it is generally thought that efficacy of riluzole is driven by overall extent of exposure (AUC). In addition, we completed dosing in three other studies: assessing tolerability of a single dose in dysphagic patients with ALS; assessing the tolerability of BHV-0223 with two-month dosing in ALS patients; and, assessing swallowing mechanics via videofluorscopic imaging in healthy volunteers after a single dose of BHV-0223. Results from these studies show that BHV-0223 is generally well tolerated and can be safely administered to patients with ALS and healthy volunteers, without evidence for novel adverse events that have not already been associated with Rilutek tablets. BHV-0223 is associated with higher rates of oral numbness (transient and generally mild) than Rilutek tablets, as expected due to the route of administration.

Development and Regulatory Pathway

In December 2016, the FDA granted orphan drug designation of BHV-0223 for the treatment of ALS, with eligibility for orphan exclusivity contingent on a showing that BHV-0223 is clinically superior to Rilutek, a previously approved form of riluzole, as well as any other versions of riluzole that may be approved for the same indication before BHV-0223 is approved. Clinical superiority may be demonstrated by showing that a drug has greater effectiveness than the approved drug, greater safety in a substantial portion of the target population, or otherwise makes a major contribution to patient care.

After a pre-NDA meeting with the FDA in the first quarter of 2018, we submitted a NDA to the FDA to pursue the regulatory approval of BHV-0223 for ALS under Section 505(b)(2) of the U.S. Federal Food, Drug, and Cosmetic Act in September 2018. The PDUFA date was in July 2019.

In July 2019, we announced that we received a CRL from the FDA for the 505(b)2 application seeking approval for BHV-0223 (riluzole) for the treatment of ALS. The sole issue identified in the CRL relates to an FDA concern regarding the use of an API manufactured by Apotex and used in the drug product supplies for the bioequivalence study in 2017. In the CRL, the FDA stated that it provided recommendations to Apotex regarding the information needed to qualify previous API batches manufactured at Apotex during the time period in question. We have been subsequently informed by the manufacturer that the manufacturer had an exemption from the FDA to supply riluzole to the U.S. market during that time period. We have been in contact with the FDA's CMC group and Apotex to resolve the matter and we have already submitted additional information to the FDA regarding this issue. We note that the API for commercial supply of BHV-0223 is currently sourced from another supplier, with whom no CMC issues have been identified. The FDA did not cite any other concerns in their CRL regarding BHV-0223.

Glutamate NMDA Receptor Antagonism

An NMDA receptor antagonist is a type of glutamate antagonist that works to inhibit the action of NMDA receptors which may play a role in degenerative diseases that affect the brain. BHV-5000 is an oral prodrug of the intravenous drug lanicemine, also referred to as BHV-5500, both of which we in-licensed from AstraZeneca AB ("AstraZeneca"). In addition to being orally available, BHV-5000 is a first-in-class, low-trapping, NMDA receptor antagonist with differentiating pharmacologic properties from other agents in development targeting this receptor. The unique property of low-trapping antagonists is their ability to uncouple from the NMDA receptor more freely than other agents, a property that is thought to contribute to their mitigated risk of dissociative effects as has been observed in the clinic. Lanicemine, the active metabolite of BHV-5000, binds within the NMDA channel pore and functionally blocks the flow of charged ions through the NMDA receptor complex. Lanicemine was initially advanced by AstraZeneca into clinical trials for the potential treatment of stroke, but this development was discontinued as initial results did not warrant continued development for this indication. We are developing BHV-5000 as a potential best-in-class NMDA receptor antagonist for treatment of neuropsychiatric indications.

Our Product Candidate BHV-5000 for Neuropsychiatric indications, such as Rett Syndrome

Overview of Rett Syndrome and Limitations of Current Treatments

Rett syndrome is a severe neurodevelopmental disorder resulting from an X-linked dominant gene mutation ("MECP2"). As a result, it occurs almost exclusively in females. After six to 18 months of apparently normal development, patients with Rett syndrome show global deceleration of psychomotor development and subsequent loss of acquired cognitive and motor skills, such as the loss of speech. Patients may also develop pathognomonic stereotyped hand movement or display autonomic dysfunction such as breathing irregularities, including brain-mediated episodes of transient respiratory suppression, or apneic periods. With intensive care, patients may survive into adulthood, yet they are severely physically and cognitively impaired. Rett syndrome occurs in all racial and ethnic groups and occurs worldwide in approximately 1 in every 10,000 live female births. There are approximately 15,000 females with Rett syndrome in the United States. No approved treatments for Rett syndrome are currently available and care is supportive.

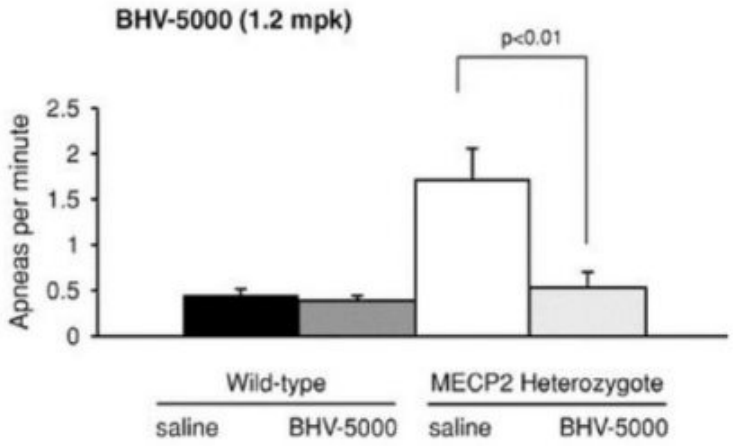
Our Clinical Program for BHV-5000 in Rett Syndrome

BHV-5000 and lanicemine have been observed to ameliorate the phenotype in transgenic mouse models of Rett syndrome, models which recapitulate key clinical features, such as irregular breathing, apneic periods, abnormal electroencephalogram ("EEG") with altered seizure threshold. Based on the preclinical experience, we have chosen to advance BHV-5000 into clinical trials for the treatment of breathing irregularities associated with Rett syndrome. The orally bioavailable prodrug BHV-5000, which was developed as an advancement on the intravenously administered lanicemine, offers an improved route of administration over lanicemine, and has thus been positioned as the lead candidate in this series. After ingestion, BHV-5000 is rapidly cleaved by the enzyme dipeptidyl peptidase-4 ("DPP-4"), yielding the active metabolite lanicemine. AstraZeneca studied BHV-5000 in a Phase 1 single and multiple ascending dose trial. Doses up to 95 mg of BHV-5000 were studied and were observed to be well tolerated without any clinically relevant safety issues. Among the AEs reported were three cases of euphoria, three cases of hallucination, or visual distortion, and eight cases of nystagmus, a visual condition. These AEs are consistent with NMDA receptor antagonism. After oral ingestion, systemic concentrations of BHV-5000 were observed to be very low, typically below the limit of quantification.

Preclinical Studies and Previous Clinical Trials with Lanicemine and BHV-5000

As noted above, BHV-5000 and lanicemine have been observed to ameliorate the phenotype in transgenic mouse models of Rett syndrome. In particular, BHV-5000 has been observed to reduce the number of apneic episodes that are driven by dysfunctions in the central nervous system. These preclinical findings are consistent with those reported for the NMDA receptor antagonist, ketamine, and have been observed at concentrations that have been well tolerated by healthy volunteers in clinical trials. The potential relevance of the preclinical models with this mechanism of action are supported by anecdotal reports on the incidental use of ketamine in patients with Rett syndrome that have been associated with clinical improvements.

The figure below shows results from a preclinical study with BHV-5000 in a transgenic mouse model. Transgenic (heterozygous for MECP2 mutation) and wild-type mice were administered a single dose of saline or BHV-5000 followed by measurement of apneic episodes. Acute administration of BHV-5000 was associated with a marked reduction in the number of apneic episodes.



Lanicemine has been administered to approximately 770 subjects in single or multiple doses in 18 clinical trials conducted by AstraZeneca and has been observed to be generally well tolerated. In clinical experience with lanicemine, the most common adverse event was dizziness. CNS-type AEs from Phase 1 trials also included headache, somnolence, asthenia, impaired concentration and dysesthesias. In one study, formal assessment of cognitive function in healthy volunteers revealed improvement in some components of memory, decreased vigilance and decreased calmness. Hypotension and hypertension have been reported as AEs, with low mean increases in blood pressure reported in some studies (e.g., 4 - 8 mmHg supine systolic blood pressure; 2 - 4 mmHg supine diastolic blood pressure —which occurred at doses higher than considered necessary for therapeutic effects). AEs related to dissociation were infrequent but more common in the lanicemine group compared to placebo. AEs potentially associated with abuse potential were low but more common in the lanicemine group than the placebo group. No pattern of clinically meaningful differences between lanicemine and placebo were noted on physical exam, clinical laboratory test results or electrocardiogram ("ECG") results.

Approximately 40 healthy volunteers have been dosed with single or multiple doses of BHV-5000 in clinical trials conducted by AstraZeneca, and it was observed to be well tolerated without any clinically relevant safety issues. We believe BHV-5000 has no pharmacologic activity of its own and is rapidly metabolized to lanicemine in humans. After oral ingestion, systemic concentrations of BHV-5000 are very low, typically below the limit of quantification.

Nonclinical Toxicology Experience with Lanicemine and BHV-5000

In nonclinical studies, the major dose limiting effects in both rats and dogs were central nervous system effects, which appeared rapidly and included ataxia, head weaving, depressed activity, and, at very high doses, convulsions. At pharmacologically effective doses, lanicemine did not elicit adverse effects on learning, memory or attention. Small increases in heart rate and blood pressure at very high doses were observed. In the rat with daily dosing, effects on adrenal gland, heart tissue, thyroid and kidney were apparent at very high doses—more than 10-fold the proposed maximum clinical exposure. These effects were not seen in dogs and intermittent dosing in the rat was not associated with effects on the kidney or heart. At very high doses, evidence of neuron degeneration was apparent in very few neurons, a finding that is associated with glutamate antagonists. Based on these preclinical findings, which were consistent with other NMDA receptor antagonists, such as ketamine, lanicemine was advanced into clinical trials. Toxicology studies with BHV-5000, up to 2 weeks in rats and dogs, revealed findings consistent with lanicemine, which was expected given the negligible concentrations of BHV-5000 as compared to the active metabolite, lanicemine. A GLP neurotoxicology study is ongoing, as required for this class of agent, in order to confirm maximum acceptable therapeutic exposures in clinic populations.

Clinical Development of BHV-5000

In July 2017, we received orphan drug designation from the FDA for BHV-5000 for the treatment of patients with Rett syndrome. Our clinical program for BHV-5000 will build upon AstraZeneca's previous development efforts for lanicemine. In support, BHV-5000 is rapidly metabolized to lanicemine and, in a Phase 1 trial, concentrations of BHV-5000 were detectable in only a few subjects who received the highest dose. As a result, we intend to rely on long-term Good Laboratory Practices ("GLP") toxicology, reproductive toxicology and carcinogenicity studies of lanicemine to potentially expedite the safety package for BHV-5000.

A lead formulation has been selected for advancing into a Phase 1 clinical trial of BHV-5000, to bridge PK with a prior formulation. Enrollment in this study commenced in the fourth quarter of 2017, with the first patient dosed in January 2018. All 10 subjects have been enrolled in a combined single and multiple dose trial (8 active; 2 placebo) and completed study participation. BHV-5000 was observed to be well tolerated with no clinically relevant safety signals. These results are consistent with prior experience. That is, prior formulations of BHV-5000 had been dosed in approximately 40 healthy subjects in a Phase 1 trial conducted by AstraZeneca, and was observed to be well tolerated with no clinically relevant safety signals. Its active metabolite, lanicemine, has been administered intravenously in clinical trials conducted by AstraZeneca to approximately 770 subjects, in single or multiple doses, and has been observed to be generally well tolerated with most AEs being mild and transient in nature.

Currently, we are conducting neurotoxicology studies that are required for NMDA antagonist drugs to define acceptable clinical exposures. Based on these results, an additional Phase 1 study may be required to establish the dose that would subsequently be used in a randomized controlled trial of BHV-5000. One of our planned indications for BHV-5000 is Rett syndrome, based on the ability of BHV-5000 and its active metabolite to favorably impact breathing abnormalities and global brain biochemical abnormalities in transgenic mouse models. The Phase 2/3 trial is being developed in collaboration with experts in the field. Potential other conditions include depression, neuropathic pain and other disorders involving NMDA receptor dysfunction. Nonclinical studies are ongoing to support future trials.

Major Depressive Disorder

Major depressive disorder ("MDD") is the leading cause of disability worldwide, according to the World Health Organization. In the United States, the prevalence rate is approximately 7%. Despite the approval of over two dozen agents, therapeutic effects are limited. More than one-third of patients who complete an initial course of antidepressant treatment will not achieve a satisfactory response, and as many as 20% of patients have chronic depression despite multiple interventions. The only class of agents approved for this population of inadequate responders (also deemed treatment resistant depression) is atypical antipsychotic medications (e.g., aripiprazole, quetiapine, olanzapine-fluoxetine combination and brexpiprazole), agents associated with significant short-term and long-term side effect burdens (sedation, metabolic syndrome, obesity, extrapyramidal side effects that can include akathisia and elevated risk of tardive dyskinesia). Other agents in clinical stages of development for major depressive disorder include rapastinel (Allergan, in Phase 2 testing), esketamine (Johnson & Johnson, in Phase 3 testing), and ALKS-5461 (a combined formulation of buprenorphine and samidorphin developed by Alkermes, which has reported positive Phase 3 data).

Clinical findings of antidepressant effects of the NMDA receptor antagonist ketamine have provided a link between the NMDA receptor function and depression and a rationale for testing BHV-5000 as an antidepressant. In nonclinical studies, BHV-5000's active metabolite is active in models of depression and anxiety. These data prompted a line of investigation with lanicemine that included four randomized controlled trials conducted by AstraZeneca in patients with treatment resistant depression, overall suggesting an adequate safety and tolerability profile and potential for therapeutic benefit. However, the clinical data to date has not established clear efficacy and additional trials are needed.

Neuropathic Pain

Neuropathic pain is a chronic condition caused by dysfunctional or damaged nerves. Neuropathic pain can be a debilitating and common problem affecting approximately 10% of adults in the United States. Despite the availability of multiple approved drugs, including Lyrica, and guidelines for the treatment of neuropathic pain, treatment of this condition remains a major therapeutic challenge. Existing analgesics are often ineffective, can cause serious side effects and have abuse potential that limits widespread use. Increased NMDA receptor activity is known to contribute to central sensitization in neuropathic pain. NMDA receptor antagonists have been shown to reduce hyperalgesia and pain in animal models of neuropathic pain induced by nerve injury and diabetic neuropathy. Clinically used NMDA receptor antagonists, including ketamine and dextromethorphan, can be effective in patients suffering from neuropathic pain syndromes. The clinical use of robust NMDA antagonists, such as ketamine, is limited due to dissociative, psychotomimetic and abuse potential properties. Novel NMDA receptor antagonists, such as BHV-5000, that are not associated with the psychotomimetic effects and abuse potential could lead to better management of neuropathic pain without causing serious side effects.

MPO Platform

Our Product Candidate Verdiperstat for Multiple System Atrophy

Verdiperstat is a first-in-class, potent, selective, brain-permeable, irreversible myeloperoxidase ("MPO") enzyme inhibitor that we are developing for the treatment of multiple system atrophy ("MSA"). Myeloperoxidase generates an array of cytotoxic oxidants and is a key driver of oxidative and inflammatory processes that underlie a broad range of disorders. MPO is plays a key role in neurodegenerative, inflammatory, and immune-mediated diseases, including MSA, Alzheimer’s disease, Parkinson’s disease, multiple sclerosis, ischemic and hemorrhagic forms of stroke, epilepsy, depression and other neuropsychiatric disorders. Clinical and experimental studies have revealed the detrimental role of MPO. Hence, suppressing MPO may be a novel treatment approach for these disorders.

Verdiperstat was progressed through Phase 2 clinical trials by AstraZeneca. Seven clinical studies have been completed by AstraZeneca, including four Phase 1 studies in healthy subjects, two Phase 2a studies in subjects with Parkinson’s disease, and one Phase 2b study in subjects with MSA.

In September 2018, we entered into an exclusive license agreement with AstraZeneca for verdiperstat (formerly named AZD3241). In February 2019, we received orphan drug designation from the FDA for the treatment of MSA. Verdiperstat has also received orphan drug designation for the treatment of MSA from the European Commission upon recommendation from the European Medicines Agency's Committee for Orphan Medicinal Products.

Overview of Multiple System Atrophy and Limitations of Current Treatments

Multiple System Atrophy

MSA is an orphan disease that is an adult-onset, fatal, neurodegenerative disease characterized by progressive autonomic failure, parkinsonian features, and cerebellar and pyramidal features in various combinations and degrees of severity. It

invariably leads to death after an average of 6 to 10 years from symptom onset. No disease-modifying treatment currently exists; only symptomatic and palliative approaches are available.

Multiple system atrophy patients are divided into 2 groups, those with parkinsonian features as the predominant symptoms ("MSA-P") and those for whom cerebellar ataxia is the predominant symptom ("MSA-C"). Approximately 60-80% of MSA patients in Europe and North America have the MSA-P subtype, whereas 65-85% of MSA patients in Japan and Korea have the MSA-C subtype. According to the consensus statement by the American Autonomic Society and American Academy of Neurology in 2007, the diagnosis of MSA includes 3 categories: definite, probable, and possible MSA. Definite MSA requires the neuropathological findings of widespread and abundant CNS α-synuclein-positive glial cytoplasmic inclusions in association with neurodegenerative changes in striatonigral or olivopontocerebellar structures. Probable and possible MSA diagnoses are based on clinical symptoms and neurologic examination findings. The diagnosis of MSA can be aided by laboratory investigations, structural and functional imaging, and a variety of other diagnostic tools. The defining molecular and cellular neuropathology of MSA is the widespread presence of glial cytoplasmic inclusions ("GCIs") containing fibrilized α-synuclein protein in oligodendrocytes. Thus, MSA is thus considered an α-synucleinopathy, similar to Parkinson's disease and dementia with Lewy bodies, but with distinct pathological and clinical features. The defining neuropathology of MSA upon postmortem examination includes variable degrees of olivopontocerebellar atrophy and striatonigral degeneration, reflecting the ataxia and parkinsonism, respectively, that are present during life. Neurodegenerative changes affecting the central autonomic nervous system are also evident, and include the hypothalamus, noradrenergic and serotonergic brainstem nuclei, dorsal nucleus of the vagus nerve, nucleus ambiguus, intermediolateral columns of the spinal cord, and Onuf's nucleus. Although the pathophysiological mechanisms underlying MSA remain unclear, evidence from preclinical models and postmortem studies in humans suggest that formation of GCIs is associated with oxidative stress, neuroinflammation, loss of neurotrophic support, and ultimately, neuronal cell death.

Current Treatments

There are currently no approved drugs for the treatment of disease progression in MSA. Existing medical management is focused exclusively on attempting to reduce symptoms by using drugs approved for various other indications along with dietary supplements. Use of these agents in MSA, however, is not supported by high-quality evidence from randomized, double-blind, placebo-controlled trials, and it is widely accepted that none of these drugs is particularly effective in alleviating MSA symptoms.

The dopaminergic agent, levodopa, which is used in Parkinson's disease, is commonly used in MSA at high doses and may reduce motor symptoms, including rigidity and bradykinesia, in a subset of patients. Amantadine is used in MSA and is purported to provide some benefits. Botulinum toxin is used in MSA and may temporarily reduce movement disorder symptoms, such as dystonias. The mitochondrial micronutrient coenzyme Q10 is also used in MSA because of its antioxidant properties. Additional nonspecific measures may be used in MSA to manage autonomic symptoms, sleep disorders, depression, and other clinical manifestations. Non-pharmacological supportive/palliative measures are commonly used in MSA. In terms of motor symptoms, physical and occupational therapy, employment of assistive devices, and speech and language therapy may be used. In terms of autonomic symptoms, intermittent or permanent urethral or suprapubic catheterization may be used for urinary symptoms and elastic stockings and adequate salt and fluid intake may be used for orthostatic hypotension.

The treatment strategies noted above focus on alleviating and managing symptoms rather than modifying the course of MSA. Specifically, there are no medications that can stop, or even slow down, the relentless progression of MSA. In contrast, verdiperstat offers a novel mechanistic approach of reducing MPO activity, which is believed to be involved in the molecular pathogenesis of the disease. This reduction of MPO activity may result in slowing down the progression of MSA.

Nonclinical Studies and Previous Clinical Trials

Non-clinical

The nonclinical pharmacodynamics, PKs, and toxicology of verdiperstat have been extensively characterized.

Verdiperstat effectively inhibits MPO in vivo and is efficacious in two different MSA models suggesting disease modification potential in MSA. The effect on motor performance, as well as the neuroprotective effect of verdiperstat, was evaluated in a mouse model of early MSA. Mice received vehicle or verdiperstat via oral gavage for 28 days. Significant neuroprotection (Figure X) was demonstrated by verdiperstat, with preservation of neurons at the level of substantia nigra pars compacta, striatum, cerebellar cortex, pontine nuclei, and inferior olivary complex, as well as functional recovery (Figure Y) measured by 4 different behavioral tests (motor score, stride length test, open field activity, rearing). The verdiperstat effect was related to suppression of microglial activation without detectable changes in astrogliosis.

Effects on neuroprotection and microglial activation of treatment with verdiperstat after disease onset were evaluated in a mouse model of advanced MSA. Treatment with verdiperstat was initiated after disease onset and continued for 19-20 days. No

improvements in behavioral tests or neuroprotection occurred, but a marked reduction in microglial activation in the brain (SNc, pontine nuclei, inferior olives, corpus callosum) was observed.

A comprehensive toxicology data package has been developed on verdiperstat including single dose toxicity, repeat-dose toxicity (including chronic toxicity in rats and dogs), genetic toxicity, reproductive and developmental toxicity, and special toxicity.

Previous Clinical Trials

Seven clinical studies have been completed, all sponsored by AstraZeneca. These studies include one Phase 2b study in subjects with MSA, two Phase 2a studies in subjects with Parkinson's Disease, and four Phase 1 studies in healthy volunteers, that inform PK, metabolic interactions, safety, tolerability and efficacy. A total of 234 subjects have received verdiperstat to date. A total of 167 subjects in Phase 1 and 2 studies have received multiple doses of verdiperstat (D0490C00002, D0490C00003, D0490C00004, D0490C00005, and D0490C00023), ranging from 50 to 600 mg BID for up to 12 weeks and 900 mg BID for 2.5 days. A total of 67 subjects have received single doses of verdiperstat in Phase 1 studies (Studies D0490C00001 and D0490C00012), ranging from 1 to 50 mg. Overall, the PK and safety profile from the Phase 1 studies provided support for the investigation of verdiperstat at doses up to 600 mg BID in Phase 2 studies.

In a Phase 2b study, subjects with MSA were randomized to receive verdiperstat 300 mg BID, verdiperstat 600 mg BID, or placebo for 12 weeks; efficacy assessments were exploratory. The verdiperstat groups exhibited numerical, but not statistically significant, improvements compared to the placebo group that were dose-related, based on changes in the Unified MSA Rating Scale scores from baseline to Week 12. Placebo-treated subjects worsened by 4.6 points, while BHV-3241 treated subjects showed less worsening of 3.7 points at the 300-mg dose and 2.6 points at the 600-mg dose, suggesting a dose-response relationship. Changes on positron emission tomography (PET) imaging with [11C]-PBR28 binding to translocator protein (TSPO), a marker for microglial activation, did not demonstrate statistically different changes between groups. Verdiperstat treatment for 12 weeks (at doses of 300 mg BID and 600 mg BID) showed statistically significant reductions in certain measures of MPO specific activity in plasma. These results support the intended mechanism of action of verdiperstat. Verdiperstat treatment was generally safe and well-tolerated in MSA subjects at doses of 300 mg and 600 mg BID.

Data from two Phase 2a studies in subjects with Parkinson's disease showed reductions in MPO activity for subjects treated with verdiperstat 600 mg BID compared with placebo-treated subjects, offering further support for the mechanism of action of verdiperstat (i.e., reduced microglial activation). The 300-mg BID dose was safe and well tolerated, and the 600-mg BID dose was generally safe and well tolerated in most subjects.

Our Clinical Program for Verdiperstat for Multiple System Atrophy

In January 2019, we received a may-proceed letter from the FDA regarding the continued development of verdiperstat in a Phase 3 randomized controlled trial in patients with MSA. The Phase 3 trial is a randomized, double-blind, placebo-controlled, parallel group study. Planned recruitment is 252 subjects across approximately 56 study sites in 7 countries (US, UK, France, Germany, Austria, Italy and China). The dose of verdiperstat (based on the Ph2 study) is 600 mg twice daily. The primary outcome measure is a modified version of the Unified MSA Rating Scale that was developed by Biohaven based on discussions with the FDA. We began enrollment in the trial in the US in July 2019. Enrollment in EU countries is expected to begin in the first quarter of 2020. The China IND approval to join the Phase 3 clinical trial of verdiperstat for the treatment of MSA was obtained in the fourth quarter of 2019.

Clinical Program for Verdiperstat for Amyotrophic Lateral Sclerosis

Another potential target indication is ALS. In September 2019, verdiperstat was selected to be studied in the HEALEY ALS Platform Trial, which is being conducted by the Sean M. Healey & AMG Center for ALS at MGH ("Healey Center") in collaboration with the Northeast ALS Consortium ("NEALS") clinical trial network. Promising investigational drugs were chosen for the HEALEY ALS Platform Trial through a competitive process, with the Healey Center providing partial financial support to successful applicants. In January 2020, we announced that the FDA had notified the Healey Center that they may proceed with clinical investigation of verdiperstat in the HEALEY ALS Platform Trial. A Phase 2/3 clinical trial of verdiperstat is anticipated to begin in the first quarter of 2020.

Preclinical

TDP-43

In May 2019, we entered into an agreement with FCCDC for FCCDC's TDP-43 assets (the "FCCDC Agreement"). The FCCDC Agreement provides the Company with a plan and goal to identify one or more new chemical entity candidates for preclinical development for eventual clinical evaluation for the treatment of one or more TDP-43 proteinopathies. In connection with the FCCDC Agreement, Biohaven and FCCDC have established a TDP-43 Research Plan that provides for certain milestones to be achieved by FCCDC, and milestone payments to be made by us.

University of Connecticut License Option

In October 2018, we signed an exclusive, worldwide option and license agreement with the University of Connecticut for the development and commercialization rights to UC1MT, a therapeutic antibody targeting extracellular metallothionein ("MT"). Extracellular MT has been implicated in the pathogenesis of autoimmune and inflammatory diseases. Under this agreement, we have the option to acquire an exclusive, worldwide license to UC1MT and its underlying patents to develop and commercialize throughout the world in all human indications.

Kleo Pharmaceuticals, Inc.

From August 2016 through November 2018, we made several investments to acquire a minority equity interest in Kleo Pharmaceuticals, Inc. ("Kleo") a privately held, development-stage company founded by a professor of chemistry and pharmacology at Yale that is developing small molecule immunotherapies that emulate biologics to fight cancers and infectious diseases. We have also entered into a consulting agreement with Kleo to assist Kleo with clinical development. To date, no services have been provided under this agreement.

On August 29, 2016, we entered into a stock purchase agreement with Kleo to purchase 3,000,000 shares of Kleo's common stock at an initial closing, with a commitment to purchase an aggregate of 5,500,000 additional shares of common stock, in each case at a share price of $1.00 per share. We purchased 3,000,000 shares upon the initial closing on August 31, 2016, and the remaining 5,500,000 shares were purchased in four equal tranches of 1,375,000 shares, which we completed in March, June and October 2017, and January 2018. In connection with the initial investment, we received the right to designate two members of Kleo's board of directors.

In March 2017, we purchased 500,000 shares of Kleo common stock directly from a co-founder of Kleo for consideration of $249,750 in cash and 32,500 shares of our common shares.

In addition to these purchases, in October 2017, we purchased an additional aggregate of 2,049,543 shares for cash consideration of $2.3 million and in November 2018 we participated in Kleo's Series B funding raise where we purchased 1,420,818 common shares for cash consideration of $5.0 million. As of the close of the Series B funding raise, and December 31, 2018, our ownership interest in the outstanding stock of Kleo was approximately 42%. There were no additional transactions involving Kleo stock during the year ended December 31, 2019, and at December 31, 2019 our ownership interest in the outstanding stock of Kleo was approximately 42%. The Company assigned its shares and the rights under the related agreements to Biohaven Therapeutics Ltd. its wholly owned subsidiary on November 12, 2018.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their safety, efficacy, convenience, price, the level of generic competition and the availability of coverage and reimbursement from government and other third-party payors.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and

retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

CGRP Receptor Antagonist Platform

With regard to rimegepant and vazegepant, our compounds target acute treatment of migraine and migraine prevention. We face competition from companies that develop and/or sell the following types of migraine treatments:

Acute Treatment of Migraine

Triptans

Clinicians use a number of pharmacologic agents for the acute treatment and/or prevention of migraine. Initial management is often with over-the-counter products (e.g. Excedrin, ibuprofen) or some prescription non-steroidal anti-inflammatories (e.g. diclofenac). The dominant class of prescription medication for the acute treatment of migraine are serotonin 5-HT$_{1B/1D}$ receptor agonists, or triptans. There are seven different triptans (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan), the first of which was developed and approved over 25 years ago and, today, all triptans are generic. The initial introduction of triptans represented a shift toward drugs more selectively targeting the suspected pathophysiology of migraine.

Serotonin 5-HT$_{1F}$ Agonists

A 5-HT$_{1F}$ receptor antagonist, lasmiditan, was approved by the FDA in October 2019. Lasmiditan was developed by CoLucid and acquired by Eli Lilly and Company in January 2017. Lasmiditan was the first new class of agent approved by the FDA for the acute treatment of migraine since the triptans. Lasmiditan was designed to act through non-vasoconstrictive mechanisms in the 5-HT$_1$ pathways such that patients who have cardiovascular risk factors, stable cardiovascular disease, or those who are dissatisfied with current triptan therapies could be treated. Lasmiditan was scheduled under the Controlled Substances Act due to its potential for abuse and dependence. Data from lasmiditan, compared with the results from the rimegepant program, would suggest ability to differentiate on both durability and benefit and AEs.

Other Oral CGRP Receptor Antagonists

Since we will be pursuing approval of our orally available, small molecule rimegepant for the acute treatment of migraine, the most relevant comparable to rimegepant is the oral CGRP receptor antagonist from Allergan, ubrogepant. In December 2019, the FDA approved ubrogepant produced by Allergan and it is currently being sold under the name Ubrelvy. Four clinical studies demonstrated the efficacy, safety and tolerability of orally-administered ubrogepant, followed by two Phase 3 clinical trials. Both the 50 and 100mg dose strengths showed a statistically greater percentage of ubrogepant patients pain free at 2 hours as compared to placebo, as well as statistical significance on the co-primary, absence of the most bothersome migraine associated symptom at 2 hours post dose. Patients were permitted to take a second dose of investigational product or rescue medication after the 2 hour time point. Durability of effect at 24 hours was not achieved with all doses (only the 100mg dose demonstrated 24-hour sustained pain relief). Ubrogepant was well tolerated with an adverse event profile similar to placebo. There were 6 cases of LFTs (ALT or AST) >3x ULN (1 on placebo, 5 on ubrogepant): 2 cases of LFTs >5x ULN on ubrogepant and 1 case of LFTs >10x ULN on ubrogepant in Achieve 1 and 4 cases of LFTs (ALT or AST) >3x ULN (1 on placebo and 3 on ubrogepant 50mg). No cases were determined to have a probable relationship to ubrogepant. There were no cases of Hy's Law. Based on the published Phase 3 studies of both rimegepant and ubrogepant, we believe rimegepant has the potential to be best-in-class given its simple-to-use Zydis oral disintegrating technology, fast onset of action, and durable effect. Allergan is a global pharmaceutical company with presence in the CNS area and, in particular, with physicians treating chronic migraine through its Botox franchise.

Other Acute Treatments for Migraine

Ergot alkaloids (such as Dihydroergotamine ("DHE")), analgesics, including opioids, NSAIDs, acetaminophen and antiemetics also are used in the acute treatment of migraine. DHE is also a potent vasoconstrictor and has been primarily displaced by the introduction of the triptans. Opioid use for migraine is associated with increased disability and health care utilization. Opioids, while effective for headache pain, are not approved for migraine and carry risk of abuse and addiction.

Migraine Prevention Treatments

Agents currently used to reduce the frequency of migraine episodes were first approved for other uses (e.g. beta blockers, antidepressants, anticonvulsants). Botox is the only product that has been approved by the FDA for the prevention of chronic migraine (defined as at least 15 headache days per month, at least 8 of which are migraine). For those patients who do not qualify as having chronic migraine, but still have significant disability due to migraine, there are five products approved by the

FDA for use: topiramate (Topamax) and valproic acid (Depakote), both anticonvulsant medicines, propranolol (Inderal) and timolol (Blocadren), both beta-blockers, and amitriptyline, a tricyclic antidepressant.

The biologic CGRP therapies have been studied for the prevention of migraine with three agents approved in 2018. The three new FDA-approved drugs, Aimovig (erenumab-aooe), Ajovy (fremanezumab-vfrm), and Emgality (galcanezumab-gnlm), are all administered subcutaneously. These therapies, while effective, do not eliminate the need for acute treatment of migraine attacks. In addition, they all require subcutaneous administration. We believe that vazegepant may have the opportunity to differentiate from these therapies due to its potential to be used as an intranasal formulation for both the acute treatment and prevention of migraine.

Glutamate Platform

With respect to troriluzole, which we are currently developing for the treatment of ataxias, OCD and Alzheimer's disease, there are currently no approved drug treatments for SCA or any other cerebellar ataxia, in the United States.

We are aware of companies with clinical stage programs in development for potential treatments for SCA and other cerebellar disorders, including Cadent Therapeutics, which is in Phase 2 development of CAD-1883, a positive allosteric modulator of SK channels (calcium-sensitive potassium ion channels); Bioblast Pharma, which is in Phase 2 development of trehalose, which targets SCA 3 and acts as a protein stabilizer; Steminent Biotherapeutics, which is currently conducting a Phase 2 trial of allogeneic adipose-derived mesenchymal stem cells that target polyglutamine SCAs; EryDel which is planning a Phase 3 trial for its product, IEDAT01, which delivers dexamethasone sodium phosphate through red blood cells, Shionogi & CO., Ltd., which is investigating Rovatirelin, a non-peptide mimetic of thyrotropin-releasing hormone, in a Phase 3 trial in Japan; Shire Plc, which is exploring Cuvitru, an intravenous immune globulin that is approved for the treatment of primary immunodeficiency disorders, in Phase 2 development. Mitsubishi Tanabe received approval for taltirelin, an oral thyrotropin releasing hormone, in Japan in 2009 but has not filed with the FDA to seek approval in the United States.

With regards to OCD, there have been no new classes of drugs approved in over a decade. We are not aware of other product candidates besides troriluzole that are currently in clinical development targeting populations with OCD.

With respect to BHV-0223, which we are developing for the treatment of ALS, we believe our primary competitor is Covis Pharmaceuticals, which sells Rilutek, the brand name for riluzole. Riluzole is also generically available. Edaravone (Radicava, Mitsubishi Tanabe Pharma) was approved by the FDA in May 2017 for the treatment of ALS, based on efficacy studies conducted in Japan with the vast majority of patients on background riluzole therapy. Edaravone is administered to patients by intravenous infusion. Aquestive Therapeutics received FDA approval in November 2019 for a riluzole oral soluble film, Exservan. Italfarmaco SpA, a private Italian company, markets an oral liquid suspension formulation of riluzole in the United Kingdom and elsewhere in Europe under the brand name Tiglutik. Tiglutik, the US brand name for Italfarmaco's oral liquid suspension formulation of riluzole was approved for marketing in the United States in September 2018. Being that an oral suspension still requires swallowing in a population prone to dysphagia, we believe an oral dissolvable tablet that may not require swallowing will have significant market preference. We are aware of several companies that are exploring potential treatments for ALS, mostly agents with novel mechanisms of action being administered with riluzole. We are not aware of any company marketing or developing a sublingual formulation of riluzole. Other companies of which we are not aware may also be developing formulations using the API riluzole; if such companies pursued regulatory approval of such product candidates using the Section 505(b)(2) regulatory pathway, those product candidates would potentially compete with BHV-0223. For example, Italfarmaco and Aquestive have obtained orphan designation for their products, and are eligible to obtain orphan exclusivity subject to a showing of clinical superiority to riluzole. Based on orphan drug designation requirements, the first approval of a novel formulation of riluzole may obligate subsequent formulations to demonstrate advantages with regard to safety, efficacy or meaningful contribution to patient care, in order to achieve marketing authorization.

With respect to BHV-5000, which we are developing for the treatment of Rett syndrome, there are currently no approved treatments for Rett syndrome in the United States. We are aware of companies with clinical stage programs in development for potential treatments for Rett syndrome, including Newron Pharmaceuticals SpA which is launching a Phase 2/3 clinical trial of sarizotan, an agent with serotonin subtype-1A (5-HT1A) receptor agonist and dopamine subtype-2 (D2) receptor antagonist activities, and Neuren Pharma, which has completed a Phase 2a trial of trofinetide in adult patients and a Phase 2 trial in pediatric patients with Rett syndrome.

If we expand our development of troriluzole, BHV-0223 or BHV-5000 into additional neuropsychiatric or other indications, we would face substantial competition from companies that develop or sell products that treat those indications.

Other Platforms

With respect to verdiperstat, which we are developing for the treatment of MSA, there are currently no approved treatments for MSA in the United States. We are not aware of any planned or ongoing late stage development programs for

MSA. Nevertheless, we are aware of companies who have, at some time, declared that they are developing potential treatments for MSA, including the following:

- Prana Biotechnology Ltd, PBT434 is a small molecule purported to inhibit the aggregation of α-synuclein and tau that was granted orphan drug designation in the US in January 2019;
- AFFiRiS AG;
- Corestem Inc;
- MitoDys Therapeutics Ltd;
- Modag GmbH; and
- Neuropore Therapies Inc.

Manufacturing

We have an experienced manufacturing leadership team that manages our relationships with third party manufacturers. We currently rely, and expect to continue to rely, on third parties for the manufacturing of our product candidates for preclinical and clinical testing, as well as for commercial manufacturing of our products.

Our lead product candidates are small molecules and are manufactured in reliable and reproducible synthetic processes from readily available starting materials. The chemistry does not require unusual equipment in the manufacturing process. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Commercialization

We intend to develop and, if approved by the FDA, commercialize our product candidates in the United States, and we may enter into distribution or licensing arrangements for commercialization rights for other regions.

With respect to rimegepant and vazegepant, we recruited a seasoned team of sales specialists, account directors and field medical professionals who will focus on targeting health care professionals and institutions serving patients with migraine, including neurologists, headache centers/specialists and primary care. We estimate that our commercial organization will comprise between 700 and 1,000 employees within the first year of launch.

With respect to the product candidates in our glutamate modulation and MPO platforms, we are confident of significant provider/stakeholder overlap which will create synergies with our current commercial footprint to maximize coverage, opportunity and efficiencies.

Intellectual Property

We strive to protect and enhance the proprietary technologies that we believe are important to our business, including seeking and maintaining patents intended to cover our products and compositions, their methods of use and any other inventions that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen and maintain the proprietary position of our products and our other development programs.

Patents and Patent Applications

We have over 500 U.S. and foreign patents and patent applications in our portfolio related to the composition of matter, methods of use, methods of manufacture or formulations of our product candidates which have been filed in major markets throughout the world, including the United States, Europe, Japan, Korea, China, Hong Kong and Australia. About 1/3 of the patents and patent applications support the Glutamate platform and 2/3 supports the CGRP platform.

Rimegepant and Vazegepant

The intellectual property rights related to rimegepant and vazegepant include patents and patent applications in-licensed from BMS, with statutory expiration dates ranging from 2023 to 2033, and patent applications filed by the Company, which if granted, will have statutory expiration dates from 2039 and later. U.S. Patent 8,314,117 covers the composition of matter of rimegepant, and has a statutory expiration date of October 12, 2030, not including patent term adjustment or any potential patent term extension. U.S. Patent 8,481,546 covers the composition of matter of vazegepant, and has a statutory expiration date of March 2, 2031, not including patent term adjustment or any potential patent term extension. These or other patents and applications cover rimegepant and vazegepant and their use in treating migraine and, in certain ex-U.S. jurisdictions, other neurological conditions. The BMS license also includes several patent families of related compounds directed to the CGRP

receptor. We also have an agreement with Catalent whereby Catalent granted an exclusive license under certain of its patents and technology to use the Zydis ODT technology for development of our rimegepant product. Catalent retains all manufacturing rights.

Troriluzole

We own several families of patent applications containing claims directed to prodrugs of riluzole. These patent families include several U.S. applications, corresponding Patent Cooperation Treaty ("PCT") applications, and U.S. Patent 10,485,791, issued November 26, 2019, which is directed to troriluzole and other prodrugs of riluzole. In addition, the use of these compounds for treating ALS, SCA, depression and other diseases is described and claimed in these patent applications. We own these patent applications subject to a license agreement with ALS Biopharma and FCCDC. In addition, the Company had filed patent applications relating to drug product formulations containing trorilizole and methods of using the formulations to treat various diseases.

BHV-0223

BHV-0223, a sublingual or ODT form of riluzole, and its use for treating various forms of pain, ALS and depression are covered by patent applications pending in the U.S. and selected foreign jurisdictions having a statutory expiration date in 2035. We have an agreement with Catalent whereby Catalent granted an exclusive license under certain of its patents and technology to use the Zydis ODT technology for our BHV-0223 product. Catalent retains all manufacturing rights. In addition to patent protection, although not an NCE, BHV-0223 may also be entitled to certain regulatory exclusivity. In addition to the patent applications we own, we have also licensed one issued patent and several pending patent applications from Yale which provide protection for the use of riluzole in treating generalized anxiety disorder and other neurological uses, respectively. Further, we have licensed several patents from Rutgers University covering the use of riluzole for treating various forms of cancer and an animal model for tumors which may cover the use of BHV-0223 for treating the specific cancers.

BHV-5000

We have also in-licensed one patent family related to certain uses of lanicemine and a patent application family containing claims directed to BHV-5000 from AstraZeneca. They contain claims directed to the use of the base compound, lanicemine, in treating depression, and the structure of the prodrug form, BHV-5000, as well as the use of the prodrug in treating a variety of neurological diseases including Rett syndrome and depression. The issued patents related to uses of lanicemine have a statutory expiration date in 2020. Two U.S. patents have been granted that are directed to BHV-5000 and its uses and have a statutory expiration date in 2034. Corresponding foreign patents are pending.

Verdiperstat

In September 2018, we in-licensed a patents from AstraZeneca relating to the composition of matter of verdiperstat, pharmaceutical compositions and various neurological diseases including muscular system atrophy. The patent applications have been filed in the U.S., Europe, Japan and other countries. Three U.S. patents have been granted. The pending applications and granted patents have expiration dates from 2025 to 2034, not including possible patent term extensions.

Patent Protection and Terms

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be extended by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review. Patent term extension is not available for all approved products and, even if an approved product is eligible, only one patent covering the approved product may be extended, the extension can only be based on a single approved product, and the total extension granted cannot extend the remaining term of the patent beyond 14 years from product approval.

Furthermore, the patent positions of biotechnology and pharmaceutical products and processes like those we intend to develop and commercialize are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in such patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries can diminish our ability to protect our inventions and enforce our intellectual property rights, can make it easier to challenge the validity, enforceability or scope of any patents that may issue, and, more generally, could affect

the value of intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

Third-Party Patent Filings

Numerous U.S. and foreign issued patents and patent applications owned by third parties exist in the fields in which we are developing products. In addition, because patent applications can take many years to issue, there may be applications unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Moreover, we may be aware of patent applications, but incorrectly predict the likelihood of those applications issuing with claims of relevance to us.

Under U.S. law, a person may be able to patent a discovery of a new way to use a previously known compound, even if such compound itself is patented, provided the newly discovered use is novel and non-obvious. Such a method-of-use patent, however, if valid, only protects the use of a claimed compound for the specified methods claimed in the patent. This type of patent does not prevent persons from using the compound for any previously known use of the compound. Further, this type of patent does not prevent persons from making and marketing the compound for an indication that is outside the scope of the patented method.

License Agreements

License Agreement with BMS

Overview

In July 2016, we entered into an exclusive, worldwide license agreement with BMS for the development and commercialization rights to rimegepant and vazegepant, as well as other CGRP-related intellectual property. Subject to certain limitations and certain retained rights of BMS, the license included an exclusive license under certain BMS patent rights and BMS know-how to the extent necessary to research, discover, develop, make, have made, use, sell, offer to sell, export and import licensed compounds and licensed products in the field of prevention, treatment or control of any disease, disorder or condition in humans. In exchange for these rights, we agreed to pay BMS initial payments, milestone payments and tiered royalties on net sales of licensed products under the agreement. Our initial payments to BMS totaled $9.0 million and were paid within 90 days after entering into the agreement. The milestone payments due to BMS under the agreement consist of development and commercial milestones. The development milestones due under the agreement depend on the licensed product being developed. Development milestones due under the agreement with respect to rimegepant or a derivative thereof total up to $127.5 million, and, for any product other than rimegepant or a derivative thereof, total up to $74.5 million. Commercial milestones total up to $150.0 million for each licensed product. If we receive revenue from sublicensing any of our rights under the agreement, we are also obligated to pay a portion of that revenue to BMS as well. The tiered royalty payments are based on annual worldwide net sales of licensed products under the agreement, with percentages in the low-to-mid teens.

We made a payment of $5.0 million to BMS pursuant to our obligations under the BMS agreement during the third quarter of 2017 for the achievement of a specified milestone. The Company was also required to pay $7.5 million to BMS in relation to the NDA filing for rimegepant, and accordingly, the Company made the milestone payment in October 2019.

Our Development, Regulatory and Commercialization Obligations

Under the agreement, we are obligated to use commercially reasonable efforts to develop licensed products using the patent rights we have licensed from BMS, including setting forth a development plan with specific development activities and timelines, updating the development plan each year, providing BMS with annual reports of our progress and keeping BMS informed of material changes that may affect the development plan. With respect to any of the licensed products, we are solely responsible for all development, regulatory and commercial activities and costs. We are also obligated to use commercially reasonable efforts to achieve specified regulatory and commercial milestones, and maintain a sufficient supply of our products to satisfy our expected commercialization efforts in each country in which we sell such products. Following our first commercial sale of a product, we must provide BMS with periodic reports of our commercial activities. In connection with the agreement, BMS agreed to use commercially reasonable efforts to assign and transfer any INDs for the licensed compounds to us.

Equity Consideration

As part of the agreement, we agreed to issue BMS common shares in the amount of $12.5 million upon the occurrence of specified events, including upon an initial public offering ("IPO"). In satisfaction of this obligation, in May 2017 upon the completion of our IPO, we issued 1,345,374 common shares to BMS.

Non-Competition

Until 2023, neither we nor our affiliates may, ourselves or through or in collaboration with a third party, engage directly or indirectly in the clinical development or commercialization of specified competitive compounds. In the event that we are or become non-compliant with this provision due to licensing, collaboration or acquisition activity, we must either divest ourselves of the competitive compound within a certain period of time, discontinue the development of the competitive compound, or negotiate with BMS to have the competitive compound included as a licensed product under our agreement with BMS. The failure to so divest or reach terms with BMS may result in the termination of our license with BMS.

Term and Termination

The agreement will terminate on a licensed product-by-licensed product and country-by-country basis upon the expiration of the royalty term with respect to each licensed product in each country. The patents related to the licensed products have statutory expiration dates ranging from 2023 to 2033.

BMS has the right to terminate the agreement upon our insolvency or bankruptcy, our uncured material breach, including our failure to meet our development and commercialization obligations, our challenge to any BMS patent rights, or our failure to close a financing within specified parameters. We have the right to terminate the agreement if BMS materially breaches the agreement or if, after we provide notice, we choose not to move forward with development and commercialization in a specific country. In the event that BMS exercises its right to terminate the agreement following our insolvency, our breach of the agreement or our failure to develop or commercialize the licensed compounds, or if we terminate the agreement after providing notice, all rights and licenses granted to us will terminate, and all patent rights and know-how transferred pursuant to the agreement will revert to BMS. In addition, upon such termination, we agree to, at BMS's election, (i) assign all regulatory filings, approvals and regulatory documents necessary to further develop and commercialize the reverted products or (ii) withdraw or inactivate such filings and approvals.

Amendment to License Agreement with Bristol-Myers Squibb Company

In March 2018, the Company entered into an Amendment to License Agreement (the “BMS Amendment”) with BMS, which amends the License Agreement between the Company and BMS from July 2016 (the “Original License Agreement” and, as amended by the BMS Amendment, the “BMS License Agreement”). Under the BMS Amendment, the Company paid BMS an upfront payment of $50.0 million in return for a low single-digit reduction in the royalties payable on net sales of rimegepant and a mid single-digit reduction in the royalties payable on net sales of vazegepant, recorded in Research and Development expense in the Consolidated Statements of Operations and Comprehensive Loss. Under the Original License Agreement, the Company was obligated to make tiered royalty payments based on annual worldwide net sales of licensed products upon their approval and commercialization, with percentages in the low- to mid-teens.

The BMS Amendment also removes BMS’s right of first negotiation to regain its intellectual property rights or enter into a license agreement with the Company following the Company’s receipt of topline data from its Phase 3 clinical trials with rimegepant, and clarifies that antibodies targeting CGRP are not prohibited as competitive compounds under the non-competition clause of the Original License Agreement.

The BMS License Agreement continues to provide the Company with exclusive global development and commercialization rights to rimegepant, vazegepant and related CGRP molecules, as well as related know-how and intellectual property. The Company’s obligations to make development and commercial milestone payments to BMS under the Original License Agreement remain unchanged.

Agreement with ALS Biopharma, LLC and Fox Chase Chemical Diversity Center Inc.

In August 2015, we entered into an agreement with ALS Biopharma and FCCDC pursuant to which ALS Biopharma and FCCDC assigned to us their worldwide patent rights to a family of over 300 prodrugs of glutamate modulating agents, including troriluzole, as well as other innovative technologies. In addition, we received a non-exclusive license to certain trade secrets and know-how of ALS Biopharma. We took assignment of these patent rights subject to the provisions of the Bayh Dole Act, as applicable, to the extent that any invention included with the assigned patent rights was funded in whole or in part by the United States government. In addition, certain of the patent rights that do not cover troriluzole were co-owned by Rutgers, and thus, we took assignment of these patent rights subject to the co-ownership interest of Rutgers. Under the agreement, we are obligated to use commercially reasonable efforts to diligently commercialize and develop markets for the patent products.

As consideration for this assignment of patent rights, we paid ALS Biopharma $2.5 million between August 2015 and November 2016 as funding for research to be performed by ALS Biopharma in connection with a mutually agreed upon research plan. We are also obligated to pay regulatory milestone payments of $3.0 million upon a specified regulatory approval for the first licensed product under the agreement as well as additional milestone payments of $1.0 million for each licensed

product that completes the specified regulatory milestone thereafter. We are also obligated to make royalty payments of a low single-digit percentage based on net sales of products licensed under the agreement, payable on a quarterly basis.

Equity Consideration

As part of the agreement, we also issued to ALS Biopharma 50,000 common shares as well as two warrants to purchase a total of 600,000 common shares with an exercise price of $5.60 per share, of which 275,000 shares were immediately exercisable at issuance and the remaining 325,000 shares became exercisable upon our achievement of a specified regulatory milestone. This milestone was achieved in May 2016. We also agreed to grant specified preemptive rights to ALS Biopharma to participate in equity offerings that are open to our other shareholders.

In January 2018, ALS Biopharma exercised a warrant for the purchase of 275,000 shares through a net share settlement. The Company issued 228,119 shares as a result of the exercise.

Term and Termination

The agreement terminates on a country-by-country basis as the last patent rights expire in each such country. Our current patent rights consist of owning several families of patent applications. If a patent covering troriluzole issues from one of these pending patent applications, it would have a statutory expiration date in 2036. ALS Biopharma has the right to terminate the agreement or its applicability to one or more countries upon 30 days' prior written notice to us if we fail to make an undisputed payment within the 60-day period after receipt of a termination notice or if we commit a material breach of the agreement that is not cured within the 60-day period after receipt of a termination notice. We have the right to terminate the agreement if ALS Biopharma commits a material breach of the agreement that is not cured within the 60-day period after written notice thereof from us or, as to a specific country, if no valid claims exist in such country. Both we and ALS Biopharma may terminate the agreement as to a specific country if we are enjoined from exercising our patent rights under the agreement in such country. If we affirmatively abandon our development, research, licensing or sale of all products covered by one or more claims of any patent or patent application assigned under the agreement, or if we cease operations, we have agreed to reassign the applicable patent rights back to ALS Biopharma.

2016 License Agreement with AstraZeneca

Overview

In October 2016, we entered into an exclusive license agreement with AstraZeneca, or the 2016 AstraZeneca Agreement, pursuant to which AstraZeneca granted us a license to certain patent rights and know-how for all human uses for the commercial development, manufacture, distribution and use of any products or processes resulting from development of those patent rights, including BHV-5000 and lanicemine.

Under the 2016 AstraZeneca Agreement, we have the right to sublicense our rights under the agreement subject to AstraZeneca's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed. We will be responsible for preparing, filing, prosecuting and maintaining the licensed patents and applications, and for listing any listable patents in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"). We have the right to enforce the licensed patents and to defend challenges to the validity or enforceability of the licensed patents. AstraZeneca, however, retains the right to apply for patent term extensions for the licensed patents. We may not assign our rights or delegate our obligations under the 2016 AstraZeneca Agreement without AstraZeneca's consent, including in the event of a change of control.

In exchange for these rights, in addition to the agreement to issue equity consideration noted below, we agreed to pay AstraZeneca an upfront payment, milestone payments and royalties on net sales of licensed products under the agreement. We made the upfront payment to AstraZeneca of $5.0 million upon signing the agreement. The milestone payments due to AstraZeneca under the agreement consist of regulatory and commercial milestones. The regulatory milestones due under the agreement depend on the indication of the licensed product being developed as well as the territory where regulatory approval is obtained. Development milestones due under the agreement with respect to Rett syndrome total up to $30.0 million, and, for any indication other than Rett syndrome, total up to $60.0 million. Commercial milestones are based on net sales of all products licensed under the agreement and total up to $120.0 million. We have agreed to pay tiered royalties of mid single-digit to low double-digit percentages based on net sales of products licensed under the agreement. If we receive revenue from sublicensing any of our rights under the agreement, we are also obligated to pay a portion of that revenue to AstraZeneca.

Our Development, Regulatory and Commercialization Obligations

Under the agreement, we are obligated to use commercially reasonable efforts to develop, and obtain and maintain regulatory approvals for, licensed products using the rights we have licensed from AstraZeneca, including providing AstraZeneca with annual reports of our development activities. With respect to any of the licensed products, we are solely

responsible for all development, regulatory and commercial activities and costs. Following our first commercial sale of a product, we must provide AstraZeneca with periodic reports of our commercial activities. AstraZeneca agreed to use commercially reasonable efforts to transfer all of its regulatory documentation related to BHV-5000 and lanicemine in each country to us, including all INDs, NDAs and approvals, promptly following the effective date of the agreement.

Right of First Negotiation

After we receive topline data from the first Phase 2b study of a product candidate licensed under the agreement, we must provide notice and a summary of the data to AstraZeneca. AstraZeneca will then have a period of time to exercise its right of first negotiation to regain its intellectual property rights or enter into a sublicense agreement with us. If AstraZeneca does not give notice of its intent to exercise its right of first negotiation during this time period, or we do not execute a definitive agreement within an additional time period, we will have the sole right, in our discretion, to negotiate and execute any agreement with third parties, or to retain our rights.

Equity Consideration

As part of the consideration, we agreed to issue to AstraZeneca common shares in the amount of $5.0 million if we completed a financing within specified parameters. This condition was satisfied upon the closing of our Series A preferred share financing, at which time we issued 538,150 Series A preferred shares to AstraZeneca which, at the completion of our IPO, automatically converted into 538,150 common shares. In addition, we agreed to issue to AstraZeneca common shares in the amount of $5.0 million upon the completion of specified events, including upon an IPO. In satisfaction of this obligation, in May 2017 upon the completion of our IPO, we issued an additional 538,149 common shares to AstraZeneca.

Term and Termination

The 2016 AstraZeneca Agreement will terminate upon the expiration of the last royalty term for the last licensed product under the agreement. Each royalty term begins on the date of the first commercial sale of the applicable licensed product in the applicable country and ends on the later of 10 years from such first commercial sale or the expiration of the last to expire of the applicable patents in that country. The patent applications related to BHV-5000 would, if issued, have a statutory expiration date in 2033. Either party may terminate the agreement upon the other party's uncured material breach or upon insolvency or bankruptcy. AstraZeneca also has the right to terminate the agreement in certain circumstances. We have the right to terminate the agreement without cause. In the event the agreement is terminated in its entirety for any reason, all rights and licenses granted to us by AstraZeneca under the agreement, and all sublicenses granted by us under the agreement, immediately terminate, and we are required to assign to AstraZeneca all of the regulatory documentation applicable to any licensed compound or licensed product owned or controlled by us or our affiliates, to transfer control of any clinical studies involving licensed products to AstraZeneca and continue such studies at our cost for six months, and to assign to AstraZeneca all of our agreements with third parties that are reasonably necessary for the exploitation of the licensed products.

2018 License Agreement with AstraZeneca

Overview

In September 2018, we entered into an exclusive license agreement with AstraZeneca, or the 2018 AstraZeneca Agreement, pursuant to which AstraZeneca granted us exclusive worldwide rights to develop and commercialize verdiperstat. In exchange for these rights, we paid AstraZeneca an upfront cash payment of $3.0 million and issued AstraZeneca 109,523 common shares, valued at $4.1 million on the date of settlement. We are obligated to pay milestone payments to AstraZeneca totaling up to $55.0 million upon the achievement of specified regulatory and commercial milestones and up to $50.0 million upon the achievement of specified sales-based milestones. In addition, we will pay AstraZeneca tiered royalties ranging from high single-digit to low double-digits based on net sales of specified approved products, subject to specified reductions.

We may sublicense our rights under the 2018 AstraZeneca Agreement and, if we do so, we will be obligated to pay a portion of any milestone payments received from the sublicensee to AstraZeneca in addition to any milestone payments we would otherwise be obligated to pay.

Our Development, Regulatory and Commercialization Obligations

Under the 2018 AstraZeneca Agreement, we are solely responsible, and have agreed to use commercially reasonable efforts, for all development, regulatory and commercial activities related to verdiperstat. We are also responsible for the prosecution and maintenance of the patents related to verdiperstat and have the first right to prosecute infringement of the patents and defend challenges to the validity or enforceability of the patents.

Term and Termination

The 2018 AstraZeneca Agreement terminates on a country-by-country basis and product-by-product basis upon the expiration of the royalty term for such product in such country. Each royalty term begins on the date of the first commercial sale of the licensed product in the applicable country and ends on the later of 10 years from such first commercial sale or the expiration of the last to expire of the applicable patents in that country. The 2018 AstraZeneca Agreement may be terminated earlier in specified situations, including termination for uncured material breach of the 2018 AstraZeneca Agreement by either party, termination by AstraZeneca in specified circumstances, termination by us on a country-by-country basis with advance notice and termination upon a party's insolvency or bankruptcy.

Agreements with Catalent U.K. Swindon Zydis Limited

In March 2015, we entered into a development and license agreement with Catalent pursuant to which we obtained certain license rights to the Zydis ODT technology in BHV-0223. BHV-0223 was developed under this agreement. Catalent has manufactured BHV-0223 for clinical testing and we expect them to do so for commercial supply. We made an upfront payment of $0.3 million to Catalent upon entering into the agreement and are obligated to pay Catalent up to $1.6 million upon the achievement of specified regulatory and commercial milestones. We are also obligated to make royalty payments of a low single-digit percentage based on net sales of products licensed under the agreement.

Under the agreement, we are responsible for conducting clinical trials and for preparing and filing regulatory submissions. We have the right to sublicense our rights under the agreement subject to Catalent's prior written consent. Catalent has the right to enforce the patents covering the Zydis technology and to defend any allegation that a formulation using Zydis technology, such as BHV-0223, infringes a third party's patent.

The development and license agreement terminates on a country-by-country basis upon the later of (i) 10 years after the launch of the most recently launched product in such country and (ii) the expiration of the last valid claim covering each product in such country, unless earlier voluntarily terminated by us. Our current patent rights with respect to BHV-0223 consist of owning several patent applications. If a patent covering BHV-0223 issues from one of these pending patent applications, it would have a statutory expiration date in 2035. The agreement automatically extends for one-year terms unless either party gives advance notice of intent to terminate. In addition, Catalent may terminate the agreement either in its entirety or terminate the exclusive nature of the agreement on a country-by-country basis if we fail to meet specified development timelines, which we may extend in certain circumstances.

In January 2018, we entered into a development and license agreement with Catalent pursuant to which we obtained certain license rights to the Zydis ODT technology for use with rimegepant. If we obtain regulatory approval or launch a rimegepant product that utilizes the Zydis ODT technology, we are obligated to pay Catalent up to $1.5 million upon the achievement of specified regulatory and commercial milestones. If we commercialize a rimegepant product that utilizes the Zydis ODT technology, the agreement permits us to purchase the commercial product from Catalent at a fixed price, inclusive of a royalty. Under the agreement, Catalent agreed that it will not develop or manufacture a formulation of any oral CGRP compound using Zydis ODT technology for itself or a third party for a specified period of time, subject to certain minimum commercial revenues.

In June 2018, we entered into a commercial supply agreement with Catalent pursuant to which Catalent will exclusively manufacture and supply our worldwide requirements for rimegepant in the Zydis ODT delivery formulation, if we receive regulatory approval of this formulation of rimegepant, for an initial term of five years after its commercial launch with optional two-year renewal periods. Under the agreement, Catalent will supply the rimegepant Zydis ODT product at a fixed price, inclusive of a royalty, and will not develop or manufacture a formulation of any oral CGRP compound using Zydis ODT technology for itself or a third party for a specified period of time, subject to certain minimum commercial revenues.

Amendment to License Agreement with Yale University

In September 2013, the Company entered into an exclusive license agreement with Yale (the "Yale Agreement") to obtain a license to certain patent rights for the commercial development, manufacture, distribution, use and sale of products and processes resulting from the development of those patent rights, related to the use of riluzole in treating various neurological conditions, such as general anxiety disorder, post-traumatic stress disorder and depression. As part of the consideration for this license, the Company issued Yale 250,000 common shares and granted Yale the right to purchase up to 10% of the securities issued in specified future equity offerings by the Company, in addition to the obligation to issue shares to prevent anti-dilution. The obligation to contingently issue equity to Yale was no longer outstanding as of December 31, 2018.

The Yale Agreement was amended and restated in May 2019. As amended, the Company agreed to pay Yale up to $2.0 million upon the achievement of specified regulatory milestones and annual royalty payments of a low single-digit percentage based on net sales of riluzole-based products from the licensed patents or from products based on troriluzole. Under the

amended and restated agreement, the royalty rates are reduced as compared to the original agreement. In addition, under the amended and restated agreement, the Company may develop products based on riluzole or troriluzole. The amended and restated agreement retains a minimum annual royalty of up to $1.0 million per year, beginning after the first sale of products covered under the agreement. If the Company grants any sublicense rights under the Yale Agreement, it must pay Yale a low single-digit percentage of sublicense income that it receives. To date, no milestone or royalty payments have been made under this agreement.

The Yale Agreement, as amended and restated, requires the Company to meet certain due diligence requirements based upon specified milestones relating to riluzole or troriluzole based products. The Company can elect to extend the deadline for its compliance with the due diligence requirements by a maximum of one year upon the payment to Yale of up to $150 million. The Company is also required to reimburse Yale for any fees that Yale incurs related to the filing, prosecution, defending and maintenance of patent rights licensed under the Yale Agreement. In the event that the Company fails to make any payments, commits a material breach, fails to maintain adequate insurance or challenges the patent rights of Yale, Yale can terminate the Yale Agreement. The Company can terminate the Yale Agreement (i) upon 90 days' notice to Yale, (ii) if Yale commits a material breach of the Yale Agreement or (iii) as to a specific country if there are no valid patent rights in such country. The Yale Agreement expires on a country-by-country basis upon the later of the date on which the last patent rights expire in such country or ten years from the date of the first sale of a product incorporating the licensed patents or the Company’s patents relating to troriluzole.

Termination of MGH Agreement

In September 2014, the Company entered into a license agreement (the "MGH Agreement") with The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH"), pursuant to which MGH granted the Company a license to certain patent rights for the commercial development, manufacture, distribution and use of any products or processes resulting from development of those patent rights, related to treating depression with a combination of ketamine and scopolamine. The Company terminated the MGH Agreement in September 2019.

License Agreement with Rutgers, The State University of New Jersey

In June 2016, we entered into an exclusive license agreement with Rutgers, The State University of New Jersey, licensing several patents and patent applications related to the use of riluzole to treat various cancers. Certain of the Rutgers patent rights were developed using federal funding. Accordingly, the U.S. Government has certain rights in the Rutgers patents and applications. We have the right to sublicense our rights under the Rutgers Agreement. We are responsible for prosecuting and maintaining the patents and applications in the Rutgers patent rights, and Rutgers has an opportunity to review and comment on correspondences with government patent offices. We have the right to prepare any documents related to the application for an extension of the term of any licensed patent and to list any listable patents in the Orange Book. We have the first right to enforce the licensed patents.

Under this agreement, we are required to pay Rutgers annual license maintenance fees of up to $25,000 per year until the first commercial sale of a licensed product. We are also obligated to pay Rutgers payments totaling up to $825,000 upon the achievement of specified clinical and regulatory milestones. We also agreed to pay Rutgers royalties of a low single-digit percentage based on net sales of licensed products sold by us, our affiliates or sublicensees, subject to a minimum of up to $100,000 per year. If we grant any sublicense rights under the license agreement, we must pay Rutgers a low double-digit percentage of sublicense income we receive. In the event that we experience a change of control or sale of substantially all of our assets prior to the initiation of a Phase 3 trial related to products licensed under the agreement, and such change of control or sale results in a full liquidation of our company, we will be obligated to pay Rutgers a change-of-control fee equal to 0.3% of the total value of the transaction, but not less than $100,000.

The agreement also requires us to meet certain due diligence requirements based upon specified milestones. We can elect to extend the due diligence requirements by a maximum of one year upon payments to Rutgers of up to $500,000 in the aggregate.

The agreement expires on a country-by-country basis upon the later of expiration of the last patent rights to expire in such country, which could occur as early as 2024, or ten years from the date of first commercial sale of a licensed product, unless terminated by either party.

Revenue Participation Right with Royalty Pharma

In June 2018, pursuant to a Funding Agreement we entered into with Royalty Pharma ("RPI") we granted to RPI the right to receive certain revenue participation payments, subject to certain reductions, based on the future global net sales of the pharmaceutical products containing the compounds rimegepant or vazegepant and certain derivative compounds thereof ("Products"), for each calendar quarter during the royalty term contemplated by the Funding Agreement, in exchange for $100.0

million in cash. Specifically, the participation rate commences at 2.1 percent on annual global net sales of up to and equal to $1.5 billion, declining to 1.5 percent on annual global net sales exceeding $1.5 billion.

Optional License Agreement with the University of Connecticut

In October 2018, we entered into an exclusive, worldwide option and license agreement (the "UConn Agreement") with the University of Connecticut ("UConn") for the development and commercialization rights to UC1MT, a therapeutic antibody targeting extracellular MT. Under this agreement, we have the option to acquire an exclusive, worldwide license to UC1MT and its underlying patents to develop and commercialize throughout the world in all human indications. If we choose to exercise the option, we would be obligated to pay UConn milestone payments upon the achievement of specified regulatory and commercial milestones, and royalties of a low single-digit percentage of net sales of licensed products.

Biotech Value Advisors

In March 2019, the Company entered into a master services agreement with Biotech Value Advisors, LLC related to the commercial preparation for several of the Company's late-stage product candidates. In addition to fixed quarterly consulting expenses under the agreement, the Company agreed to pay up to $2.0 million upon achievement of specified commercial milestones.

Fox Chase Chemical Diversity Center Inc. Agreement

In May 2019, Biohaven entered into the FCCDC Agreement in which the Company purchased certain intellectual property relating to the TDP-43 protein from FCCDC. The FCCDC Agreement provides the Company with a plan and goal to identify one or more new chemical entity candidates for preclinical development for eventual clinical evaluation for the treatment of one or more TDP-43 proteinopathies. As consideration, Biohaven issued 100,000 of its common shares to FCCDC valued at $5.6 million.

In addition, Biohaven is obligated to pay FCCDC milestone payments totaling up to $4.5 million with $1.0 million for each additional NDA filing. The Company also issued a warrant to FCCDC, granting FCCDC the option to purchase up to 100,000 Biohaven common shares, at a strike price of $56.46 per share, subject to vesting upon achievement of certain milestones in development of TD-43.

In connection with the FCCDC Agreement, Biohaven and FCCDC have established a TDP-43 Research Plan that provides for certain milestones to be achieved by FCCDC, and milestone payments to be made by the Company up to $1.5 million over a period of up to 30 months as success fees for research activities by FCCDC. In addition to the milestone payments, the Company will pay FCCDC an earned royalty equal to zero to ten percent of net sales of any TD-43 patent products with a valid claim as defined in the FCCDC Agreement. The Company may also license the rights developed under the FCCDC Agreement and, if it does so, will be obligated to pay a portion of any payments received from such licensee to FCCDC in addition to any milestones payments it would otherwise be obligated to pay. The Company is also responsible for the prosecution and maintenance of the patents related to the TDP-43 assets.

The FCCDC Agreement can be terminated on a country-by-country basis and product-by-product basis upon expiration of the royalty term for such product in such country. Each royalty term begins on the date of the first commercial sale of the licensed product in the applicable country and ends on the expiration of the last to expire of the applicable patents in that country. The FCCDC Agreement may be terminated earlier in specified situations, including termination for uncured material breach of the FCCDC Agreement by either party, termination by FCCDC in specified circumstances, termination by the Company on a country-by-country basis with advance notice and termination upon a party's insolvency or bankruptcy.

Government Regulation

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act ("FDCA") and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including imposition of a clinical hold, refusal by the FDA to approve applications, withdrawal of an approval, import/export delays, issuance of warning letters and other types of enforcement letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by the FDA and the Department of Justice or other governmental entities.

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are governed by extensive regulation by governmental authorities

in the United States and other countries. The FDA, under the FDCA, regulates pharmaceutical products in the United States. The steps required before a drug may be approved for marketing in the United States generally include:

- preclinical laboratory tests and animal tests conducted under Good Laboratory Practices ("GLP");
- the submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials commence;
- approval by an independent institutional review board ("IRB"), representing each clinical site before each clinical trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for each indication and conducted in accordance with Good Clinical Practices ("GCP");
- the preparation and submission to the FDA of an NDA;
- FDA acceptance, review and approval of the NDA, which might include an Advisory Committee review;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product, or components thereof, are made to assess compliance with current Good Manufacturing Practices ("cGMPs").

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain. The FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

Preclinical and Human Clinical Trials in Support of an NDA

Preclinical studies include laboratory evaluations of the product candidate, as well as *in vitro* and animal studies to assess the potential safety and efficacy of the product candidate. The conduct of preclinical trials is subject to federal regulations and requirements including GLP regulations. The results of the preclinical studies, together with manufacturing information and analytical data, among other things, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. The FDA may nevertheless initiate a clinical hold after the 30 days if, for example, significant public health risks arise.

Clinical trials involve the administration of the product candidate to human subjects under the supervision of qualified investigators in accordance with GCP requirements. Each clinical trial must be reviewed and approved by an IRB at each of the sites at which the trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution.

Clinical trials are typically conducted in three sequential phases prior to approval, but the phases may overlap or be combined. These phases generally include the following:

Phase 1. Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics.

Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance and optimal dosage and (3) identify possible adverse effects and safety risks.

Phase 3. If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 clinical trials, the clinical trial program will be expanded to Phase 3 clinical trials to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical trial sites.

Phase 4. clinical trials may be conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in enforcement action or withdrawal of approval.

A Phase 2/3 trial design, which we are using in our vazegepant and troriluzole development programs, is often used in the development of pharmaceutical and biological products. The trial includes Phase 2 elements, such as an early interim analysis of safety or activity, and Phase 3 elements, such as larger patient populations with less restrictive enrollment criteria. The early interim analysis of clinical or physiologic activity and/or safety allows the study to be stopped, changed or continued before a large number of patients have been enrolled, while still allowing all data from enrolled patients to count in the analysis used to support approval.

Submission and Review of an NDA

The results of preclinical studies and clinical trials, together with detailed information on the product's manufacture, composition, quality, controls and proposed labeling, among other things, are submitted to the FDA in the form of an NDA, requesting approval to market the product. The application must be accompanied by a significant user fee payment, which typically increases annually, although waivers may be granted in limited cases. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies.

Once an NDA has been accepted for filing, which occurs, if at all, 60 days after submission, the FDA sets a user fee goal date that informs the applicant of the specific date by which the FDA intends to complete its review. This is typically 10 months from the date that the FDA accepts the application for filing for standard review NDAs (*i.e.*, NDAs seeking approval of drugs that are not new molecular entities). The review process can be extended by FDA requests for additional information or clarification. The FDA reviews NDAs 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 cGMPs to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA typically will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facilities comply with cGMPs. Additionally, the FDA will typically inspect one or more clinical trial sites for compliance with GCP and integrity of the data supporting safety and efficacy.

During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy ("REMS") is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS, and the FDA will not approve the application without an approved REMS, if required. A REMS can substantially increase the costs of obtaining approval. The FDA could also require a special warning, known as a boxed warning, to be included in the product label in order to highlight a particular safety risk. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The FDA may require post-marketing testing and surveillance to monitor safety or efficacy of a product.

On the basis of the FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA will issue either an approval of the NDA or a CRL, detailing the deficiencies in the submission and the additional testing or information required for reconsideration of the application. Even with submission of this additional information, the FDA may ultimately decide that the application does not satisfy the regulatory criteria for approval.

Post-Approval Requirements

Approved drugs that are manufactured or distributed in the United States pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims and some manufacturing and supplier changes are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for marketed products, as well as new application fees for certain supplemental applications.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance programs to further assess and monitor the product's safety and effectiveness after commercialization. The FDA may also require a REMS, which could involve requirements for, among other things, medication guides, special trainings for prescribers and dispensers, patient registries, and elements to assure safe use.

In addition, entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. The FDA has promulgated specific requirements for drug cGMPs. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented.

FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may issue enforcement letters or withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Corrective action could delay product distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities.

Section 505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of drugs previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This type of application permits reliance for such approvals on literature or on an FDA finding of safety, effectiveness or both for an approved drug product. As such, under Section 505(b)(2), the FDA may rely, for approval of an NDA, on data not developed by the applicant. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for the new indication sought by the 505(b)(2) applicant.

Our clinical programs for troriluzole for the treatment of SCA and BHV-0223 for the treatment of ALS are each based on a regulatory pathway under section 505(b)(2) of the FDCA that allows reference to data on riluzole for the purpose of safety assessments.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents whose claims cover the applicant's product or an approved method of using the product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an Abbreviated New Drug Application ("ANDA"), seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify, for each patent listed in the Orange Book for the referenced drug, to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA, (2) such patent has expired, (3) if such patent has not expired, the date on which it expires or (4) such patent is invalid, unenforceable, or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. The fourth certification described above is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a

"section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of- use rather than certify to a listed method-of-use patent. This section viii statement does not require notice to the patent holder or NDA owner. There might also be no relevant patent certification.

If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the applicant. Even if the 45 days expire, a patent infringement lawsuit can be brought and could delay market entry, but it would not extend the FDA-related 30-month stay of approval.

The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent exclusivity, during which the FDA cannot approve an ANDA or 505(b)(2) application that relies on the listed drug.

A drug, including one approved under a 505(b)(2) application, may obtain a three-year period of non-patent market exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, the FDA can accept an application and begin the review process during the three-year exclusivity period. A 505(b)(2) NDA may also be subject to a five-year exclusivity period for a new chemical entity, whereby the FDA will not accept for filing, with limited exception, a product seeking to rely upon the FDA's findings of safety or effectiveness for such new chemical entity.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan drugs may be eligible for certain incentives, including tax credits for qualified clinical testing. In addition, an NDA for a product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication other than the rare disease or condition for which the drug was designated. A Company must request orphan drug designation before submitting an NDA.

Generally, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same active moiety for the same indication for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. Competitors, however, may receive approval of different active moieties for the same indication or obtain approval for the same active moiety for a different indication. In some cases, orphan drug status is contingent on a product with an orphan drug designation showing that it is clinically superior to a previously approved product or products.

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union and other geographies, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Coverage, Reimbursement and Pricing

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States and foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and the adequacy of reimbursement from third-party payors. Third-party payors include government authorities, and private entities, such as managed care organizations, private health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Moreover, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor's reimbursement payment rate may not be adequate or may require co-payments that patients find unacceptably high. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. However, one third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product, or will provide coverage at an adequate reimbursement rate. 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. Further, some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they provide reimbursement for use of such therapies.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of products and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. Thus, obtaining and maintaining reimbursement status is time-consuming and costly.

The U.S. and foreign governments regularly consider reform measures that affect health care coverage and costs. For example, the U.S. and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription products. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act ("collectively, the ACA") contains provisions that may reduce the profitability of products, including, for example, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. The Centers for Medicare and Medicaid Services ("CMS") may develop new payment and delivery models, such as bundled payment models. For example, the U.S. Department of Health and Human Services ("HHS") moved 30% of Medicare payments to alternative payment models tied to the quality or value of services by 2016. Additionally, HHS had set a goal of moving 50% of Medicare payments into these alternative payment models by the end of 2018, but due to a policy shift under the Trump Administration, it is unclear how and when such changes will be implemented. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our products.

The marketability of any products 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, the focus on cost containment measures, particularly in the United States, has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if we attain favorable coverage and reimbursement status for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

European Union Coverage Reimbursement and Pricing

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular drug candidate to currently available therapies, or so called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company.

Healthcare Laws and Regulations

Physicians, other healthcare providers, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors are and will be subject to various federal, state and foreign fraud and abuse laws and other healthcare laws and regulations. These laws and regulations may impact, among other things, our arrangements with third-party payors, healthcare professionals who participate in our clinical research programs, healthcare professionals and others who purchase, recommend or prescribe our approved products, and our proposed sales, marketing, distribution, and education programs. The U.S. federal and state healthcare laws and regulations that may affect our ability to operate include, without limitation, the following:

- The federal Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value;

- The federal civil and criminal false claims laws, including, without limitation, the federal civil monetary penalties law and the civil False Claims Act (which can be enforced by private citizens through *qui tam* actions), prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government;

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program and creates federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans, and healthcare clearinghouses and their respective business associates;

- The federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid ("CHIP") to report to HHS information related to payments and other transfers of value provided to physicians and teaching hospitals and physician ownership and investment interests; and

- Analogous state laws and regulations, such as state anti-kickback and false claims laws, that impose similar restrictions and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to implement compliance programs, comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or to track and report gifts, compensation and other remuneration provided to physicians and other health care providers; and state health information privacy and data breach notification laws, which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. For example, the ACA amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that liability under these statutes does not require a person or entity to have actual knowledge of the statutes or a specific intent to violate them. Moreover, the ACA provides that the government may assert that a claim that includes 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. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and reputational harm, we

may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

Healthcare Reform

The legislative landscape in the United States continues to evolve. 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. In March 2010, the ACA was enacted, which includes measures that have significantly changed health care financing by both governmental and private insurers. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (and 70% commencing January 1, 2019) point-of-sale discounts off 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;
- new requirements to report certain financial arrangements with physicians and certain others, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's 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 certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- 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 the Center for Medicare Innovation at the Centers for Medicare and Medicaid Services ("CMS"), to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. President Trump has signed two Executive Orders designed to delay the implementation of any certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 23, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices.

In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2027 unless additional Congressional action is taken. Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 also introduced a quality payment program under which certain individual Medicare providers will be subject to certain incentives or penalties based on new program quality standards. Payment adjustments for the Medicare quality payment program were scheduled to begin in 2019. At this time, it is unclear how the introduction of the quality payment program will impact overall physician reimbursement under the Medicare program.

Further, there have been several recent Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion. The Trump Administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the 2020 budget process or in future legislation. Additionally, the Trump Administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs. The U.S. Department of Health and Human Services has solicited feedback on some of these measures and, at the same time, has implemented others under its existing authority. Although a number of these, and other measures may require additional authorization to become effective, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the state level, legislatures are increasingly aggressive in passing legislation and implementing 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. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (the "FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

Employees

As of December 31, 2019, we employed 647 employees. Nearly all of our employees are located in the United States. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Information about Segments

We currently operate in a single business segment developing a portfolio of innovative, late-stage product candidates targeting neurological diseases, including rare disorders. See additional information in our financial statements contained in Part II, Item 8 of this Annual Report.

Corporate Information

We were incorporated as a business company limited by shares organized under the laws of the British Virgin Islands in September 2013. Our registered office is located at P.O. Box 173, Road Town, Tortola, British Virgin Islands and our telephone number is +1 (284) 852-3000. Our U.S. office and the office of our U.S. subsidiary is located at 215 Church Street, New Haven, Connecticut 06510 and our telephone number is (203) 404-0410.

Available Information

Our internet website address is www.biohavenpharma.com. In addition to the information about us and our subsidiaries contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports 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 Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission ("SEC"). A copy of these reports is also available at the SEC's (www.sec.gov).

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Annual Report on Form 10-K. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common shares to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history and have never generated any product revenues, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We were incorporated in 2013, and our operations to date have been largely focused on organizing and staffing our company, raising capital and in-licensing the rights to, and advancing the development of, our product candidates, including conducting preclinical studies and clinical trials. We have not yet demonstrated an ability to obtain marketing approvals for any product candidates, manufacture products on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to eventually transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant operating losses. Our net loss was $528.8 million and $240.9 million for the year ended December 31, 2019 and for the year ended December 31, 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $972.4 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. None of our product candidates have been approved for marketing in the United States, or in any other jurisdiction, and they may never receive such approval. It could be several years, if ever, before rimegepant or other product candidates generate significant revenues. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue establishing a sales, marketing and distribution infrastructure to commercialize rimegepant and any other product candidate for which we may obtain marketing approval;
- complete our ongoing Phase 3 clinical trial to evaluate rimegepant as a preventive therapy for migraine;
- complete the ongoing extension phase of the Phase 2/3 clinical trial and Phase 3 of troriluzole in SCA and our ongoing Phase 2/3 trials of troriluzole in OCD and Alzheimer’s disease;
- continue to work with the FDA and our manufacturer to bring BHV-0223 to market;
- conduct support activities for future clinical trials of BHV-5000;
- conduct our planned Phase 3 clinical trial of vazegepant and related support activities;
- complete our ongoing Phase 3 clinical trial of verdiperstat in multiple system atrophy;

- continue to initiate and progress other supporting studies required for regulatory approval of our product candidates, including long-term safety studies, drug-drug interaction studies, preclinical toxicology and carcinogenicity studies;
- make required milestone and royalty payments under the license agreements by which we acquired some of the rights to our product candidates;
- make required royalty payments to RPI Finance Trust ("RPI"), under the funding agreement, entered into June 2018, between us and RPI ("Funding Agreement");
- initiate preclinical studies and clinical trials for any additional indications for our current product candidates and any future product candidates that we may pursue;
- continue to build our portfolio of product candidates through the acquisition or in-license of additional product candidates or technologies;
- continue to develop, maintain, expand and protect our intellectual property portfolio;
- pursue regulatory approvals for our current and future product candidates that successfully complete clinical trials, including rimegepant and BHV-0223;
- hire additional clinical, medical, commercial, and development personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

In addition to the fluctuation of our operating expenses, our financial results may also be materially impacted in the future by material changes in the operating results of Kleo Pharmaceuticals, Inc. ("Kleo") or if we conclude that the value of our investment in Kleo is impaired and, as a result, we are required by U.S. GAAP to write down the carrying value of our investment.

To become and remain profitable, we must develop and eventually commercialize one or more product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing and selling any current and future product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We are only in the early stages of many of these activities and, in some cases, have not yet commenced certain of these activities.

We may never succeed in any or all of these activities and, even if we do, we may never generate sufficient revenue to achieve profitability. In addition, our potential obligation to pay RPI royalties on future sales of rimegepant, vazegepant and certain derivative compounds thereof pursuant to the Funding Agreement would impact the profitability of these products.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will obtain marketing approval to commercialize any of our product candidates. If we are required by the FDA or other regulatory authorities such as the EMA or the NMPA to perform studies and trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current or future product candidates, our expenses could increase and profitability could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We will need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed or on terms favorable to us, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to develop our product candidates. Our expenses could increase beyond our current expectations if the FDA requires us to perform clinical trials and other studies in addition to those that we currently anticipate. For example, for our troriluzole clinical program, we are conducting an additional Phase 3 clinical trial in SCA incorporating feedback from the FDA in response to discussion that we had with the FDA regarding proposed modifications to the SARA scale, the primary endpoint in the trial. With regard to our BHV-5000 program, due to the small number of patients with CRPS and Rett syndrome, we believe that BHV-5000 will require only a single pivotal trial for each disorder. However, the FDA ordinarily requires two well-controlled clinical trials prior to marketing approval of a product candidate. If the FDA requires us

to conduct additional clinical trials of troriluzole or BHV-5000, or any of our other product candidates, we would incur substantial additional, unanticipated expenses in order to obtain regulatory approval of those product candidates.

In addition, our product candidates, if approved, may not achieve commercial success. Additionally, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution and, with respect to certain of our product candidates, the payment of milestone and royalty fees. In addition, in June 2018 we entered into the Funding Agreement with RPI pursuant to which we issued to RPI the right to receive certain revenue participation payments, subject to certain reductions, based on the future global net sales of pharmaceutical products containing the compounds rimegepant or vazegepant and certain derivative compounds thereof, in exchange for $100 million. Even if we are able to obtain marketing approval for rimegepant or vazegepant, we cannot guarantee that sales of such products, if any, will be sufficiently profitable due to our obligations under the Funding Agreement. Furthermore, we expect to incur additional costs associated with operating as a public company.

As of December 31, 2019, we had cash of $316.7 million, excluding restricted cash of $1.0 million. We expect that our existing cash, net proceeds received from the January 2020 offering, and our available issuance of additional Series A Preferred Shares under the Preferred Share Agreement will be sufficient to fund our planned operating expenses, financial commitments and other cash requirements for at least twelve months from the date of filing of this report. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the costs and timing of commercialization activities, including drug manufacturing, marketing, sales and distribution, for any of our product candidates, including for which we receive marketing approval;
- the scope, progress, results and costs of our ongoing and planned preclinical studies and clinical trials for our product candidates;
- the timing and amount of milestone and royalty payments we are required to make under our license agreements and the Funding Agreement and any required redemption payments for the Series A Preferred Shares;
- the extent to which we in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates that we may pursue, and other indications for our current product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish strategic collaborations for the development or commercialization of some of our product candidates; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims brought by third parties against us.

We will require additional capital to complete our planned clinical development programs for our current product candidates to seek regulatory approval. If we receive regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

In addition, we cannot guarantee that future financing will be available on a timely basis, in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities by us, whether equity or debt, or the market perception that such issuances are likely to occur, could cause the market price of our common shares to decline. As a result, we may not be able to access the capital markets as frequently as comparable U.S. companies. If we are unable to obtain funding on a timely basis on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired.

We are subject to significant obligations, including to potentially make significant payments under the license agreements by which we acquired the rights to several of our product candidates and under our funding agreement related to rimegepant and vazegepant.

In July 2016, we acquired the rights to rimegepant and another product candidate, vazegepant, pursuant to a license agreement with BMS, and in October 2016, we acquired the rights to BHV-5000 pursuant to a license agreement with AstraZeneca. We are subject to significant obligations under these agreements, including payment obligations upon achievement of specified milestones and royalties on product sales, as well as other material obligations. We may be obligated to pay BMS up to $127.5 million in development milestones for rimegepant or a derivative thereof, up to $74.5 million in development milestones for any licensed product other than rimegepant, and up to $150.0 million in commercial milestones for each licensed product. In July 2017, we paid BMS $5.0 million due to the achievement of a specified milestone. We may also be obligated to pay AstraZeneca up to $30.0 million in development milestones for licensed products for the treatment of Rett syndrome, up to $60.0 million in development milestones for licensed products for CRPS and indications other than Rett syndrome, and up to $120.0 million in commercial milestones. We are also obligated to pay fixed royalties based on net sales of rimegepant, vazegepant and BHV-5000, or any other product that is a licensed product under those agreements. If these payments become due under the terms of our license agreements with BMS and AstraZeneca, we may not have sufficient funds available to meet our obligations and our development efforts may be materially harmed.

In September 2018, we entered into the 2018 AstraZeneca Agreement. Under the 2018 AstraZeneca Agreement, we are obligated to pay milestone payments to AstraZeneca totaling up to $55.0 million upon the achievement of specified regulatory and commercial milestones and up to $50.0 million upon the achievement of specified sales-based milestones. In addition, we will pay AstraZeneca tiered royalties ranging from high single-digit to low double-digits based on net sales of any approved products based on verdiperstat, subject to specified reductions. We may sublicense our rights under the agreement and, if we do so, we will be obligated to pay a portion of any milestone payments received from the sublicensee to AstraZeneca in addition to any milestone payments we would otherwise be obligated to pay.

In addition, our license agreements with BMS and AstraZeneca obligate us to use commercially reasonable efforts to develop and commercialize product candidates, to provide BMS and AstraZeneca with development reports documenting our progress, and to provide them with data from certain clinical trials. In addition, the 2016 AstraZeneca Agreement provides with rights of first negotiation, triggered by their receipt of a summary of certain topline data from certain of our clinical trials, to regain the respective rights we have in-licensed from them. If AstraZeneca exercises their right of first negotiation, we will be required to negotiate in good faith, as the case may be, for a specified period of time before we can enter into negotiations with third parties to sublicense these rights. AstraZeneca's rights of first negotiation may adversely impact or delay our ability to enter into collaborations with third parties for the development of these compounds. Our license agreement with BMS further provides that any sublicense, other than to an affiliate or a third-party manufacturer, requires BMS' prior written consent, not to be unreasonably withheld or delayed. Each of our license agreements with AstraZeneca further provide that, except with respect to wholly owned subsidiaries, we cannot assign the agreement without their consent, even in the event of a change of control. This could adversely impact or delay our ability to effect certain transactions.

In June 2018, we entered into the Funding Agreement with RPI, which requires us to make revenue participation payments, subject to certain reductions, based on the future global net sales of pharmaceutical products containing the compounds rimegepant or vazegepant and certain derivative compounds thereof. The participation rate commences at 2.1 percent on global annual net sales of products up to and equal to $1.5 billion, declining to 1.5 percent on global annual net sales of products exceeding $1.5 billion. If these payments become due under the terms of the Funding Agreement, they will have a negative impact on our cash flows and on the future profitability of rimegepant and vazegepant.

In addition, under the Funding Agreement, we are obligated to take certain steps to complete clinical trials and commercialize products containing the compounds rimegepant or vazegepant and certain derivative compounds thereof. These obligations could adversely impact or delay our ability to develop our other product candidates.

We may be required to redeem our outstanding Series A Preferred Shares.

In April 2019, we closed the sale of 2,495 Series A Preferred Shares to RPI at a price of $50,100 per Series A Preferred Share, resulting in gross proceeds of $125.0 million before offering expenses. As described herein, we used $105.0 million of these proceeds to fund the purchase price of the Priority Review Voucher ("PRV'). The holders of our outstanding Series A Preferred Shares (consisting of 2,495 shares as of the filing of this report), will have the right to require us to redeem their shares in certain circumstances. If a Change of Control, as defined in our Amended and Restated Memorandum and Articles of Association, occurs and the Series A Preferred Shares have not previously been redeemed, we must redeem the Series A Preferred Shares for two times (2x) the original purchase price of the Series A Preferred Shares payable in a lump sum at the closing of the Change of Control or in equal quarterly installments following the closing of the Change of Control through December 31, 2024.

If an NDA for rimegepant is not approved by December 31, 2021, the holder of the Series A Preferred Shares has the option at any time thereafter to require us to redeem the Series A Preferred Shares for one point two times (1.2x) the original purchase price of the Series A Preferred Shares.

If no Change of Control has occurred and the Series A Preferred Shares have not previously been redeemed, we must redeem the Series A Preferred Shares for two times (2x) the original purchase price, payable in a lump sum or in equal quarterly installments through December 31, 2024.

If no Change of Control has occurred, the Series A Preferred Shares have not previously been redeemed and (i) rimegepant is approved on or before December 31, 2024, following approval and starting one-year after approval, the Company must redeem the Series A Preferred Shares for two times (2x) the original purchase price, payable in a lump sum or in equal quarterly installments through December 31, 2024 (provided that if rimegepant is approved in 2024, the entire redemption amount must be paid by December 31, 2024) or (ii) rimegepant is not approved by December 31, 2024, the Company must redeem the Series A Preferred Shares for two times (2x) the original purchase price on December 31, 2024.

We may redeem the Series A Preferred Shares at our option at any time for two times (2x) the original purchase price, which redemption price may be paid in a lump sum or in equal quarterly installments through December 31, 2024.

In the event that we default on any obligation to redeem Series A Preferred Shares when required, the redemption amount shall accrue interest at the rate of eighteen percent (18%) per annum. If any such default continues for at least one year, the holders of such shares shall be entitled to convert, subject to certain limitations, such Series A Preferred Shares into common shares, with no waiver of their redemption rights.

Our obligation to redeem the Series A Preferred Shares would require a substantial amount of cash, the expenditure of which would likely have a material adverse effect on our liquidity, capital resources and business prospects. The purchase agreement pursuant to which the Series A Preferred Shares were issued provides for the potential sale of up to 1,497 additional Series A Preferred Shares under specified circumstances. The terms of our Series A Preferred Shares or any new preferred shares we may issue could also have the effect of delaying, deterring or preventing a change in control.

Our Series A Preferred Shares have rights, preferences and privileges that are not held by, and are preferential to, the rights of our common shareholders, which could result in the interests of the holders of our Series A Preferred Shares differing from those of our common shareholders.

In addition to the redemption rights discussed above, the holders of our Series A Preferred Shares have the right to receive a liquidation preference, equal to two times (2x) the original purchase price of such shares, entitling them to be paid out of our assets available for distribution to shareholders before any payment may be made to holders of any common shares. The existence of a liquidation preference may reduce the value of our common shares, make it harder for us to sell common shares in offerings in the future, or prevent or delay a change of control. Additionally, each Series A Preferred Share is entitled to vote with the common shares on the basis of 1,000 votes per share. Our memorandum and articles of association grant the Series A Preferred Shares customary protective provisions which provide that, without the approval of holders of a majority of the Series A Preferred Shares, we may not adversely affect the rights of the Series A Preferred Shares or create, authorize or issue any class or series of equity securities senior to, or pari passu with, the Series A Preferred Shares.

The preferential rights of the Series A Preferred Shares could result in divergent interests between the holders of the Series A Preferred Shares and holders of our common shares.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.

Until such time as we can generate substantial product revenue, if ever, we expect to finance our operations through a combination of equity offerings, debt financings and license and development agreements in connection with any future collaborations. We do not have any committed external source of funds. In the event we seek additional funds, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, our existing shareholders may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of the holders of our common shares. Debt financing, if available, could result in increased fixed payment obligations and may involve agreements that include restrictive covenants, such as limitations on our ability to incur additional debt, make capital expenditures, acquire, sell or license intellectual property rights or declare dividends, and other operating restrictions that could hurt our ability to conduct our business.

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

Risks Related to the Development of Our Product Candidates

We depend entirely on the success of a limited number of product candidates, which are in clinical development. If we do not obtain regulatory approval for and successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We expect that a substantial portion of our efforts and expenses over the next few years will be devoted to the development of our product candidates; specifically, the completion of the ongoing extension phase of the Phase 2/3 clinical trial and the completion of our Phase 3 clinical trial of troriluzole in SCA, completion of our Phase 2/3 clinical trials of troriluzole in OCD and Alzheimer's disease and patient tolerability studies, completion of a fourth Phase 3 clinical trial of rimegepant for the preventive treatment of migraine; and completion of our planned Phase 3 trial for vazegepant. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of these product candidates. Notwithstanding the NDAs submitted in 2019 for rimegepant, we cannot be certain that we will be able to submit additional NDAs for any of our current product candidates within the timeframes we expect, that any NDA we submit will be accepted by the FDA for filing in a timely manner or at all, or that any of our product candidates will receive regulatory approval or will be successfully commercialized even if they receive regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates in the United States will prevent us from commercializing and marketing our product candidates. The success of our product candidates will depend on several additional factors, including:

- completing clinical trials that demonstrate their efficacy and safety;
- receiving marketing approvals from applicable regulatory authorities;
- completing any post-marketing studies required by applicable regulatory authorities;
- establishing commercial manufacturing capabilities;
- launching commercial sales, marketing and distribution operations;
- the prevalence and severity of adverse events experienced with our product candidates;
- acceptance of our product candidates by patients, the medical community and third-party payors;
- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates;
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved; and
- qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. 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 complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would materially harm our business, financial condition and results of operations.

Clinical trials are very expensive, time-consuming and difficult to design and implement and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans for use in each target indication. Clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

For example, in February 2020 we reported negative topline results from our Phase 2/3 clinical trial evaluating troriluzole compared to placebo for the treatment of patients with GAD. While these efficacy results do no support continued development of troriluzole as a monotherapy in GAD, we have multiple ongoing studies evaluating troriluzole in other disease indications and with different dosing paradigms. There can be no assurance that any of these trials will produce positive results.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Further, we have limited clinical data for many of our product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. 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 of their products.

For example, the Phase 2 clinical trial of verdiperstat in patients with MSA completed by AstraZeneca failed to meet its primary endpoint of change from baseline in microglia activation assessed by PET. While we believe that directionally positive signals on certain components of the exploratory efficacy endpoint of Unified Multiple System Atrophy Rating Scale ("UMSARS") warrant further study of verdiperstat in MSA, there is no guarantee that future studies of verdiperstat will be successful.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen, and the rate of dropout among clinical trial participants. For example, we initiated a second randomized, controlled clinical trial of troriluzole in SCA in the first quarter of 2019 which incorporated trial design modifications compared to our Phase 2/3 clinical trial, including the use of a modified SARA scale to measure patient improvement. We cannot predict the impact these modifications may have on the results of this second trial.

Additionally, the data we have presented herein and upon which we have based our determination to proceed with the clinical development of troriluzole in SCA is drawn from post-hoc analyses of data subsets from our Phase 2/3 clinical trial, as well as comparisons to a natural history study cohort. While we believe these data may be useful in informing the design of our future randomized, controlled clinical trial of troriluzole, post-hoc analyses performed after unmasking trial results can result in the introduction of bias and may not be predictive of success in future clinical trials.

If we fail to produce positive results in our planned pre-clinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

We have limited experience in drug discovery and drug development, and we have never had a drug approved.

Because we in-licensed rimegepant and vazegepant from BMS and BHV-5000 and verdiperstat from AstraZeneca, we were not involved in and had no control over the preclinical and clinical development of these product candidates prior to entering into these in-license agreements. In addition, we are relying on BMS and AstraZeneca to have conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of the applicable product candidate, and having correctly collected and interpreted the data from these studies and trials. To the extent any of these has not occurred, our expected development time and costs may be increased, which could adversely affect our prospects for marketing approval of, and receiving any future revenue from, these product candidates. We have submitted NDAs for rimegepant and BHV-0223 but have not received drug approval for any products to date.

Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop our product candidates.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The commencement and completion of clinical trials for our clinical product candidates may be delayed, suspended or terminated as a result of many factors, including:

- the FDA disagreeing as to the design, protocol or implementation of our clinical trials;

- the FDA's decision not to allow us to proceed to initiate clinical trials upon our submission of an IND or a request to reactivate an IND;
- the delay or refusal of regulators or institutional review boards ("IRBs") to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organization ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol or dropping out of a trial;
- negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- reports from pre-clinical or clinical testing of other similar therapies that raise safety or efficacy concerns;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality or stability of the product candidate falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of the product candidate to commence or complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice ("GCP") regulations, or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

In order to commence our additional planned clinical trials of BHV-5000 the FDA has required that we conduct additional nonclinical toxicology studies. There is no assurance that these studies will be successful or that we will be permitted to conduct further clinical studies of BHV-5000.

If we experience delays in the commencement or completion of any clinical trial of our product candidates, or if any of our clinical trials are terminated, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenue from sales of any of these product candidates will be delayed or not realized at all.

We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue from product sales. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Significant preclinical study or clinical trial

delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

Additionally, we regularly assess our portfolio based on emerging data from pre-clinical studies and clinical trials, and we may make changes to expand or discontinue programs based on these assessments. Expansion of the number or scope of clinical trials may result in additional expenses compared to our expectations.

The regulatory approval process of the FDA and comparable foreign jurisdictions is lengthy, time-consuming and unpredictable.

Our future success is dependent upon our ability to successfully develop, obtain regulatory approval for and then successfully commercialize one or more of our product candidates. The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval is generally uncertain, may change during the course of a product candidate's clinical development and may vary among jurisdictions. Moreover, any potential purchase and redemption of a rare pediatric disease priority review voucher, or PRV, for one of our future regulatory submissions to the FDA, may not result in faster review or approval compared to products considered for approval under conventional FDA procedures and, in any event, does not assure ultimate approval by FDA. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States or abroad until we receive regulatory approval of an NDA from the FDA or approval from the EMA, NMPA or other applicable foreign regulatory agency.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we must demonstrate to the satisfaction of the FDA, EMA, NMPA or any comparable foreign regulatory agency, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. The FDA, EMA, NMPA or any comparable foreign regulatory agency can delay, limit or deny approval of our product candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA, EMA, NMPA or the applicable foreign regulatory agency's disagreement with the number, design, conduct or implementation of our preclinical studies and clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA, EMA, NMPA or any comparable foreign regulatory agency for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA, EMA, NMPA or the applicable foreign regulatory agency that our product candidates are safe and effective for their proposed indications;
- the FDA's, EMA's, NMPA's or the applicable foreign regulatory agency's disagreement with the interpretation of data from preclinical studies or clinical trials;
- actions by the CROs that we retain to conduct our preclinical studies and clinical trials, which are outside of our control and that materially adversely impact our preclinical studies and clinical trials;
- the FDA's, EMA's, NMPA's or other applicable foreign regulatory agencies' disagreement with the interpretation of data from preclinical studies or clinical trials;
- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's, EMA's, NMPA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the FDA's, EMA's, NMPA's or the applicable foreign regulatory agency's disagreement regarding the formulation, labeling or the specifications of our product candidates;
- the FDA's, EMA's, NMPA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA, EMA, NMPA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

For example, in July 2019 we received a CRL with respect to our 505(b)2 application to the FDA for the treatment of ALS with BHV-0223 (riluzole). The CRL cited issues with the active pharmaceutical ingredient (API) used in the Biohaven 2017

bioequivalence study that was manufactured between 2014 and 2016 in an Apotex Pharmachem India Private Limited (Apotex) facility. In the CRL, the FDA stated that it provided recommendations to Apotex regarding the information that would be needed to qualify previous API batches manufactured at Apotex during the time period in question. We are working with the FDA and Apotex to resolve the matter but there is no assurance that the FDA will approve the BHV-0223 505(b)2 application.

Any of our current or future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and other key global markets. To obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdiction. Failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. Failure to obtain marketing authorization for our product candidates will result in our being unable to market and sell such products. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates or may grant approvals for more limited patient populations than requested.

Even if we eventually complete clinical testing and receive approval of an NDA or foreign marketing application for our product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials or the implementation of a Risk Evaluation and Mitigation Strategy ("REMS") which may be required to ensure safe use of the drug after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

Our product candidates may fail to demonstrate safety and efficacy in clinical trials, or may cause serious adverse or unacceptable side effects that could prevent or delay regulatory approval and commercialization, limit the commercial profile of an approved label, increase our costs, necessitate the abandonment or limitation of the development of some of our product candidates or result in significant negative consequences following marketing approval, if any.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate efficacy or safety of the product candidate studied for the target indication.

For example, in February 2020 we reported negative topline results from our Phase 2/3 clinical trial evaluating troriluzole compared to placebo for the treatment of patients with GAD. The eight-week trial randomized 402 adult patients equally at more than 45 centers in the United States. In this trial, troriluzole monotherapy at 100mg twice daily did not differentiate from placebo on the primary endpoint of the mean change from baseline on the Hamilton Anxiety Rating Scale (HAM-A) after eight weeks of treatment. Troriluzole was well tolerated with a low discontinuation rate due to adverse events, however these efficacy results do not support continued development of troriluzole as a monotherapy in GAD.

As another example, in its Phase 2b clinical trial, rimegepant dosed at 75 mg showed statistically significant improvement as compared to placebo on all four key migraine symptoms—pain, nausea, photophobia, phonophobia—which are inherently subjective endpoints that are difficult to measure. Patients in the trial were provided with an electronic data capturing device, or an electronic subject diary, which they used to record and rank their assessments of pain, nausea, photophobia and phonophobia at specified time points after they had taken the study medication following the occurrence of a migraine attack with moderate to severe pain intensity. The measurements from the trial were based on subjective patient feedback as recorded on their electronic subject diary, which can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial. The placebo effect also tends to have a more significant impact on clinical trials involving subjective measures such as pain. In our three completed Phase 3 clinical trials, although rimegepant met the co-primary efficacy endpoints of all three trials, we did not achieve statistically significant improvements. as compared to placebo, on the symptom of nausea, which was a secondary efficacy endpoint of the trials.

Moreover, undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, the limitation of commercial potential or the delay or

denial of regulatory approval by the FDA. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Accordingly, we may need to abandon their development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. If any of our studies identify safety issues, we may need to complete additional studies, or abandon development of the applicable product candidate. Many compounds that initially showed promise in preclinical or early-stage testing have later been found to cause side effects that restricted their use and prevented further development of the compound in the tested indication.

In animal studies, at very high doses, rimegepant was observed to have a negative effect on the liver. We observed elevated liver enzymes in one patient that received very high doses of rimegepant in a drug-drug interaction study and in the completed Phase 2b trial of rimegepant conducted by BMS, one patient dosed with rimegepant experienced an asymptomatic and mild increase in certain hepatic enzymes, which are a type of liver enzyme measured in a LFT to detect damage and inflammation to the liver. In our recently completed Phase 3 clinical trials of rimegepant, we did not observe any instances of liver enzyme elevations that exceeded the level that is considered by the FDA to be a potentially meaningful indicator of severe drug-induced liver injury. However, we cannot guarantee that these safety and tolerability results will be replicated in our long-term safety study described below, and it is possible that rimegepant may be observed to cause unacceptable levels of adverse effects or serious adverse effects.

In addition, at our end of Phase 2 meeting, the FDA stated its desire to see a safety study in which patients received daily or near-daily dosing of rimegepant for at least three months. This desire stems from the FDA's concern about a potential liver signal with the class of CGRP antagonists. The FDA stated that any risk of liver injury has to be very low and that exposure with the drug has to be sufficient to cap the risk of liver injury at a level acceptable for the migraine population. We believe the design of our long-term safety study may adequately address this concern by providing for the enrollment of approximately 600 patients who experience eight or more migraine days per month, who will, in the study, be allowed to use rimegepant on a daily basis, which we believe will generate safety data with respect to long-term, frequent use of rimegepant. However, the FDA may determine that our trial design or the data we collect is insufficient to address their concerns, in which case we could be required to conduct additional trials.

Occurrence of serious treatment-related side effects could impede subject recruitment and clinical trial enrollment or the ability of enrolled patients to complete the trial, require us to halt the clinical trial, and prevent receipt of regulatory approval from the FDA. They could also adversely affect physician or patient acceptance of our product candidates or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If any of our product candidates that receives marketing approval is discovered to be less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

Clinical trials of our product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If any of our products that receives marketing approval is discovered to be less effective than previously believed, or cause undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a "black box" warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to approval or post-marketing studies required by regulatory authorities of such product;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and

- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

Our clinical drug development program may not uncover all possible adverse events that patients who use our products may experience. The number of subjects exposed to treatment and the average exposure time in the clinical development program may be inadequate to detect rare adverse events, or chance findings, that may only be detected once our products are administered to more patients and for greater periods of time.

Clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients are exposed to the product.

Although we have monitored the subjects in our studies for certain safety concerns and we have not seen evidence of significant safety concerns in our clinical trials, patients treated with our product candidates, if approved, may experience adverse reactions. If safety problems occur or are identified after one of our products reaches the market, the FDA or comparable foreign regulatory authorities may require that we amend the labeling of our product, recall our product, or even withdraw approval for our product. Series adverse events deemed to be caused by our product candidates, either before or after receipt of marketing approval, could have a material adverse effect on the development of our drug candidates and our business as a whole.

We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the trial until its conclusion. If we are unable to enroll a sufficient number of patients in our clinical trials, our timelines for recruiting patients, conducting clinical trials and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of our clinical trials altogether. We cannot predict how successful we will be at enrolling patients in future clinical trials. Patient enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size of the patient population required for analysis of the trial's primary endpoints;
- competition for patients for competitive product candidates undergoing clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the design of the trial;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion;
- the ability to obtain and maintain patient consents;
- the number of patients with the indication being studied; and
- the proximity and availability of clinical trial sites for prospective patients.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and

generate revenue. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Under the Funding Agreement, we are obligated to take certain steps to complete clinical trials and commercialize products containing the compounds rimegepant or vazegepant and certain derivative compounds thereof. These obligations could adversely impact or delay our ability to develop other product candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. 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 more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. In addition, we have agreed to indemnify the licensors of the intellectual property related to our product candidates against certain intellectual property infringement claims. Any claims against us, or with respect to which we are obligated to provide indemnification, regardless of their merit, could be difficult and costly to defend or settle, and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

If SAEs or other undesirable side effects are identified during the use of our product candidates in investigator-sponsored trials, it may adversely affect our development of such product candidates.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt nonclinical studies and clinical trials, or could make it more difficult for us to enroll patients in our clinical trials. If SAEs or other undesirable side effects or unexpected characteristics of our product candidates are observed in investigator-sponsored trials, further clinical development of such product candidate may be delayed or we may not be able to continue development of such product candidate at all, and the occurrence of these events could have a material adverse effect on our business. Undesirable side effects caused by our product candidates could also result in the delay or denial of regulatory approval by the FDA or other regulatory authorities or in a more restrictive label than we expect.

There can be no assurance that our NDAs for rimegepant will be approved by the FDA.

During the second quarter of 2019, we submitted NDAs for the acute treatment of migraine to the FDA for the Zydis ODT and tablet formulations of rimegepant. The NDA submission of the Zydis ODT formulation of rimegepant was submitted using a FDA priority review voucher, purchased in March 2019, providing for an expedited 6-month review.

During the third quarter of 2019, we received communication from the FDA that our Zydis ODT and tablet formulation of rimegepant NDA submissions were accepted and we were given a PDUFA date in the first quarter of 2020 for our Zydis ODT submission. In December 2019, we also received a late-cycle communication update from the FDA in which no major issues

were identified by the FDA. All comments from the FDA are preliminary and do not reflect a final decision on the review or approval of our NDA. There can be no assurance that our NDAs for rimegepant will be approved by the FDA.

If we are unable to obtain FDA approval for rimegepant, it would materially adversely affect our business, financial condition, results of operations and prospects and the value of our common shares.

Risks Related to Commercialization of Our Product Candidates

We have never successfully commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize rimegepant or any of our other products that may receive regulatory approval on our own or together with collaborators.

We have never successfully commercialized a product candidate. Until 2019, our operations were limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have only recently hired a sales force and started developing marketing and distribution capabilities, and the success of the commercialization of rimegepant, if approved by the FDA, will depend on such capabilities.

Factors that may affect our ability to successfully commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing and maintaining a sales and marketing organization will continue to require significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

We operate in a highly competitive and rapidly changing industry.

Biopharmaceutical product development is highly competitive and subject to rapid and significant technological advancements. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the United States, the European Union and other jurisdictions.

With respect to our CGRP receptor antagonists, rimegepant and vazegepant, we face competition from other companies that market or are developing migraine treatments. These include products in the class of products known as triptans, the 5-HT_{1F} receptor antagonist lasmiditan developed by Eli Lilly and Company, as well as other small molecule CGRP receptor antagonists such as ubrogepant, and atogepant in Phase 3 clinical trials, being developed by Allergan. Lasmiditan and ubrogepant were approved by the FDA in October 2019 and December 2019 and sold under the names Reyvow and Ubrelvy, respectively. Our other CGRP product candidate, vazegepant, is in an earlier stage of development than atogepant and rimegepant. In addition, three biologic CGRP receptor binding mAbs entered the market in 2018, including Aimovig (Amgen/Novartis), Ajovy (Teva), and Emgality (Lilly) for the preventive treatment of migraine in adults. As these other products received marketing approval before our migraine product candidates it could be more difficult for our products to achieve commercially successful market acceptance. The market opportunity for rimegepant for the acute treatment of migraine may decrease if the antibodies are successful in preventing migraine in patients. Wide adoption of Aimovig, Emgality and/or Ajovy may also cause clinicians to be more hesitant in prescribing an oral CGRP for acute treatment in a patient who is receiving a biologic CGRP for prevention. Finally, as acute treatment of migraine moves from a relatively generic market to a branded market, it is anticipated that payers will implement new or more stringent prior authorization procedures, such as step therapy in which a patient must try a less expensive drug first, for patients to receive these newer and more expensive medications, thereby potentially slowing new product uptake and adoption.

With respect to BHV-0223, which we are developing for the treatment of ALS, we believe our primary competition is Covis Pharmaceuticals, which sells Rilutek, the brand name for riluzole, and the six approved generic versions of Rilutek. Edaravone (Radicava, Mitsubishi Tanabe Pharma) has been approved by the FDA for the treatment of ALS, based on efficacy studies conducted in Japan, with the vast majority of patients on background riluzole therapy. Edaravone is administered to patients by intravenous infusion. We are aware of at least two other company planning to market a new formulation of riluzole. In November 2019, Aquestive Therapeutics, Inc. (previously called MonoSol Rx) announced that it had received FDA approval for Exservan™ (riluzole) oral film. Italfarmaco SpA, or Italfarmaco, a private Italian company, markets an oral liquid suspension formulation of riluzole in the United Kingdom and elsewhere in Europe under the brand name Teglutik. Tiglutik,

the US brand name for Italfarmaco's oral liquid suspension formulation of riluzole, was approved for marketing in the United States in September 2018. To our knowledge based on publicly available information, no other companies are marketing sublingual formulations of riluzole. Other companies of which we are not aware may also be developing formulations using riluzole; if such companies pursued regulatory approval of such product candidates using the Section 505(b)(2) regulatory pathway, those product candidates would potentially compete with BHV-0223. For example, Italfarmaco has obtained orphan designation for Tiglutik and Aquestive Therapeutics has obtained orphan drug designation for its oral soluble film product candidate, and these companies are eligible to obtain orphan exclusivity subject to a showing of clinical superiority to riluzole. If Tiglutik is shown to be clinically superior to Rilutek and is granted orphan exclusivity, then BHV-0223 would need to demonstrate clinical superiority to Tiglutik in order to receive marketing approval. Additionally, if the oral soluble film being developed by Aquestive Therapeutics is shown to be clinically superior to Rilutek and also receives marketing approval before BHV-0223, then BHV-0223 would need to demonstrate clinical superiority to such agents in order to receive marketing approval. If we expand our development of BHV-0223 into additional neuropsychiatric or other indications, we would face substantial competition from companies that develop or sell products that treat those indications.

With respect to troriluzole, which we are currently developing for the treatment of ataxias and other neurologic disorders, with SCA as our initial indication, there are currently no approved drug treatments for spinocerebellar ataxias in the United States. We are also developing troriluzole for the potential treatment of Alzheimer's disease and OCD and if we continue to pursue those indications, we would face substantial competition from companies that develop or sell products that treat Alzheimer's disease or OCD. With respect to BHV-5000, which we are developing for the treatment of neuropsychiatric conditions the market size and competition will depend on each indication. For example, indications such as CRPS and Rett syndrome have limited treatment options while other indications, such as depression, have multiple approved treatments.

With respect to verdiperstat, which we are currently developing for the treatment of MSA as our initial indication, there are currently no approved drug treatments for MSA in the United States. Verdiperstat is also being developed for the potential treatment of ALS; and if we purse that indication, we would face substantial competition from companies that develop or sell products that treat ALS.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors.

Competition may further increase as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop.

Established biopharmaceutical companies may invest heavily to accelerate research and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

The successful commercialization of certain of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third-party payors, is essential for most patients to be able to afford products such as our product candidates, including rimegepant, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by third-party payors will have an effect on our ability to successfully commercialize our product candidates, if approved, and attract additional collaboration partners to invest in the development of our product candidates. Coverage under certain government programs, such as Medicare, Medicaid and Tricare, may not be available for certain of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that

coverage and adequate reimbursement in the United States, the European Union 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.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable by less expensive therapies and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates, once approved. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of rimegepant and any of our other product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and adequate reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Even after we obtain regulatory approval for our product candidates, they remain subject to ongoing regulatory oversight.

Even after we obtain regulatory approval for any of our product candidates, they remain subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices ("cGMP") regulations and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include:

- issuing warning or untitled letters;
- seeking an injunction or imposing civil or criminal penalties or monetary fines;
- suspension or imposition of restrictions on operations, including product manufacturing;
- seizure or detention of products, refusal to permit the import or export of products, or requesting that we initiate a product recall;
- suspension or withdrawal of our marketing authorizations;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to applications submitted by us; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations.

Any of our product candidates, including rimegepant, that may in the future receive marketing approval may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if the FDA approves the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue or any profits from operations. The degree of market acceptance of our product candidates that are approved for commercial sale will depend on a variety of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products, if approved, for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects;
- any restrictions on the use of our products, if approved, together with other medications; and
- other potential advantages over alternative treatment methods.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our products, including rimegepant, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates.

Because we expect sales of our product candidates, including rimegepant, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of such product candidates to find market acceptance would harm our business and could require us to seek additional financing.

In addition, the potential market opportunity for rimegepant and our other product candidates is difficult to estimate precisely. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for our product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our revenue from product sales may be limited and we may be unable to achieve or maintain profitability.

We have only recently built out our marketing, sales or distribution infrastructure. If our efforts in developing sales, marketing and distribution capabilities are unsuccessful, or if we fail to achieve adequate pricing or reimbursement we will not be successful in commercializing our products candidates, including rimegepant, if approved.

Over the past year, we have expanded our marketing, sales and distribution capabilities in advance of the potential rimegepant launch. This expansion has greatly increased our expenses and has been very time-consuming for management. If approved, we plan to market, sell and distribute rimegepant through our own sales and marketing organization. Our current sales force may not be sufficient in size and may not have adequate expertise in the medical markets that we intend to target. Any deficiency in our sales, marketing and distribution capabilities or delay in the future development of such capabilities would adversely impact the commercialization of our products.

To the extent that in the future we enter into any collaboration agreements with respect to marketing, sales or distribution for our product candidates, including rimegepant, if approved, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a “reference listed drug” in the FDA’s publication, “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications ("ANDAs") in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical element ("NCE"). Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug.

While we believe that rimegepant contains active ingredients that would be treated as NCEs by the FDA and, therefore, if approved, should be afforded five years of data exclusivity, the FDA may disagree with that conclusion and may approve generic products after a period that is less than five years. Moreover, while we believe that troriluzole, a prodrug of riluzole, and BHV-5000 will also be treated as NCEs under current FDA interpretations, if approved, the FDA may ultimately disagree with

our conclusion. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

Competition that our products may face from generic versions of our products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

Risks Related to Our Dependence on Third Parties

If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are party to several license agreements under which we in-license patent rights and other intellectual property related to our business, including a license agreement with BMS, under which we were granted an exclusive license relating to rimegepant and vazegepant, a license agreement with ALS Biopharma and FCCDC, pursuant to which we were assigned intellectual property rights relating to troriluzole, a license agreement with Catalent, pursuant to which we were granted an exclusive license to use their Zydis technology in the development of BHV-0223 and rimegepant, license agreements with AstraZeneca, pursuant to which we were granted exclusive licenses relating to BHV-5000 and verdiperstat.

We have also entered into other license agreements that relate to other patent rights and other indications we are pursuing or may pursue in the future. We may enter into additional license agreements in the future. Our license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. Any uncured, material breach under these license agreements could result in our loss of rights to practice the patent rights and other intellectual property licensed to us under these agreements, and could compromise our development and commercialization efforts for our product candidates.

Our intellectual property in-licenses with third parties may be subject to disagreements over contract interpretations, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

The agreements under which we currently in-license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. If any of our current or future licenses or material relationships or any in-licenses upon which our current or future product candidates are based are terminated or breached, we may:

- lose our rights to develop and market our product candidates;
- lose patent protection for our product candidates;
- experience significant delays in the development or commercialization of our product candidates;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- incur liability for damages.

If we experience any of the foregoing, it could harm our business, financial condition and results of operations.

We rely on third parties to conduct our preclinical studies and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed.

We have historically conducted, and we intend to continue to conduct our clinical trials, using our own clinical resources, while also leveraging expertise and assistance from contract research organizations ("CROs") as appropriate. We do not currently have the ability to independently conduct large-scale clinical trials, such as a Phase 3 clinical trial, without outside assistance.

We have relied upon and plan to continue to rely upon medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or assist us in conducting GCP-compliant clinical trials on our product candidates properly and on time, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROs, we will have only limited control over their actual performance of these activities.

We and our CROs and other vendors are required to comply with cGMP, GCP and good laboratory practices ("GLP"), which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European

Union and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and other contractors. Although we rely on CROs to conduct any current or planned GLP-compliant preclinical studies and GCP-compliant clinical trials and have limited influence over their actual performance, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or any comparable foreign regulatory agency may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory agency, such regulatory agency will determine that all of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP requirements. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process.

While we will have agreements governing their activities, our CROs will not be our employees, and we will not be able to control whether or not they devote sufficient time and resources to our future preclinical and clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs 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 reason, our clinical trials may be extended, delayed or terminated, the clinical data generated in our clinical trials may be deemed unreliable, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus, and could delay development and commercialization of our product candidates. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition.

We currently rely on third parties for the production of our clinical supply of our product candidates and we intend to continue to rely on third parties for our clinical and commercial supply.

We currently rely on and expect to continue to rely on third parties for the manufacturing and supply of chemical compounds for the clinical trials of our product candidates and, if approved, our commercial supply. Reliance on third-party suppliers may expose us to different risks than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or comparable foreign marketing application to the FDA or other foreign regulatory agency.

Although we have auditing rights with all our manufacturing counterparties, we do not have control over a supplier's or manufacturer's compliance with these laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted or of satisfactory quality or continue to be available at acceptable prices. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. In the event that any of our manufacturers fails to comply with regulatory requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, or if the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities. Any replacement of our manufacturers could require significant effort, time and expense, which could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

Any failure to achieve and maintain compliance with these laws, regulations and standards could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of our product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- subjecting third-party manufacturing facilities or our own facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates;
- suspension of manufacturing of our product candidates;
- revocation of obtained approvals; and
- inability to meet commercial demands for our product candidates in the event of approval.

Furthermore, third-party providers may breach agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreements because of their own financial difficulties or business priorities, potentially at a time that is costly or otherwise inconvenient for us. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

In addition, the fact that we are dependent on third parties for the manufacture, storage and distribution of our product candidates means that we are subject to the risk that our product candidates and, if approved, commercial products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could result in recalls or regulatory enforcement action that could adversely affect our business, financial condition and results of operations. Our reliance on third parties also exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may appropriate our trade secrets or other proprietary information.

We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates, including rimegepant, receive regulatory approval; and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.

We do not currently have, nor do we plan to acquire, the internal infrastructure or capability to supply, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products.

Our ability to develop our product candidates depends and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the active pharmaceutical ingredients ("APIs") and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates.

We do not have direct control over the ability of our contract suppliers and manufacturers to maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMPs for production of both APIs and finished products. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates, and could entail higher costs or result in our being unable to effectively commercialize our approved products on a timely basis, or at all. For example, in July 2019 we received a CRL from the FDA relating to our BHV-0223 application relating to an FDA concern regarding the use of an API manufactured by Apotex and used in the drug product supplement for the BHV-0223 bioequivalence study in 2017.

We also rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. For example, Catalent is the sole-source supplier for the Zydis formulation of BHV-0223, and the ODT formulation of rimegepant. We may also have sole-source suppliers for one or more of our other product candidates. Some of the APIs and other substances and materials used in our product candidates are currently available only from one or a

limited number of domestic or foreign suppliers and foreign manufacturers and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers. In the event an existing supplier fails to supply product on a timely basis or in the requested amount, supplies product that fails to meet regulatory requirements, becomes unavailable through business interruption or financial insolvency or loses its regulatory status as an approved source or if we or our manufacturers are unable to renew current supply agreements when such agreements expire and we do not have a second supplier, we likely would incur added costs and delays in identifying or qualifying replacement manufacturers and materials and there can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. In certain cases we may be required to get regulatory approval to use alternative suppliers, and this process of approval could delay production of our products or development of product candidates indefinitely. We and our manufacturers do not currently maintain inventory of these APIs and other substances and materials. Any interruption in the supply of an API or other substance or material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects.

In addition, these contract manufacturers are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates, which may include transferring production to new third-party suppliers or manufacturers. In order to conduct larger or late-stage scale clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any of such product candidates in a timely or cost-effective manner or at all. Significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA and foreign regulatory authorities must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product. If our third-party contractors are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

We expect to continue to depend on third-party contract suppliers and manufacturers for the foreseeable future. Our supply and manufacturing agreements, if any, do not guarantee that a contract supplier or manufacturer will provide services adequate for our needs. We and our contract suppliers and manufacturers continue to improve production processes, certain aspects of which are complex and unique, and we may encounter difficulties with new or existing processes. While we attempt to build in certain contractual obligations on such third-party suppliers and manufacturers, we may not be able to ensure that such third parties comply with these obligations. Depending on the extent of any difficulties encountered, we could experience an interruption in clinical or commercial supply, with the result that the development, regulatory approval or commercialization of our product candidates may be delayed or interrupted. In addition, third-party suppliers and manufacturers may have the ability to increase the price payable by us for the supply of the APIs and other substances and materials used in our product candidates, in some cases without our consent.

Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to have our product candidates manufactured on a timely basis. Furthermore, if a contract manufacturer or supplier becomes financially distressed or insolvent, or discontinues our relationship beyond the term of any existing agreement for any other reason, this could result in substantial management time and expense to identify, qualify and transfer processes to alternative manufacturers or suppliers, and could lead to an interruption in clinical or commercial supply.

Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information.

In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries

as a result of, among other things, regulatory agency approval requirements or import inspections, incomplete or inaccurate import documentation or defective packaging.

We, or third-party manufacturers on whom we rely, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct clinical trials of our product candidates and commercialize any approved product candidates, we, or our manufacturers, will need to manufacture them in large quantities. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any of our manufacturers, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

We may in the future enter into collaborations with third parties to develop our product candidates. If these collaborations are not successful, our business could be harmed.

We may potentially enter into collaborations with third parties in the future. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- the clinical trials conducted as part of these collaborations may not be successful;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our shareholders about the status of such product candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If any such potential future collaborations do not result in the successful development and commercialization of product candidates, or if one of our future collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, the development of our product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, if one of our future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization apply to the activities of our potential future collaborators.

If we are not able to establish or maintain collaborations, we may have to alter some of our future development and commercialization plans.

Our product development programs and the commercialization of our product candidates will require substantial additional capital to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the future development and potential commercialization of those product candidate. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA, National Medical Products Administration or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may 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 may not be able to further develop our product candidates or bring them to market and generate product revenue.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Risks Related to Regulatory Compliance

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

In the United States, the European Union, and other foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed 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 and improve the quality of healthcare. For example, in March 2010, the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively ACA was enacted, which substantially changes the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer and 70% point-of-sale discounts off 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;
- new requirements to report certain financial arrangements with physicians and certain others, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's 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 certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- 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 the Center for Medicare Innovation at the Centers for Medicare and Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders, and other directives, designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA or our business or financial condition.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have an adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS is developing new payment and delivery models, such as bundled payment models. The U.S. Department of Health and Human Services (“HHS”) moved 30% of Medicare payments to alternative payment models tied to the quality or value of services in 2016. Additionally, HHS had set a goal of moving 50% of Medicare payments into these alternative payment models by the end of 2018, but due to a policy shift under the Trump Administration, it is unclear how and when such changes will be implemented. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Further, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, the Trump Administration’s budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, President Trump laid out his administration’s "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or

Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. Although some of these and other proposals will require authorization through additional legislation to become effective, members of Congress and the Trump Administration have stated that they will continue to seek new legislative and administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

More recently, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 ("Right to Try Act") was signed into law. The law, among other things, provides a federal framework for patients to access certain investigational new drug products that have completed a Phase 1 clinical trial. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA approval under the FDA expanded access program.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize any of our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any products on the market, if we obtain FDA approval for our product candidates, such as rimegepant, and begin commercializing those products in the United States, our operations may be directly, or indirectly through our prescribers, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and Physician Payments Sunshine Act and regulations. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things our current business operations, including our clinical research activities proposed sales and marketing and education programs and constrain the business or financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The U.S. laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which

payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing regulations, and as amended again by the Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to HIPAA, i.e. health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;
- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities;
- state and local laws that require the registration of pharmaceutical sales representatives;
- state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of these laws, including reporting requirements detailing interactions with and payments to healthcare providers.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company's attention from the business.

Ensuring that our internal operations and current and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

We have obtained orphan drug designation in the United States for troriluzole in SCA, BHV-0223 in ALS, BHV-5000 in Rett syndrome and verdiperstat in multiple system atrophy. We may seek orphan drug designation for other product candidates in the future. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Our ability to obtain orphan drug exclusivity for BHV-0223 for ALS is contingent upon a showing that BHV-0223 is clinically superior to Rilutek and Tiglutik in the treatment of ALS. Clinical superiority may be demonstrated by showing that a drug has greater effectiveness than the approved drug, greater safety in a substantial portion of the target population, or otherwise makes a major contribution to patient care. If we are unable to demonstrate that BHV-0223 is clinically superior to other approved riluzole products, we will not be entitled to the orphan drug exclusivity for BHV-0223 for ALS, which could adversely affect our business and our ability to market and sell BHV-0223 if it is approved for sale. Additionally, if Tiglutik, or any other approved riluzole product, receives orphan exclusivity, then BHV-0223 would need to demonstrate clinical superiority to Tiglutik or such other product in order to receive either marketing approval or orphan drug exclusivity.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for the same indication during that time period. The applicable period is seven years in the United States and ten years in the European Union. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

We cannot assure you that any future application for orphan drug designation with respect to any other product candidate will be granted. If we are unable to obtain orphan drug designation with respect to other product candidates in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even when we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a later drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process and does not assure FDA approval of our product candidate.

Fast track designation provides opportunities for frequent interactions with FDA review staff, as well as eligibility for priority review, if relevant criteria are met, and rolling review. Fast track designation is intended to facilitate and expedite development and review of an NDA to address unmet medical needs in the treatment of serious or life-threatening conditions. However, fast track designation does not accelerate clinical trials or mean that the regulatory requirements are less stringent, nor does it ensure that troriluzole will receive marketing approval or that approval will be granted within any particular timeframe. We may seek fast track designation for any of our product candidates. We may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for product candidates, we may not be able to compete effectively in our markets.

Market exclusivity for pharmaceutical products is based upon patent rights and certain regulatory forms of exclusivity. The failure to obtain patents of commercially relevant scope, or limitations on the use or loss of patent rights, could have a negative effect on our business. In addition, the patent environment can be unpredictable and the validity and enforceability of patents cannot be predicted with certainty. Absent relevant patent protection for a product, once the regulatory exclusivity periods expire, generic versions can be approved and marketed. Regulatory forms of exclusivity vary from country-to-country and are not available in certain countries.

We rely upon patents to protect the intellectual property related to our development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our current and future product candidates. We have sought to protect our proprietary positions by filing and in-licensing patents and patent applications.

The patent prosecution process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development in time to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries. If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, products. Any such outcome could have a negative effect on our business.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity, patentability or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity, patentability or enforceability of a claim.

Even if patents are granted and even if such patents cover our current or future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable, which could allow third parties to compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

Our patents and pending patent applications related to troriluzole and BHV-0223 only protect or seek to protect the formulation, prodrug or method of administration of our product candidates and not the active pharmaceutical ingredient, riluzole, a compound for which patent protection is no longer available.

We own several families of patent applications covering prodrugs and formulations of riluzole. These patent applications include several U.S. applications, U.S. patents and corresponding international and PCT applications. These families of patent applications cover troriluzole and numerous other prodrugs of riluzole as well as BHV-0223, a sublingual or ODT form of riluzole. Other patent applications provide coverage for alternative formulations of riluzole prodrugs and their uses. The applications also cover prodrugs related to riluzole and prodrugs relating to lanicemine. The patent for riluzole, which is the active pharmaceutical ingredient in these product candidates, expired in 2013, and so only novel riluzole-containing pharmaceutical compositions and their uses can be protected by one or more patent applications.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We are dependent on licensed intellectual property. If we were to lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates, if approved. If we breach any of the agreements under which we license the use, development and commercialization rights to our product candidates or technology from third parties or, in certain cases, we fail to meet certain development deadlines, we could lose license rights that are important to our business.

We are a party to a number of license agreements under which we are granted rights to intellectual property that are important to our business and we may need or choose to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose on us, various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. Our business could suffer, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners;
- our right to transfer or assign the license; and
- the effects of termination.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We have entered into several licenses to support our various programs. Termination of any of these license agreements would have a material adverse impact on our ability to develop and commercialize derived products under each respective agreement.

We may enter into additional licenses to third-party intellectual property that are necessary or useful to our business. Our current licenses and any future licenses that we may enter into impose various royalty payment, milestone, and other obligations on us. Under some license agreements, we may not control prosecution of the licensed intellectual property, or may not have the first right to enforce the intellectual property. In those cases, we may not be able to adequately influence patent prosecution or enforcement, or prevent inadvertent lapses of coverage due to failure to pay maintenance fees. If we fail to comply with any of our obligations under a current or future license agreement, the licensor may allege that we have breached our license agreement, and may accordingly seek to terminate our license. Termination of any of our current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop and commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects. Under some license agreements, termination may also result in the transfer of or granting in rights under certain of our intellectual property and information related to the product candidate being developed under the license, such as regulatory information.

In addition, if our licensors fail to abide by the terms of the license, if the licensors fail to prevent infringement by third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms, our business could suffer.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the statutory expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. In the United States, only one patent per approved product can be extended, and the extension cannot extend the total patent term

beyond fourteen years from approval. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Because riluzole has already been approved, we will not be eligible to obtain patent term extension for any of our patents, should they issue, that cover BHV-0223.

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such technology, or if we are forced to license such technology, on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek 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. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims which are the subject of the challenge, or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business or our innovations or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology, such as compounds or formulations that are similar to our product candidates, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operations.

Changes in intellectual property laws or jurisprudence could impair our ability to protect our product candidates.

Changes in intellectual property laws or regulations in the U.S., or other countries, could negatively affect our business. Similarly, changes in the interpretation of such laws or regulations could have an impact on our business.

The current law in the United States, as in most other countries in the world, uses a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. This requires that we promptly file patent applications on our inventions. The failure to do so could result in another patent applicant being awarded a patent, even though we may have made the invention first. Current U.S. law also provides a lower evidentiary standard in U.S. Patent and Trademark Office ("USPTO") proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim. Hence, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, such as Impression Products, Inc. v. Lexmark International, Inc., Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I), Mayo Collaborative Services v. Prometheus Laboratories, Inc., and Alice Corporation Pty. Ltd. v. CLS Bank International, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Some intellectual property which we have in-licensed may have been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have licensed or acquired, including rights licensed to us by Rutgers, the State University of New Jersey, and rights assigned to us by ALS Biopharma may have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980 ("Bayh-Dole Act"). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Generic manufacturers as well as other groups seeking financial gain are also increasingly seeking to challenge patents before they expire. Our commercial success depends, in part, upon our ability, and the ability of our future collaborators, to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, inter partes reviews, post grant reviews and re-examination proceedings before the USPTO, and corresponding foreign patent offices. 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. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference or derivation proceedings, post grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Similarly, we or our licensors or collaborators may initiate such proceedings or litigation against third parties, including to challenge the validity or scope of intellectual property rights controlled by third parties. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our technology, such as our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents 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 or is finally determined to be invalid, unenforceable or not infringed by our technology. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Furthermore,

even in the absence of litigation, we may need or may choose 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 such an event, we would be unable to further practice our technologies or develop and commercialize any of our product candidates at issue, which could harm our business significantly.

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, if approved. If, in the context of seeking approval for one of our product candidates subject to approval via Section 505(b)(2), we were required to file a Paragraph IV certification against any patents of a third party, we would additionally be at risk of an automatic stay if litigation is initiated, thereby potentially delaying our approval or market entry. 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. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than we or our licensors or collaborators can. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may become 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 or our licensors' patents or misappropriate or otherwise violate our or our licensor's 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. Our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable or claims challenging the scope of the intellectual property rights we own or control. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of adequate written description or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte re-examinations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we, our licensors and the patent examiner were unaware during prosecution.

For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. Therefore, these patents and applications may not be defended in a manner consistent with the best interests of our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. In addition, if the breadth or strength of protection provided by our or our licensors' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

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

We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if obtained, or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights, whether owned or licensed to us, in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets.

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We do and may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our licensors, competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to claims challenging the inventorship or ownership of our patents, patent applications or other intellectual property, or our licensors may be subject to similar such claims.

Although we are not currently experiencing any claims challenging the inventorship or ownership of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor, or that an employee, consultant, or other third party performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, or we may have disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. This risk similarly applies to any intellectual property that we in-license. If a licensor is subject to a claim challenging inventorship or ownership, it could adversely impact our exclusivity under or rights to use valuable in-licensed intellectual property.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and product candidates, via intellectual property we own or license, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Moreover, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us. Any misappropriation, disclosure or independent development of our trade secrets could harm our competitive position.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled

in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us.

We may not be able to prevent misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could 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 substantial adverse effect on the price of our common shares.

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 and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO 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 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 fail to maintain the patents and patent applications covering our products, our competitors might be able to enter the market, which would harm our business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent application in-licensed from a third party, any failure on our part to maintain the in-licensed rights could jeopardize our rights under the relevant license and may expose us to liability.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

We are highly dependent on the management, development, clinical, financial and business development experience of our senior management. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees.

The competition for qualified personnel in the biopharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement business strategy, which could harm our business.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating and implementing our 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. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in markets outside of the United States and the European Union. If we commercialize our product candidates in foreign markets, we will be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- tariffs and trade barriers;
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad ;
- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing foreign reimbursement landscapes;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Laws and regulations governing our international operations may preclude us from developing, manufacturing and selling certain product candidates and products outside of the United States and require us to develop and implement costly compliance programs.

As we expand our operations outside of the United States, we will be required to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate, as well as with the Foreign Corrupt Practices Act ("FCPA"), compliance with which is expensive and difficult, particularly in countries in which corruption is a recognized problem. As a result, these laws may preclude us from developing, manufacturing or selling certain product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We have substantially increased our number of employees over the past year as we prepare for our potential upcoming rimegepant launch and we expect to continue to expand our sales, marketing, distribution, development and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

During 2019, our number of employees increased from 63 to 647. As of December 31, 2019, most of our employees were employed directly by our U.S. subsidiary, Biohaven Pharmaceuticals, Inc. The vast majority of our recent hires are working on the sales, marketing and distribution aspects of our potential upcoming rimegepant launch. This expansion of our operations has resulted in a significant increase in our commercial organization, which may divert our management and business development resources from our clinical development group. To manage our recent growth and anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our

operations or recruit and train additional qualified personnel. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation.

Although we have adopted a code of business conduct and ethics, it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

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

Our share price has been, and may continue to be, volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Our business and operations may be materially adversely affected in the event of computer system failures or security breaches.

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including protected health information or personal data of employees or former employees, access to our clinical data or disruption of the manufacturing process, we could incur liability and the further development of our product candidates could be delayed. We may also be vulnerable to cyberattacks by hackers or other malfeasance. This type of breach of our cybersecurity may compromise our confidential information or our financial information and adversely affect our business or result in legal proceedings.

Additionally, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the EU General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018. The GDPR is wide–ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third–party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside

the EU, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR will be a rigorous and time–intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any European activities.

Risks Related to Ownership of Our Common Shares

The trading price of our common shares has been, and may continue to be, volatile and may fluctuate due to factors beyond our control, and purchasers of our common shares could incur substantial losses.

Our share price has been and may continue to be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common shares at or above the price paid for the shares. The market price for our common shares may be influenced by many factors, including:

- positive or negative results, including preliminary or topline results, of preclinical studies and clinical trials reported by us, strategic partners or competitors;
- any delay in the commencement, enrollment and the ultimate completion of clinical trials;
- technological innovations or commercial product introductions by us or competitors;
- failure to successfully develop and commercialize any of our product candidates;
- developments, announcements or changes in government regulations relating to drug products, including related to drug pricing, reimbursement and healthcare coverage;
- delays in in-licensing or acquiring additional complementary product candidates;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions, or inability to obtain additional funding;
- announcements relating to our arrangements with BMS, AstraZeneca or RPI;
- failure to meet or exceed expectations of the investment community;
- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our shares;
- announcements by therapeutic drug product providers related to pricing of therapeutics;
- announcements of significant licenses, acquisitions, strategic partnerships or joint ventures by us or our competitors;
- publication of research reports or comments by securities or industry analysts;
- recruitment or departure of key personnel;
- sales of our common shares, including sales by our directors and officers or specific shareholders;
- general market or regulatory conditions in the pharmaceutical industry or in the economy as a whole; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common shares.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and resources. Furthermore, during the course of

litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common shares.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our common shares and our trading volume could decline.

The trading market for our common shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or to continue to provide research coverage of our common shares, and such lack of research coverage may adversely affect the market price of our common shares. Even if we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause our share price or trading volume to decline.

Concentration of ownership of our common shares among our executive officers, directors and their affiliated entities may prevent new investors from influencing significant corporate decisions.

Our directors and executive officers, and entities affiliated with them, in the aggregate, beneficially own approximately 21% of our common shares. These shareholders, acting together, would be able to control or significantly influence all matters requiring shareholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. Some of these persons or entities may have interests different than yours. For example, because many of these shareholders purchased their shares at prices substantially below the current market price of our common shares and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other shareholders.

Provisions in our memorandum and articles of association could make an acquisition of us, which may be beneficial to our shareholders, more difficult and may prevent attempts by our shareholders to replace or remove our current management and limit the market price of our common shares.

Provisions in our memorandum and articles of may discourage, delay or prevent a merger, acquisition or other change in control of us that shareholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for our common shares, thereby depressing the market price of our common shares. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our shareholders to replace or remove our current management by making it more difficult for shareholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which shareholders can remove directors from the board;
- establish advance notice requirements for shareholder proposals that can be acted on at shareholder meetings and nominations to our board of directors;
- require that shareholder actions must be effected at a duly called shareholder meeting and prohibit actions by our shareholders by written consent;
- limit who may call shareholder meetings;
- authorize our board of directors to issue preferred shares without shareholder approval, which could be used to institute a shareholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our shareholders would be entitled to cast to amend or repeal certain provisions of our memorandum and articles of association.

Any provision of our memorandum and articles of association or BVI law that has the effect of delaying or deterring a change of control could limit the opportunity for our shareholders to receive a premium for their common shares, and could also affect the price that some investors are willing to pay for our common shares.

Sales of a substantial number of our common shares in the public market could occur at any time. This could cause the market price of our common shares to drop significantly, even if our business is doing well.

Sales of a substantial number of our common shares in the public market, or the perception that these sales might occur, could depress the market price of our common shares and could impair our ability to raise capital through the sale of additional equity securities.

As of February 21, 2020, we had 58,282,598 common shares outstanding, and all of these shares are freely tradable without restrictions or further registration under the Securities Act except, subject to certain restrictions applicable to shares held by our affiliates as defined in Rule 144 under the Securities Act.

In addition, we have filed a registration statement on Form S-8 registering the issuance of 16,857,649 common shares subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement on Form S-8 are available for sale in the public market subject to vesting arrangements and exercise of options for granted awards and, in the case of our affiliates, the restrictions of Rule 144.

Additionally, some holders of our common shares, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. If we were to register the resale of these shares, they could be freely sold in the public market without limitation. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common shares could decline.

Because we do not expect to pay dividends on our common shares in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any dividends on our common shares. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. The decision to pay future dividends to shareholders will be at the discretion of our board of directors after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. Accordingly, investors cannot rely on dividend income from our common shares and any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares.

We will have broad discretion in the use of our existing cash, and may invest or spend our cash in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of our cash. You may not agree with our decisions, and our use of cash may not yield any return on your investment. We expect to use our existing cash to commercialize and market rimegepant, if approved, advance and expand the development of the rest of our CGRP receptor antagonist platform, including our planned NDA filings in 2019, and glutamate modulation platform product candidates, continue development of our myeloperoxidase platform and for working capital and general corporate purposes, including satisfaction of any of our milestone payment obligations under our license agreements and obligations under our Series A Preferred Shares. In addition, we may use a portion of our existing cash to pursue our strategy to in-license or acquire additional drug candidates. Our failure to apply our cash effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of this cash. You will not have the opportunity to influence our decisions on how to use our cash.

We will continue to incur increased costs as a result of operating as a public company, and our management and board of directors will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company listed in the United States, we have and will continue to, incur significant incremental legal, accounting and other expenses. These costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the New York Stock Exchange, may increase legal and financial compliance costs and make some activities more time consuming. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities.

Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage, which in turn could make it more difficult for us to attract and retain qualified members of our management and board of directors.

In addition, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and

governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Our management is also required to annually evaluate our internal control over financial reporting and include a report on the effectiveness of these controls in our Annual Reports on Form 10-K. If we are unable to continue to conclude that we have effective internal control over financial reporting or, if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal controls over financial reporting, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our common stock.

The holders of our common shares may have fewer protections as a shareholder of our company, as the rights of shareholders under BVI law differ from those under U.S. law.

Our corporate affairs are governed by our memorandum and articles of association, the BVI Business Companies Act, 2004 (the "BVI Act") and the common law of the BVI. The rights of shareholders to take legal action against our directors, actions by minority shareholders and the fiduciary responsibilities of our directors under BVI law are to a large extent governed by the common law of the BVI and by the BVI Act. The common law of the BVI is derived in part from comparatively limited judicial precedent in the BVI as well as from English common law, which has persuasive, but not binding, authority on a court in the BVI. The rights of our shareholders and the fiduciary responsibilities of our directors under BVI law therefore are not as clearly established as they would be under statutes or judicial precedents in some jurisdictions in the United States. In particular, the BVI has a less developed body of securities laws as compared to the United States, and some states, such as Delaware, have more fully developed and judicially interpreted bodies of corporate law.

As a result of all of the above, holders of our common shares may have more difficulty in protecting their interests through actions against our management, directors or major shareholders than they would as shareholders of a U.S. company. They may have greater difficulty securing legal advice about the law of the BVI than they would U.S. and state law, and the relatively less developed nature of that country's securities law may leave investors with less certainty about the validity and strength of any claims they believe they may have against us. In addition, other differences between BVI and U.S. law, as well as the terms of our articles of association, may result in shareholders having different potential influence than they would under various U.S. state laws with respect to matters such as officer and director actions, mergers and acquisitions, takeover efforts, and other corporate decision making.

Shareholders in BVI business companies may not be able to initiate shareholder derivative actions, thereby depriving a shareholder of the ability to protect its interests.

While statutory provisions do exist in BVI law for derivative actions to be brought in certain circumstances, shareholders in BVI business companies may not have standing to initiate a shareholder derivative action in a federal court of the United States. The circumstances in which any such action may be brought, and the procedures and defenses that may be available in respect to any such action, may result in the rights of shareholders of a BVI business company being more limited than those of shareholders of a company organized in the United States. Accordingly, shareholders may have fewer alternatives available to them if they believe that corporate wrongdoing has occurred. The BVI courts are also unlikely to: (i) recognize or enforce against us judgments of courts in the United States based on certain civil liability provisions of U.S. securities law; or (ii) to impose liabilities against us, in original actions brought in the BVI, based on certain civil liability provisions of U.S. securities laws that are penal in nature or that relate to taxes or similar fiscal or revenue obligations or would be viewed as contrary to BVI public policy or the proceedings pursuant to which judgment was obtained were contrary to natural justice. There is no statutory recognition in the BVI of judgments obtained in the United States, although any final and conclusive monetary judgment obtained against a BVI business company in a U.S. court, for a definite sum, may be treated by the courts of the BVI as a cause of action in itself so that no retrial of the issues would be necessary provided that in respect of the judgment of the U.S. court:

- The U.S. court issuing the judgment had jurisdiction in the matter and the company either submitted to such jurisdiction or was resident or carrying on business within such jurisdiction and was duly served with process;
- The judgment given by the U.S. court was not in respect of penalties, taxes, fines or similar fiscal or revenue obligations of the company;
- In obtaining judgment there was no fraud on the part of the person in whose favor judgment was given or on the part of the U.S. court;
- Recognition or enforcement of the judgment in the BVI would not be contrary to public policy; and
- The proceedings pursuant to which judgment was obtained were not contrary to natural justice.

The laws of the BVI relating to the protection of minority shareholders differ from those under U.S. law and, in some circumstances, may offer less protection.

The BVI Act includes the following statutory remedies which minority shareholders in the company can rely upon:

- If the company or a director of the company engages in or proposes to engage in conduct, that contravenes the BVI Act or our memorandum and articles of association, a shareholder may apply to the BVI court for an order directing the company or its director(s) to comply with or restraining the company or a director from engaging in conduct that contravenes the BVI Act or our memorandum and articles of association.
- Under the BVI Act, minority shareholders have a statutory right to bring a derivative action in the name of and on behalf of the company in circumstances where the company has cause of action against its directors. This remedy is available at the discretion of the BVI court which will take a number of factors into account before granting or refusing a leave to proceed to the relevant shareholder, including whether such action is in the interests of the company, the cost of such action and whether there are alternative remedies that the shareholder concerned may rely upon.
- A shareholder of the company may bring an action against the company for breach of duty owed to him or her as a shareholder. This would typically be relevant in a situation where a shareholder is aggrieved by the company for breach of an entitlement or right under the company's memorandum and articles of association.
- A shareholder of the company who considers that the affairs of the company have been, are being or likely to be, conducted in a manner that is, or any act or acts of the company have been, or are, likely to be oppressive, unfairly discriminatory, or unfairly prejudicial to him in that capacity, may apply to the BVI court for an order to remedy the situation. Again, this is a discretionary remedy and the BVI court will only award it if they are satisfied that it is just and equitable to do so.
- A shareholder may apply for a liquidation of the company under the Insolvency Act 2003 of the BVI, and the BVI court should not refuse such an application merely because there are no assets to distribute to the shareholder. Shareholders can also by resolution appoint a liquidator of a BVI business company under the BVI Act if the company is solvent or under the Insolvency Act 2003 if the company is insolvent.

In addition to the statutory rights outlined above, there are common law rights for the protection of shareholders that may be invoked, largely dependent on English common law. Under the general rule pursuant to English common law known as the rule in Foss v. Harbottle, a court will generally refuse to interfere with the management of a company at the insistence of a minority of its shareholders who express dissatisfaction with the conduct of the company's affairs by the majority or the board of directors. However, every shareholder is entitled to have the affairs of the company conducted properly according to law and the constituent documents of the company. As such, if those who control the company have persistently disregarded the requirements of company law or the provisions of the company's memorandum and articles of association, then the courts will grant relief. Generally, the areas in which the courts will intervene are the following: (1) an act complained of which is outside the scope of the authorized business or is illegal or not capable of ratification by the majority; (2) acts that constitute fraud on the minority where the wrongdoers control the company; (3) acts that infringe on the personal rights of the shareholders, such as the right to vote; and (4) where the company has not complied with provisions requiring approval of the shareholders, which are more limited than the rights afforded minority shareholders under the laws of many states in the United States.

Having regard to the above, the protection available to minority shareholders under BVI law may be more limited than under the laws of some jurisdictions in the United States.

Risks related to recent and potential changes to regulatory legislation in the British Virgin Islands could lead to increased costs for us to comply with additional regulatory and reporting requirements.

As the global regulatory and tax environment evolves, we may be subject to new or different statutory and regulatory requirements. It is difficult to predict what effect future regulatory changes may have on us, however, compliance with various additional obligations may create additional costs that may be borne by us or otherwise affect our management and operation.

It may be difficult to enforce a U.S. or foreign judgment against us, our directors and our officers outside the United States, or to assert U.S. securities laws claims outside of the United States.

As a BVI business company, it may be difficult for a shareholder to effect service of process within the United States upon us, our directors and officers, or to enforce against us, or them, judgments obtained in U.S. courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state therein. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of

applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides.

Changes in tax law, determinations by tax authorities or changes in our effective tax rates may adversely affect our business and financial results.

Under current law, we expect to be treated as a non-U.S. corporation for U.S. federal income tax purposes. The tax laws applicable to our business activities, however, are subject to change and uncertain interpretation. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in jurisdictions in which we do business. Our actual tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) our ability to use net operating loss carryforwards to offset future taxable income and any adjustments to the amount of the net operating loss carryforwards we can utilize; and (5) changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles.

As a company organized under the laws of the BVI, we are principally subject to taxation in the BVI. Under the current laws of the BVI, tax on a company's income is assessed at a zero percent tax rate. For U.S. federal tax purposes, a corporation is generally considered a "domestic corporation" if it is incorporated or organized in the United States, and a "foreign corporation" if it is incorporated or organized in a non-U.S. jurisdiction. Because we are a BVI incorporated entity, we would be classified as a foreign corporation under these general rules. Section 7874 of the Code ("Section 7874") however, contains rules that can result in a foreign corporation being treated as a domestic corporation for U.S. federal tax purposes. Under Section 7874, a foreign corporation will nevertheless be treated as a domestic corporation for U.S. federal tax purposes if (1) the foreign corporation directly or indirectly acquires substantially all of the assets held directly or indirectly by a domestic corporation (including the indirect acquisition of assets by acquisition of all the outstanding shares of a domestic corporation), (2) the shareholders of the acquired domestic corporation hold at least 80% (by either vote or value) of the shares of the acquiring foreign corporation after the acquisition by reason of holding shares in the acquired domestic corporation (including the receipt of the foreign corporation's shares in exchange for the domestic corporation's shares) (the "ownership test"), and (3) the foreign corporation's "expanded affiliated group" does not have substantial business activities in the foreign corporation's country of organization or incorporation relative to the expanded affiliated group's worldwide activities. For purposes of Section 7874, "expanded affiliated group" means the foreign corporation and all subsidiaries in which the foreign corporation, directly or indirectly, owns more than 50% of the shares by vote and value.

On December 31, 2016, we entered into an agreement with the stockholders of Biohaven Pharmaceuticals, Inc., a Delaware corporation ("BPI") to purchase all of the outstanding capital stock of BPI for an aggregate purchase price of $0.6 million, payable by the issuance of promissory notes to each BPI stockholder. Although we and BPI had certain shareholders in common before December 31, 2016, based on the rules for determining share ownership under Section 7874, we believe the stockholders of BPI owned less than 80% of our company. Accordingly, we do not believe that this transaction meets the ownership test under Section 7874 and therefore do not believe that we should be treated as a domestic corporation for U.S. federal tax purposes. However, the tax law in this area could be changed, including changed on a retroactive basis, and the application of Section 7874 to our acquisition of BPI could substantially increase our effective tax rate.

We may also become subject to income, withholding or other taxes in jurisdictions by reason of our activities and operations, and it is possible that taxing authorities in such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. For example, we formed an Irish subsidiary that will be the principal operating company for conducting our business and the entity that will hold our intellectual property rights in certain of our product candidates. This new Irish subsidiary is subject to taxation in Ireland. In addition to the establishment of this Irish entity as our principal operating company, we, as the parent company, may also be subject to taxation in Ireland in the future, even as we remain a company organized under the laws of the BVI. Any of these transactions may result in higher tax liabilities and a higher overall effective tax rate. Any significant increase in our future effective tax rates could reduce net income for future periods.

If we are a passive foreign investment company there could be adverse U.S. federal income tax consequences to U.S. holders.

Under the Code, we will be a passive foreign investment company ("PFIC") for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. If we are a PFIC for any taxable year during which a U.S. holder holds our shares, the U.S.

holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

Although we do not believe we were a PFIC for our taxable year ended December 31, 2019 and do not currently expect to be a PFIC for our taxable year ending December 31, 2020 or future taxable years, we cannot provide any assurances regarding our PFIC status for any past, current or future taxable years. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies which in some circumstances are unclear and subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans which are subject to change. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our shares from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which, in our current and future taxable years, we may not be able to fully control, for example, with respect to income attributed to us from entities owned 25% or more by us. The composition of our income and assets is also affected by how, and how quickly, we spend the cash we raise in any offering.

In certain circumstances, a U.S. holder of shares in a PFIC may alleviate some of the adverse tax consequences described above by making a "qualified electing fund" ("QEF") election to include in income its pro rata share of the corporation's income on a current basis. However, a U.S. holder may make a qualified electing fund election with respect to our common shares only if we agree to furnish such U.S. holder annually with a PFIC annual information statement as specified in the applicable U.S. Treasury Regulations. We currently do not intend to prepare or provide the information that would enable U.S. holders to make a QEF election if we are treated as a PFIC for any taxable year, and prospective investors should assume that a QEF election will not be available.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our U.S. headquarters are located in New Haven, Connecticut, where, as of December 31, 2019, we occupied approximately 10,366 square feet of office space, used for executive and corporate office functions. We purchased the property in December 2018.

In August 2019, the Company entered into a lease agreement in Yardley, Pennsylvania for 21,082 square feet of office space to support expansion of the Company's commercial operations in anticipation of the rimegepant commercial launch. The lease is expected to commence on March 1, 2020 and have a term of 88 months, with the ability to extend to 148 months. The lessor has provided the Company a temporary space to occupy while leasehold improvements are completed prior to commencement in the first quarter of 2020.

We believe that our current facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. Legal Proceedings

From time to time, we may be subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common shares began trade on the New York Stock Exchange under the symbol "BHVN".

Stock Performance Graph

* $100 invested on May 4, 2017 in stock or index, including reinvestment of dividends. Fiscal year ending December 31.

Shareholders

As of February 21, 2020, there were 57 shareholders of record of our common shares. The actual number of holders of our common shares is greater than this number of record holders, and includes shareholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include shareholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid dividends on our share capital. We do not anticipate paying any dividends on our share capital in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. Any future determination to declare dividends will be subject to the discretion of our board of directors and will depend on various factors, including applicable laws, our results of operations, financial condition, future prospects and any other factors deemed relevant by our board of directors.

Recent Sales of Unregistered Securities

Not applicable.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report.

Use of Proceeds from Registered Securities

Not applicable.

Item 6. Selected Consolidated Financial Data

We have derived the consolidated statement of operations data for the years ended December 31, 2019, 2018 and 2017 and the consolidated balance sheet data as of December 31, 2019 and 2018 from our audited consolidated financial statements appearing at the end of this Annual Report on Form 10-K. The consolidated statement of operations data for the year ended December 31, 2016 and 2015 and the consolidated balance sheet data as of December 31, 2017, 2016 and 2015 was derived from our historical audited consolidated financial statements not included in this Annual Report on Form 10-K.

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Statement of Operations Data:					
Operating expenses:					
Research and development[1][2]	$ 344,673	$ 189,951	$ 89,441	$ 55,529	$ 7,559
General and administrative[2]	134,449	34,603	18,141	5,109	2,137
Total operating expenses	479,122	224,554	107,582	60,638	9,696
Loss from operations	(479,122)	(224,554)	(107,582)	(60,638)	(9,696)
Other income (expense):					
Non-cash interest expense on mandatorily redeemable preferred shares	(12,711)	—	—	—	—
Non-cash interest expense on non-recourse debt related to sale of future royalties	(26,580)	(11,726)	—	—	—
Change in fair value of warrant liability	—	(1,182)	(3,241)	154	—
Change in fair value of derivative liability	(3,875)	—	512	(65)	(370)
Change in fair value of contingent equity liability	—	—	(13,082)	(2,263)	—
Loss from equity method investment	(6,076)	(2,808)	(1,885)	(247)	—
Other	(22)	(185)	(906)	(385)	—
Total other income (expense), net	(49,264)	(15,901)	(18,602)	(2,806)	(370)
Loss before provision for income taxes	(528,386)	(240,455)	(126,184)	(63,444)	(10,066)
Provision for income taxes	419	467	1,006	90	—
Net loss and comprehensive loss	(528,805)	(240,922)	(127,190)	(63,534)	(10,066)
Net loss attributable to non-controlling interest	—	—	—	143	(4)
Accretion of beneficial conversion feature on Series A preferred shares	—	—	(12,006)	—	—
Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.	$ (528,805)	$ (240,922)	$ (139,196)	$ (63,677)	$ (10,062)
Net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.—basic and diluted	$ (10.91)	$ (6.15)	$ (5.00)	$ (5.05)	$ (0.91)
Weighted average common shares outstanding—basic and diluted	48,489,890	39,188,458	27,845,576	12,608,366	11,009,077

(1) Includes one-time $105.0 million payment for a priority review voucher to expedite the regulatory review of the Zydis ODT version of rimegepant in the second quarter of 2019

(2) Includes non-cash stock-based compensation expense, as follows:

	Year Ended December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Research and development	$ 26,284	$ 8,371	$ 6,933	$ 2,382	$ 1,527
General and administrative	28,688	8,554	6,306	2,221	1,310
	$ 54,972	$ 16,925	$ 13,239	$ 4,603	$ 2,837

	As of December 31,				
	2019	2018	2017	2016	2015
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash	$ 316,727	$ 264,249	$ 131,468	$ 23,565	$ 1,460
Working capital[(1)]	262,108	252,805	127,236	16,093	1,558
Total assets	344,264	290,012	146,888	27,017	1,892
Note payable, net of discount	—	—	—	4,216	—
Accounts payable	14,071	10,752	4,721	746	68
Accrued expenses	52,102	8,782	4,708	2,980	261
Warrant liability	—	—	4,021	780	—
Liability related to sale of future royalties, net	144,111	117,515	—	—	—
Mandatorily redeemable preferred shares, net	103,646	—	—	—	—
Derivative liability	37,690	—	—	512	447
Contingent equity liability, non-current	—	—	—	18,938	—
Note payable to related parties	—	—	—	595	—
Convertible preferred shares	—	—	—	43,270	—
Total shareholders' equity	(7,424)	150,920	131,971	(45,033)	1,087

(1) We define working capital as current assets less current liabilities.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K, or this Annual Report. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this report, including those set forth under Item 1A. "Risk Factors" and under "Cautionary Note Regarding Forward-Looking Statements" in this Annual Report.

Overview

We are a clinical-stage biopharmaceutical company with a portfolio of innovative, late-stage product candidates targeting neurological diseases, including rare disorders. Our product candidates are small molecules based on three distinct mechanistic platforms — calcitonin gene-related peptide ("CGRP"), receptor antagonists, glutamate modulators and myeloperoxidase, or MPO, inhibition — which we believe have the potential to significantly improve existing treatment approaches across a diverse set of neurological indications with high unmet need in both large markets and orphan indications. Our programs include the following:

Product	Platform	Indication	Development Stage
Rimegepant	CGRP	Acute treatment and prevention of migraine	Acute: New drug applications ("NDA") submitted with the United States Food and Drug Administration ("FDA") in the second quarter of 2019 for the Zydis orally dissolving tablet ("ODT") and tablet formulations of rimegepant. Prescription Drug User Fee Act ("PDUFA") date given (for Zydis ODT formulation) in the first quarter of 2020. Prevention: Phase 3 trial for prevention initiated in the fourth quarter of 2018 and results are expected in the first quarter of 2020.
Rimegepant	CGRP	Trigeminal Neuralgia	Phase 2 proof of concept trial ongoing.
Vazegepant	CGRP	Acute treatment and prevention of migraine	Phase 2/3 trial in acute treatment of migraine was positive on primary endpoints of freedom from pain and MBS at two hours for the 10 mg and 20 mg doses; Phase 3 replicative study planned for mid-2020.
Troriluzole	Glutamate	Ataxias	Phase 2/3 randomization phase in spinocerebellar ataxia ("SCA") complete; extension trial ongoing. Phase 3 trial ongoing.
Troriluzole	Glutamate	Obsessive Compulsive Disorder ("OCD")	Phase 2/3 trial ongoing; results are expected in the second quarter of 2020.
Troriluzole	Glutamate	Alzheimer's disease	Phase 2/3 trial ongoing; passed interim analysis in the fourth quarter of 2019.
Troriluzole	Glutamate	Generalized Anxiety Disorder ("GAD")	Phase 2/3 trial reported negative topline results in the first quarter of 2020. Program discontinued.
BHV-0223	Glutamate	Amyotrophic Lateral Sclerosis ("ALS")	Complete Response Letter ("CRL") received from the FDA in July 2019. Currently working with FDA to develop a timely path forward.
BHV-5000	Glutamate	Neuropsychiatric disorders	Phase 1 trial completed 2018; additional nonclinical studies planned and regulatory interactions ongoing.
Verdiperstat	MPO	Multiple System Atrophy ("MSA")	Phase 3 trial initiated in third quarter of 2019. Results expected in 2021.
Verdiperstat	MPO	ALS	Selected for study in HEALEY ALS Platform Trial at Massachusetts General Hospital ("MGH") and received May Proceed Letter from FDA to begin clinical trial.

CGRP Platform

In July 2016, we acquired exclusive, worldwide rights to our CGRP receptor antagonist platform, including rimegepant and vazegepant (previously known as BHV-3500), through a license agreement with Bristol-Myers Squibb Company ("BMS"), which was amended in March 2018.

Rimegepant

The most advanced product candidate from our CGRP receptor antagonist platform is rimegepant, an orally available, potent and selective small molecule human CGRP receptor antagonist that we are developing for the acute and preventive treatment of migraine. During the second quarter of 2019, we submitted NDAs for the acute treatment of migraine to the FDA for the Zydis ODT and tablet formulations of rimegepant. The NDA submission of the Zydis ODT formulation of rimegepant was submitted using a FDA priority review voucher, purchased in March 2019, providing for an expedited 6-month review.

During the third quarter of 2019, we received communication from the FDA that our Zydis ODT and tablet formulation of rimegepant NDA submissions were accepted and we were given a PDUFA date in the first quarter of 2020 for our Zydis ODT submission. In December 2019, we also received a late-cycle communication update from the FDA in which no major issues were identified by the FDA. All comments from the FDA are preliminary and do not reflect a final decision on the review or approval of our NDA.

Study 301/Study 302

In March 2018, we announced positive topline data from our first two pivotal Phase 3 trials ("Study 301 and Study 302") for the acute treatment of migraine. In each trial, treatment with a single 75 mg dose of rimegepant met the co-primary efficacy endpoints of the trial, which were superior to placebo, at two hours post-dose, on measures of pain freedom and freedom from the patient's MBS. In addition to achieving both co-primary endpoints in each of the trials, rimegepant also was observed to be generally safe and well-tolerated in the trials, with a safety profile similar to placebo. The co-primary endpoints achieved in the Phase 3 trials are consistent with regulatory guidance from the FDA and provide the basis for the submission of a NDA to the FDA.

Study 303

A third Phase 3 clinical trial for the acute treatment of migraine with a bioequivalent ODT formulation of rimegepant was commenced in February 2018. On December 3, 2018, we announced positive topline data from this randomized, controlled Phase 3 clinical trial ("BHV3000-303" or "Study 303") evaluating the efficacy and safety of our Zydis ODT formulation of rimegepant for the acute treatment of migraine. Rimegepant differentiated from placebo on the two co-primary endpoints using a single dose, pain freedom and freedom from the MBS at two hours. In total, rimegepant was significantly differentiated from the placebo in the first 21 consecutive primary and secondary outcome measures that were pre-specified. Patients treated with the rimegepant Zydis ODT formulation began to numerically separate from placebo on pain relief as early as 15 minutes, and this difference was statistically significant at 60 minutes. Additionally, a significantly greater percentage of patients treated with rimegepant Zydis ODT returned to normal functioning by 60 minutes and lasting clinical benefit compared to placebo was observed through 48 hours after a single dose of rimegepant on freedom from pain, pain relief, freedom from the MBS, and freedom from functional disability. The safety and tolerability observations of rimegepant in Study 303 were consistent with our previous observations. The overall rates of adverse events were similar to placebo (13.2% with respect to rimegepant compared to 10.5% with placebo).The efficacy and safety profile of rimegepant has now been observed across three randomized controlled trials to date. The co-primary endpoints achieved in the Phase 3 trials are consistent with regulatory guidance from the FDA. We continue to advance the rimegepant Zydis ODT and tablet formulation development programs towards potential commercialization for the acute treatment of migraine.

Study 305

In November 2018, we initiated a double-blind, placebo-controlled Phase 3 clinical trial examining regularly scheduled dosing of rimegepant 75 mg to evaluate its efficacy and safety as a preventive therapy for migraine ("BHV3000-305" or "Study 305"). We anticipate receiving topline results in the first quarter of 2020.

Long-term Safety Study

In August 2017, we commenced a long-term safety study of rimegepant in patients with migraine. On December 10, 2018, we announced the results of an interim analysis from our ongoing long-term safety study ("BHV3000-201" or "Study 201").

On May 8, 2019, we announced updated interim results from the long-term safety study. As of February 20, 2019 (the database cutoff date of the interim assessment), 105,192 doses of rimegepant 75 mg had been administered across 1,784 patients with migraine. As of February 20, 2019, approximately 527 patients have received near daily dosing (14 or more doses in 4 weeks) of rimegepant 75 mg to date for a duration ranging between 4 and 52 weeks. Interim hepatic data as of February 21, 2019 were reviewed by an external independent panel of liver experts who concluded that there was no liver safety signal

detected through the data analysis cut-off date and, compared to placebo arms of other migraine treatments, there was a very low incidence of overall elevations of liver laboratory abnormalities (1% incidence of serum ALT or AST > 3x the upper limit of normal ("ULN") through the data analysis cut-off date). Based on this interim analysis, there are indications that rimegepant may be safe and well tolerated with long-term dosing in patients with migraine.

On May 8, 2019, we also reported the safety and preliminary exploratory efficacy data from the scheduled dosing cohort in the study. In this cohort of patients with a history of 4 to 14 moderate to severe migraine attacks per month, patients were treated with rimegepant 75 mg every other day for up to 12 consecutive weeks. Patients in this cohort could also supplement their scheduled rimegepant dosing with additional as-needed dosing on nonscheduled dosing days. In this cohort, 286 patients received a total of 11,296 doses of rimegepant 75 mg tablets at least every other day, with a median number of 14.2 tablets per 4 week period. During the on-treatment period, no rimegepant-treated patients (n=281) experienced ALT or AST levels >3x the ULN. There were also no rimegepant-treated patients who experienced alkaline phosphatase or bilirubin >2x the ULN. With regard to efficacy, 48.4% of subjects in the scheduled dosing cohort experienced a ≥50% reduction in the frequency of monthly migraine days with moderate-to-severe pain intensity during the third month of treatment. This preliminary exploratory open-label efficacy data from Study 201 suggest that rimegepant may be associated with a reduction in migraine days per month (30 days) compared to the observational lead-in period, suggesting a potential preventive effect that warrants further study.

Study 201 concluded during the third quarter of 2019 with additional data analyses submitted to the FDA in connection with the NDA submissions, including the required 120-day safety update. The final report is expected in the first quarter of 2020. Additionally, this program for the acute treatment of migraine will be supported by results of 20 Phase 1/2 trials.

Pediatric Study Plan

In November 2017, the FDA agreed to our initial acute treatment Pediatric Study Plan. In June 2019, the FDA provided agreement for the amended Pediatric Study Plan.

Trigeminal Neuralgia

In the second quarter of 2019, we initiated a Phase 2 proof of concept trial to evaluate the safety and efficacy of rimegepant in patients with treatment refractory trigeminal neuralgia. Trigeminal neuralgia is a chronic facial pain syndrome characterized by paroxysmal, severe, and lancinating episodes of pain in the distribution of one or more branches of the trigeminal nerve. The trigeminal nerve, or fifth cranial nerve, is the largest of the 12 cranial nerves and provides sensory innervation to the head and neck, as well as motor innervation to the muscles of mastication. These episodic bouts of severe facial pain can last seconds to minutes, occur several times per day, and often result in significant disability. Over the long- term course of the disease, symptoms often become refractory to medical therapy and current treatment options remain suboptimal.

International Health Authority Interactions

In February 2018, a request for scientific advice for rimegepant was submitted to the Committee for Medicinal Products for Human Use ("CHMP"), a committee of the European Medicines Agency ("EMA"), and feedback was received in June 2018. Based on this feedback, we believe we have several potential pathways to approval.

In January 2019, we and our wholly owned subsidiary, BioShin Consulting Services Company Ltd. ("BioShin"), a Shanghai based limited liability company, jointly announced that the National Medical Products Administration ("NMPA," formerly, the China FDA) has accepted the investigational new drug ("IND") application for rimegepant for the treatment of migraine. As previously announced, BioShin was established to develop and potentially commercialize our late-stage migraine and neurology portfolio in China and other Asia-Pacific markets. Following the results of Study 303, we submitted a second IND application to the NMPA for the Zydis ODT formulation of rimegepant for the acute treatment of migraine. The IND application for the Zydis ODT formulation of rimegepant was accepted by the NMPA in the fourth quarter of 2019.

Vazegepant

Administration of intranasal vazegepant in a Phase 1 clinical trial was initiated in October 2018 and has achieved targeted therapeutic exposures. We advanced vazegepant into a Phase 2/3 trial to evaluate its efficacy for the acute treatment of migraine in the first quarter of 2019. We believe that intranasal vazegepant may provide an ultra-rapid onset of action that could be used in a complimentary fashion with other migraine treatments when the speed of onset is critical to a patient. In December 2019, we announced positive topline results from the Phase 2/3 trial. Vazegepant 10 and 20 mg was statistically superior to placebo on the co-primary endpoints of pain freedom and freedom from the MBS at two hours using a single dose. Additional results from this study are anticipated to be presented at upcoming scientific meetings in 2020, and a Phase 3 replicative study is planned for mid-2020.

Glutamate Platform

We are developing three product candidates that modulate the body's glutamate system. Two of these product candidates, troriluzole (previously referred to as trigriluzole and BHV-4157) and BHV-0223, act as glutamate transporter modulators, while our product candidate BHV-5000 is an antagonist of the glutamate N-methyl-D-aspartate ("NMDA") receptor.

Troriluzole

Ataxias

We are developing troriluzole for the treatment of ataxias; our initial focus has been SCA. We have received both orphan drug designation and fast track designation from the FDA for troriluzole for the treatment of SCA. A Phase 3 trial began enrollment in March 2019 to evaluate the efficacy of troriluzole in SCA. We believe that the non-statistically significant clinical observations from our first Phase 2/3 trial and open-label extension phase in SCA support our decision to advance troriluzole into a Phase 3 trial that could provide the data needed to serve as the basis for an NDA. We expect to complete enrollment in the Phase 3 trial of troriluzole in SCA in the first quarter of 2020.

Other Indications

A Phase 2/3 double-blind, randomized, controlled trial to assess the efficacy of troriluzole in OCD commenced in December 2017. We expect to complete the enrollment of this trial in the first quarter of 2020.

In addition, a Phase 2/3 double-blind, randomized, controlled trial of troriluzole in the treatment of mild-to-moderate Alzheimer's disease has advanced with the Alzheimer's Disease Cooperative Study, a consortium of sites funded by the National Institutes of Health. In the fourth quarter of 2019, we completed enrollment in the study and announced that the study passed the interim futility analysis. In order to pass the interim futility analysis, troriluzole had to demonstrate numerically greater benefit over placebo on at least one of the two pre-specified criteria at 26 weeks: either (i) cognitive function as measured by the Alzheimer's Disease Assessment Scale-Cognitive Subscale ("ADAS-cog") or (ii) hippocampal volume as assessed by magnetic resonance imaging.

In February 2020 we reported negative topline results from our Phase 2/3 clinical trial evaluating troriluzole compared to placebo for the treatment of patients with GAD. This eight-week trial randomized 402 adult patients equally at more than 45 centers in the United States. In this trial, troriluzole monotherapy at 100mg twice daily did not differentiate from placebo on the primary endpoint of the mean change from baseline on the Hamilton Anxiety Rating Scale (HAM-A) after eight weeks of treatment. The efficacy results do not support continued development of troriliuzole as a monotherapy in GAD.

BHV-0223

We are developing BHV-0223 for the treatment of ALS. In January 2018, we announced positive results of a bioequivalence study with BHV-0223 and marketed riluzole, thus providing pivotal data that we believed was sufficient for the filing of an NDA with the FDA, allowing us to pursue the regulatory approval of BHV-0223 for ALS under Section 505(b)(2) of the U.S. Federal Food, Drug, and Cosmetic Act. We submitted an NDA in September 2018, and the PDUFA date was in July 2019. In July 2019, we announced that we received a CRL from the FDA for the 505(b)2 application seeking approval for BHV-0223 (riluzole) for the treatment of ALS. The sole issue identified in the CRL relates to an FDA concern regarding the use of an active pharmaceutical ingredient ("API") manufactured by Apotex Pharmachem India Private Limited ("Apotex") and used in the drug product supplies for the bioequivalence study in 2017. In the CRL, the FDA stated that it provided recommendations to Apotex regarding the information needed to qualify previous API batches manufactured at Apotex during the time period in question. We have been subsequently informed by the manufacturer that the manufacturer had an exemption from the FDA to supply riluzole to the U.S. market during that time period. We have been in contact with the FDA's Chemistry, Manufacturing, and Controls ("CMC") group and Apotex to resolve the matter and we have already submitted additional information to the FDA regarding this issue. We note that the API for commercial supply of BHV-0223 is currently sourced from another supplier, with whom no CMC issues have been identified. The FDA did not cite any other concerns in their CRL regarding BHV-0223.

BHV-5000

We are also developing BHV-5000, an orally available, low-trapping NMDA receptor antagonist, for the treatment of neuropsychiatric diseases. One potential target indication includes Complex Regional Pain Syndrome ("CRPS"). CRPS is a rare, chronic pain condition typically affecting limbs and triggered by traumatic injury. Accompanying symptoms also include chronic inflammation and reduced mobility in the affected areas. Other disorders of interest include treatment-resistant major depressive disorder and Rett syndrome. Rett syndrome is a rare and severe genetic neurodevelopmental disorder for which no approved treatments are currently available. We acquired worldwide rights to BHV-5000 under an exclusive license agreement with AstraZeneca AB in October 2016. We selected a lead formulation at the end of 2017 and completed single dosing in a Phase 1 clinical trial of BHV-5000 in January 2018 to evaluate its pharmacokinetic properties. Nonclinical studies are ongoing to support future trials.

MPO Platform

Verdiperstat

We are developing verdiperstat (previously BHV-3241), an oral myeloperoxidase inhibitor for the treatment of neurodegenerative diseases. One target indication is MSA, a rare, rapidly progressive and fatal neurodegenerative disease with no cure or effective treatments. Verdiperstat has received orphan drug designation for the treatment of MSA from both the FDA and the European Medicines Agency. A Phase 3 trial began enrollment in July 2019 to evaluate the efficacy of verdiperstat in MSA. The China IND approval to join the Phase 3 clinical trial of verdiperstat for the treatment of MSA was obtained in the fourth quarter of 2019. Another potential target indication is ALS. In September 2019, we announced that verdiperstat was selected to be studied in the HEALEY ALS Platform Trial, which is being conducted by the Sean M. Healey & AMG Center for ALS at MGH in collaboration with the Northeast ALS Consortium (“NEALS”) clinical trial network. Promising investigational drugs were chosen for the HEALEY ALS Platform Trial through a competitive process, with the Healey Center providing partial financial support to successful applicants. Verdiperstat was progressed through Phase 2 clinical trials by AstraZeneca. We have entered into an exclusive license agreement with AstraZeneca for the product candidate. A Phase 2/3 clinical trial of verdiperstat is anticipated to begin in the second quarter of 2020.

Preclinical

In May 2019, we entered into an agreement with Fox Chase Chemical Diversity Center Inc. (“FCCDC”) for FCCDC’s TDP-43 assets (the “FCCDC Agreement”). The FCCDC Agreement provides the Company with a plan and goal to identify one or more new chemical entity candidates for preclinical development for eventual clinical evaluation for the treatment of one or more TDP-43 proteinopathies. In connection with the FCCDC Agreement, Biohaven and FCCDC have established a TDP-43 Research Plan that provides for certain milestones to be achieved by FCCDC, and milestone payments to be made by us. (See Note 13).

Financings and Other Recent Developments

Since our inception, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. We have funded our operations primarily with proceeds from sales of equity, and other financing transactions. Subsequent to our initial public offering ("IPO"), we raised funds through sales of our equity, as well as through the sale of a revenue participation right related to future royalties.

In May 2017, our registration statement on Form S-1 relating to our IPO was declared effective by the SEC. The IPO closed on May 9, 2017 and we issued and sold 9,900,000 common shares at a public offering price of $17.00 per share, resulting in net proceeds of $152.7 million after deducting underwriting discounts and commissions and other offering expenses. In addition, on May 9, 2017, the underwriters of our IPO fully exercised their option to purchase additional shares, and on May 11, 2017, we issued and sold an additional 1,485,000 common shares, resulting in additional net proceeds to us of $23.5 million, after deducting underwriting discounts and commissions and other offering expenses. The aggregate net proceeds we received from the IPO, after deducting underwriting discounts and commissions and offering expenses, were $176.1 million.

In March 2018, we sold an aggregate of 2,000,000 common shares in a private placement at a price of $27.50 per share, for net proceeds of $52.0 million after deducting underwriting discounts and commissions of $2.8 million and other offering expenses of $0.2 million. Subsequent to the closing of the Private Placement, we paid BMS the $50.0 million upfront payment under the BMS Amendment.

In June 2018, we entered into a funding agreement ("Funding Agreement") to sell tiered, sales-based royalty rights on global net sales of the pharmaceutical products containing the compounds rimegepant or vazegepant and certain derivative compounds thereof ("Products") to RPI Finance Trust ("RPI"). We issued to RPI the right to receive certain revenue participation payments, subject to certain reductions, based on the future global net sales of the Products, for each calendar quarter during the royalty term contemplated by the Funding Agreement, in exchange for $100.0 million in cash. Specifically, the participation rate commences at 2.1 percent on annual global net sales of up to and equal to $1.5 billion, declining to 1.5 percent on annual global net sales exceeding $1.5 billion.

Concurrently, we entered into a common stock purchase agreement with RPI, pursuant to which we issued and sold 1,111,111 common shares to RPI. RPI paid $45.00 per share, resulting in net proceeds of $49.9 million after deducting offering expenses of $0.1 million.

In December 2018, we closed on an underwritten public offering of 3,859,060 common shares, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $37.25 per share. The aggregate net proceeds to us from the offering, after deducting the underwriting discounts and commissions and offering expenses payable, were approximately $143.8 million.

In June 2019, the Company issued and sold 6,976,745 common shares at a public offering price of $43.00 per share for net proceeds of approximately $281.1 million after deducting underwriting discounts and commissions of approximately $18.0 million and other offering expenses of approximately $0.9 million. In addition, in July 2019, the underwriters of the follow-on

offering partially exercised their option to purchase additional shares, and the Company issued and sold 525,000 common shares for net proceeds of approximately $21.2 million after deducting underwriting discounts and commissions of approximately $1.4 million. Thus, the aggregate net proceeds to the Company from the follow-on offering, after deducting underwriting discounts and commissions and other offering costs, were approximately $302.3 million.

In January 2020, the Company issued and sold 4,830,917 common shares at a public offering price of $51.75 per share for net proceeds of approximately $245.9 million after deducting underwriting discounts and commissions of approximately $3.6 million and other offering expenses of approximately $0.5 million. In addition, in February 2020, the underwriter of the follow-on offering exercised its option to purchase additional shares, and the Company issued and sold 724,637 common shares for net proceeds of approximately $37.0 million after deducting underwriting discounts and commissions of approximately $0.5 million. Thus, the aggregate net proceeds to the Company from the follow-on offering, after deducting underwriting discounts and commissions and other offering costs, were approximately $282.8 million.

As of December 31, 2019, we had cash of $316.7 million, excluding restricted cash of $1.0 million. Cash in excess of immediate requirements is invested in non-interest-bearing accounts with a view to liquidity and capital preservation. We believe that our cash as of December 31, 2019, the net proceeds received from the January 2020 offering, and our available issuance of additional Series A Preferred Shares under the Preferred Share Agreement will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources." Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales. If our development efforts for our product candidates are successful and result in regulatory approval or additional license agreements with third parties, we may generate revenue in the future from product sales.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations ("CROs") or contract manufacturing organizations ("CMOs"), as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- employee-related expenses, including salaries, benefits, travel and non-cash share-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements;
- payments made in cash, equity securities or other forms of consideration under third-party licensing agreements; and
- payment for a FDA PRV to expedite the regulatory review of the NDA submission for the Zydis ODT formulation of rimegepant.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using estimates of our clinical personnel or information provided to us by our service providers.

Our external direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs, contract manufacturing organizations, and central laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under license agreements. We do not allocate employee costs or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee the research and development as well as for managing our preclinical development, process development, manufacturing and

clinical development activities. Many employees work across multiple programs, and we do not track personnel costs by program.

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. As a result, we expect that our research and development expenses will remain significant over the next several years as we increase personnel costs conduct clinical trials and prepare regulatory filings for our product candidates. We also expect to incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into license agreements to acquire the rights to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishment of an appropriate safety profile with IND-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- establishment of commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- acquisition, maintenance, defense and enforcement of patent claims and other intellectual property rights;
- significant and changing government regulation;
- initiation of commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintenance of a continued acceptable safety profile of the product candidates following approval.

General and Administrative Expenses

General and administrative expenses include salaries, benefits, travel expense and non-cash share-based compensation expense for personnel in executive, commercial, finance and administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our general and administrative headcount to support our continued research and development, and commercialization activities of our product candidates. We also continue to incur accounting, audit, legal, regulatory, compliance, public relations, director and insurance costs associated with being a public company. Additionally, as our product candidates progress to or obtain regulatory approval, we expect further increases in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

Other Income (Expense)

Change in Fair Value of Derivative Liability

The fair value of the derivative liability recognized in connection with contingent payments under the Preferred Share Agreement is determined using the with-and-without valuation method. As inputs into the valuation, we considered the type and probability of occurrence of certain events, the amount of the payments, the expected timing of certain events, and a risk-adjusted discount rate. In accordance with ASC 815, Derivatives and Hedging, the fair value of the derivative is recorded on the balance sheet as a derivative liability with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss.

Non-Cash Interest Expense on Liability Related to Sale of Future Royalties

We have accounted for the Funding Agreement with RPI as a liability financing, primarily because it has significant continuing involvement in generating the future revenue on which the royalties are based. The liability related to sale of future royalties and the related non-cash interest expense are measured based on the Company's current estimate of the timing and amount of expected future royalties expected to be paid over the estimated term of the Funding Agreement with RPI Trust using

a discounted cash flow model. The liability is amortized using the effective interest rate method, resulting in recognition of non-cash interest expense over the estimated term of the agreement. Each reporting period, the Company assesses the estimated timing and amount of future expected royalty payments over the estimated term. If there are changes to the estimate, the Company recognizes the impact to the liability's amortization schedule and the related non-cash interest expense prospectively. The Company's estimate of the amount of expected future royalties to be paid considers the probability of success of the compounds being approved for sale, market penetration rates of the compounds upon approval, compliance rate and net pricing. Additionally, the transaction costs associated with the liability will be amortized to non-cash interest expense over the estimated term of the Funding Agreement.

Loss from Equity Method Investment

From August 2016 through November 2018, we purchased shares of common stock in Kleo Pharmaceuticals, Inc., a privately held Delaware corporation ("Kleo"). As of December 31, 2019 and 2018, we owned approximately 42% of the outstanding shares of Kleo's common stock. We account for our investment in Kleo under the equity method of accounting. As a result, our proportionate share of Kleo's net income or loss each reporting period is included in other income (expense), net, in our consolidated statement of operations and comprehensive loss and results in a corresponding adjustment to the carrying value of the equity method investment on our consolidated balance sheet.

Change in Fair Value of Warrant Liability

In connection with entering into a credit agreement, we issued warrants to purchase common shares to two of our directors in connection with a guarantee of our obligations under the agreement. We previously classified the warrants as a liability on our consolidated balance sheet because each warrant represented a freestanding financial instrument that was not indexed to our shares. The warrant liability was initially recorded at fair value upon entering into the credit agreement and was subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability was recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. On January 26, 2018, the anti-dilution price protection provisions contained within the warrants expired. Due to the expiration of these provisions, we discontinued classification of these warrants as a liability, and have accordingly reclassified them to additional paid-in capital within shareholders' equity. Both warrants were exercised in March 2019, and are no longer outstanding.

Provision for Income Taxes

As a company incorporated in the British Virgin Islands ("BVI"), the Company is principally subject to taxation in the BVI. Under the current laws of the BVI, tax on a company's income is assessed at a zero percent tax rate. As a result, the Company has not recorded any income tax benefits from its losses incurred in the BVI during each reporting period, and no net operating loss carryforwards will be available to the Company for those losses. We have historically outsourced all of the research and clinical development for its programs under a master services agreement with BPI. As a result of providing services under this agreement, BPI was profitable during the years ended December 31, 2019 and 2018, and BPI is subject to taxation in the United States.

As of December 31, 2019, we evaluated our deferred tax assets and determined that a full valuation allowance on these assets was appropriate due to the generation of tax credits in excess of forecasted taxes. The Company recorded an income tax provision during the year ended December 31, 2019 of $0.4 million which primarily represents certain state taxes for the period and federal taxes due to general business credit limitations.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,		
	2019	2018	Change
In thousands			
Operating expenses:			
Research and development	$ 344,673	$ 189,951	$ 154,722
General and administrative	134,449	34,603	99,846
Total operating expenses	479,122	224,554	254,568
Loss from operations	(479,122)	(224,554)	(254,568)
Other income (expense):			
Non-cash interest expense on mandatorily redeemable preferred shares	(12,711)	—	(12,711)
Non-cash interest expense on liability related to sale of future royalties	(26,580)	(11,726)	(14,854)
Change in fair value of warrant liability	—	(1,182)	1,182
Change in fair value of derivative liability	(3,875)	—	(3,875)
Loss from equity method investment	(6,076)	(2,808)	(3,268)
Other	(22)	(185)	163
Total other income (expense), net	(49,264)	(15,901)	(33,363)
Loss before provision for income taxes	(528,386)	(240,455)	(287,931)
Provision for income taxes	419	467	(48)
Net loss and comprehensive loss	(528,805)	(240,922)	(287,883)
Accretion of beneficial conversion feature on Series A preferred shares	—	—	—
Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.	$ (528,805)	$ (240,922)	$ (287,883)
Net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.—basic and diluted	$ (10.91)	(6.15)	(4.76)
Weighted average common shares outstanding—basic and diluted	48,489,890	39,188,458	

Research and Development Expenses

	Year Ended December 31,		
	2019	2018	Change
In thousands			
Direct research and development expenses by program:			
BHV-0223	$ 849	$ 6,134	$ (5,285)
Troriluzole	37,812	13,222	24,590
Rimegepant:			
Priority review voucher purchase	105,000	—	105,000
Program expenses	88,948	75,719	13,229
Vazegepant	44,821	11,241	33,580
BHV-5000	850	2,147	(1,297)
Verdiperstat	10,922	—	10,922
Unallocated research and development costs:			
Personnel related (including non-cash share-based compensation)	45,683	19,882	25,801
BMS Amendment upfront license payment	—	50,000	(50,000)
Preclinical research programs	6,193	—	6,193
Other	3,595	11,606	(8,011)
Total research and development expenses	$ 344,673	$ 189,951	$ 154,722

Research and development expenses including one-time regulatory and license fees were $344.7 million for the year ended December 31, 2019, compared to $190.0 million for the year ended December 31, 2018. The increase of $154.7 million was primarily due to:

- one-time $105.0 million payment for a PRV to expedite the regulatory review of the Zydis ODT version of rimegepant in the second quarter of 2019;
- filing fees of $7.6 million related to our NDA submissions to the FDA in the second quarter of 2019;
- expense for development milestone paid in the fourth quarter of 2019 to BMS of $7.5 million for rimegepant NDA submissions in the second quarter of 2019;
- increases in costs for rimegepant commercial drug supply and product validation batches of $12.7 million in 2019;
- increases in direct costs of $24.6 million for our troriluzole program, which include increases for our GAD, OCD, and Alzheimer's Disease trials;
- increases in direct costs of $33.6 million for our vazegepant program, including expenses for development milestones payable to BMS of $10.0 million in 2019;
- increase of $6.2 million for our preclinical research programs mainly due to a $5.6 million non-cash research and development expense due to the issuance of common shares in the second quarter of 2019 relating to the collaborative discovery program with FCCDC; and
- increases in personnel costs of $25.8 million resulting from an increase of $17.9 million in non-cash share-based compensation in 2019 as a result of additional share-based compensation awards and hiring additional research and development personnel.

The increases in direct costs during the period were partially offset by the $50.0 million one-time upfront payment to BMS in the year ended December 31, 2018.

General and Administrative Expenses

General and administrative expenses were $134.4 million for the year ended December 31, 2019, compared to $34.6 million for the year ended December 31, 2018. The increase of $99.8 million was primarily due to preparation for rimegepant commercialization activities, including increases in personnel-related costs, including non-cash share-based compensation, due to the hiring of additional personnel, and professional and consulting fees supporting the potential commercial launch of rimegepant. Non-cash share-based compensation expense, included in personnel related costs, was $28.7 million for the year ended December 31, 2019, an increase of $20.1 million as compared to the same period in 2018.

Other Income (Expense), Net

Other income (expense), net was a net expense of $49.3 million for the year ended December 31, 2019, compared to net expense of $15.9 million for the year ended December 31, 2018. The increase of $33.4 million in net expense was primarily due to the change in fair value of derivative liability and the non-cash interest expense on our liability related to the mandatorily redeemable preferred shares resulting from the sale of Series A Preferred Shares to RPI in April 2019, and an increase in the non-cash interest expense recognized on our liability related to the sale of future royalties.

Provision for Income Taxes

We recorded a provision for income taxes of $0.4 million for the year ended December 31, 2019, compared to a provision for income taxes of $0.5 million for the year ended December 31, 2018. We recorded a tax provision for the year ended December 31, 2019 for the state income taxes of BPI's profitable operations in the United States during that period and federal income taxes due to general business credit limitations.

Comparison of the Years Ended December 31, 2018 and 2017

The following table summarizes our results of operations for the years ended December 31, 2018 and 2017:

	Year Ended December 31,		
	2018	2017	Change
In thousands			
Operating expenses:			
Research and development	$ 189,951	$ 89,441	$ 100,510
General and administrative	34,603	18,141	16,462
Total operating expenses	224,554	107,582	116,972
Loss from operations	(224,554)	(107,582)	(116,972)
Other income (expense):			
Non-cash interest expense on mandatorily redeemable preferred shares	—	—	—
Non-cash interest expense on liability related to sale of future royalties	(11,726)	—	(11,726)
Change in fair value of warrant liability	(1,182)	(3,241)	2,059
Change in fair value of derivative liability	—	512	(512)
Change in fair value of contingent equity liability	—	(13,082)	13,082
Loss from equity method investment	(2,808)	(1,885)	(923)
Other	(185)	(906)	721
Total other income (expense), net	(15,901)	(18,602)	2,701
Loss before provision for income taxes	(240,455)	(126,184)	(114,271)
Provision for income taxes	467	1,006	(539)
Net loss and comprehensive loss	(240,922)	(127,190)	(113,732)
Accretion of beneficial conversion feature on Series A preferred shares	—	(12,006)	12,006
Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.	$ (240,922)	$ (139,196)	$ (101,726)
Net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.—basic and diluted	$ (6.15)	$ (5.00)	$ (1.15)
Weighted average common shares outstanding—basic and diluted	39,188,458	27,845,576	

Research and Development Expenses

In thousands	Year Ended December 31, 2018	2017	Change
Direct research and development expenses by program:			
BHV-0223	$ 6,134	$ 3,950	$ 2,184
Trigriluzole	13,222	13,139	83
Rimegepant	75,719	48,122	27,597
Vazegepant	11,241	5,728	5,513
BHV-5000	2,147	1,918	229
Verdiperstat	—	—	—
Unallocated research and development costs:			
Personnel related (including share-based compensation)	19,882	14,304	5,578
BMS Amendment upfront license payment	50,000	—	50,000
Preclinical research programs	—	—	—
Other	11,606	2,280	9,326
Total research and development expenses	$ 189,951	$ 89,441	$ 100,510

Research and development expenses were $190.0 million for the year ended December 31, 2018, compared to $89.4 million for the year ended December 31, 2017. The increase of $100.5 million was primarily due to an increase of $50.0 million due to the BMS Amendment upfront payment, $27.6 million in direct costs for our rimegepant program, $5.6 million in personnel costs, $5.5 million in direct costs for our vazegepant program, $2.2 million in direct costs for our BHV-0223 program and $9.3 million in unallocated external costs.

The increases in direct costs for our rimegepant and BHV-0223 programs were primarily due to an increase in the number of clinical trials during the year ended December 31, 2018. The increase in costs for vazegepant was primarily a result of further clinical development and advancement of the programs compared to the prior period.

The increase in personnel costs of $5.6 million was primarily a result of hiring additional research and development personnel. Non-cash share-based compensation expense, included in personnel-related costs, was $8.4 million for the year ended December 31, 2018 compared to $6.9 million for the year ended December 31, 2017, an increase of $1.4 million.

General and Administrative Expenses

General and administrative expenses were $34.6 million for the year ended December 31, 2018, compared to $18.1 million for the year ended December 31, 2017. The increase of $16.5 million was primarily due to increases in personnel-related costs, including non-cash share-based compensation, due to the hiring of additional personnel in our general and administrative functions, preparation for commercialization activities, professional fees supporting ongoing business operations, and additional costs to comply with requirements of operating as a public company. Non-cash share-based compensation expense, included in personnel-related costs, was $8.6 million for the year ended December 31, 2018, an increase of $2.3 million as compared to the same period in 2017.

Other Income (Expense), Net

Other income (expense), net was a net expense of $15.9 million for the year ended December 31, 2018, compared to net expense of $18.6 million for the year ended December 31, 2017. The decrease of $2.7 million in net expense was primarily due to a $13.1 million decrease in fair value of the contingent equity liabilities associated with our license agreements with BMS and AstraZeneca in 2017, which did not occur in 2018, and a $2.1 million larger decrease in fair value of the warrant liabilities associated with the warrants issued in connection with our Wells Fargo credit agreement during 2017 compared to 2018, which was satisfied upon our initial public offering in May 2017 ("IPO"), mostly offset by an increase in the expense related to the non-cash interest expense on our liability related to the sale of future royalties of $11.7 million.

Provision for Income Taxes

We recorded a provision for income taxes of $0.5 million for the year ended December 31, 2018, compared to $1.0 million for the year ended December 31, 2017. We recorded a tax provision for the year ended December 31, 2018 for the state income taxes of BPI's profitable operations in the United States during that period and federal income taxes due to general business credit limitations. Due to tax reform enacted in the United States in December 2017, we are no longer subject to the alternative minimum tax.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. Prior to the completion of our IPO in May 2017, we funded our operations primarily with proceeds from the sale of preferred shares and common shares through private placements and borrowings under our credit agreement with Wells Fargo. Prior to the completion of our IPO, we had received net cash proceeds of $96.4 million from sales of our preferred shares and common shares and gross proceeds of $5.0 million from borrowings under the credit agreement.

On May 3, 2017, our registration statement on Form S-1 relating to our IPO was declared effective by the SEC. The IPO closed on May 9, 2017 and we issued and sold 9,900,000 common shares at a public offering price of $17.00 per share, resulting in net proceeds of $152.7 million after deducting underwriting discounts and commissions and other offering expenses. In addition, on May 9, 2017, the underwriters of our IPO fully exercised their option to purchase additional shares, and on May 11, 2017, we issued and sold an additional 1,485,000 common shares, resulting in additional net proceeds to us of $23.5 million, after deducting underwriting discounts and commissions and other offering expenses. The aggregate net proceeds we received from the IPO, after deducting underwriting discounts and commissions and offering expenses, were $176.1 million.

In March 2018, we sold an aggregate of 2,000,000 common shares in a private placement at a price of $27.50 per share, for net proceeds of $52.0 million after deducting underwriting discounts and commissions of $2.8 million and other offering expenses of $0.2 million. Subsequent to the closing of the Private Placement, we paid BMS the $50.0 million upfront payment under the BMS Amendment.

In June 2018, we entered into the Funding Agreement to sell tiered, sales-based royalty rights on global net sales of pharmaceutical products containing the compounds rimegepant or vazegepant and Products to RPI. We issued to RPI the right to receive certain revenue participation payments, subject to certain reductions, based on the future global net sales of the Products, for each calendar quarter during the royalty term contemplated by the Funding Agreement, in exchange for $100.0 million in cash. Specifically, the participation rate commences at 2.10 percent on annual global net sales of up to and equal to $1.5 billion, declining to 1.50 percent on annual global net sales exceeding $1.5 billion.

Concurrently, we entered into a common stock purchase agreement with RPI, pursuant to which we issued and sold 1,111,111 common shares to RPI. RPI paid $45.00 per share, resulting in net proceeds of $49.9 million after deducting offering expenses of $0.1 million.

In December 2018, we closed on an underwritten public offering of 3,859,060 common shares, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $37.25 per share. The aggregate net proceeds to us from the offering, after deducting the underwriting discounts and commissions and offering expenses payable, were approximately $134.5 million.

In April 2019, we closed the sale of 2,495 Series A Preferred Shares to RPI at a price of $50,100 per preferred share, resulting in gross proceeds of $125.0 million, before offering expenses. As described above, we used $105.0 million of these proceeds to fund the purchase of the PRV.

In June 2019, we issued and sold 6,976,745 common shares at a public offering price of $43.00 per share for net proceeds of $281.1 million after deducting underwriting discounts and commissions of $18.0 million and other offering expenses of approximately $0.9 million. In addition, in July 2019, the underwriters of the follow-on offering partially exercised their option to purchase additional shares, and we issued and sold 525,000 common shares for net proceeds of $21.2 million after deducting underwriting discounts and commissions of $1.4 million. Thus, the aggregate net proceeds to us from the follow-on offering, after deducting underwriting discounts and commissions and other offering costs, were $302.3 million.

In January 2020, the Company issued and sold 4,830,917 common shares at a public offering price of $51.75 per share for net proceeds of approximately $245.9 million after deducting underwriting discounts and commissions of approximately $3.6 million and other offering expenses of approximately $0.5 million. In addition, in February 2020, the underwriter of the follow-on offering exercised its option to purchase additional shares, and the Company issued and sold 724,637 common shares for net proceeds of approximately $37.0 million after deducting underwriting discounts and commissions of approximately $0.5 million. Thus, the aggregate net proceeds to the Company from the follow-on offering, after deducting underwriting discounts and commissions and other offering costs, were approximately $282.8 million.

As of December 31, 2019, we had cash of $316.7 million, excluding restricted cash of $1.0 million. Cash in excess of immediate requirements is invested in non-interest-bearing accounts with a view to liquidity and capital preservation.

Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Year Ended December 31,		
	2019	2018	2017
		(in thousands)	
Net cash used in operating activities	$ (377,331)	$ (197,141)	$ (94,815)
Net cash used in investing activities	(3,784)	(10,540)	(7,168)
Net cash provided by financing activities	434,593	340,462	209,759
Net increase in cash and restricted cash	$ 53,478	$ 132,781	$ 107,776

Operating Activities

During the year ended December 31, 2019, operating activities used $377.3 million of cash, an increase of $180.2 million as compared to the year ended December 31, 2018. The increase in cash usage was primarily due to the $105 million PRV payment, and increases in cash paid for clinical trials, commercial supply and other commercialization activities, personnel, professional fees and other infrastructure costs, partially offset by the one-time $50 million upfront payment under the BMS Amendment made in 2018.

During the year ended December 31, 2018, operating activities used $197.1 million of cash resulting primarily from the $50.0 million upfront payment under the BMS Amendment, and increases in cash paid for clinical trials, including increases in upfront payments to CROs related to our rimegepant clinical trials, personnel, professional fees and other infrastructure costs.

During the year ended December 31, 2017, operating activities used $94.8 million of cash, resulting from our net loss of $128.0 million, including a $5.0 million payment to BMS upon commencement of our Phase 3 trial, partially offset by non-cash charges of $31.8 million and net cash provided by changes in our operating assets and liabilities of $1.4 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2017 consisted primarily of a $1.4 million increase in accrued expenses and a $4.0 million increase in accounts payable partially offset by an increase of $4.0 million in prepaid expense and other current assets. The increases in accrued expenses, accounts payable and prepaid expenses and other current assets were primarily due to increases in clinical trial activities, as well as professional fees associated with the preparation, audit and review of our financial statements.

Investing Activities

During the year ended December 31, 2019, we used $3.8 million of cash in investing activities, a decrease of $6.8 million as compared to the year ended December 31, 2018. The decrease was primarily due to a reduction in the amount invested in Kleo during the year ended December 31, 2019, as compared to the same period in 2018.

During the year ended December 31, 2018, we used $10.5 million of cash in investing activities, primarily consisting of an increase in the amount invested for building improvements, and the purchase of our headquarters for $2.7 million, during the year ended December 31, 2018, as compared to the year ended December 31, 2017. In November 2018 we purchased 1,420,818 shares of Kleo's preferred stock for cash consideration of $5.0 million. As of December 31, 2019 and 2018 our ownership in the outstanding stock of Kleo was approximately 42%.

During the year ended December 31, 2017, we used $7.2 million of cash in investing activities, primarily consisting of $6.6 million of our purchases of 6,674,543 shares of Kleo common stock, and $0.5 million of our purchases of property and equipment.

Financing Activities

During the year ended December 31, 2019, net cash provided by financing activities was $434.6 million, an increase of $94.1 million compared to the year ended December 31, 2018. The increase was primarily due to $302.3 million in net proceeds received from the June 2019 follow-on issuance of common shares.

During the year ended December 31, 2018, net cash provided by financing activities was $340.5 million, primarily due to an increase in funds raised through equity offerings and sales of future royalties, proceeds from the exercise of stock options, and a decrease in the amount of offering costs paid in the year ended December 31, 2018, as compared to the year ended December 31, 2017.

During the year ended December 31, 2017, net cash provided by financing activities was $209.8 million, primarily consisting of net proceeds of $176.1 million from our issuance of common shares in our IPO and $38.6 million from our issuance of Series A preferred shares, partially offset by our repayment of notes payable of $5.0 million in connection with the Wells Fargo credit agreement.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance the preclinical activities, clinical trials and potential commercialization of our product candidates, including rimegepant. Our costs will also increase as we:

- fund the planned U.S. commercial launch of rimegepant (if approved by the FDA) and other product candidates, including commercial infrastructure, marketing and distribution costs;
- advance and expand the development of our CGRP and glutamate modulation platform product candidates and continue development of our MPO platform;
- continue to advance our strategy for commercialization of rimegepant for the acute treatment of migraine;
- continue to evaluate rimegepant as a preventive therapy for migraine and our ongoing Phase 2 proof of concept trial to evaluate the safety and efficacy of rimegepant in patients with treatment refractory trigeminal neuralgia;
- complete the ongoing extension phase of the Phase 2/3 clinical trial of troriluzole in SCA and our ongoing Phase 2/3 trials of troriluzole in OCD, and Alzheimer's disease and, complete our ongoing Phase 3 randomized controlled trial to assess the efficacy of troriluzole in SCA;
- conduct support activities for future clinical trials of BHV-5000;
- complete the Phase 3 replicative clinical trial of vazegepant planned for mid-2020 and related support activities;
- conduct our planned Phase 3 clinical trial of verdiperstat in MSA;
- continue to initiate and progress other supporting studies required for regulatory approval of our product candidates, including long-term safety studies, drug-drug interaction studies, preclinical toxicology and carcinogenicity studies;
- make required milestone and royalty payments under the license agreements by which we acquired some of the rights to our product candidates;
- make required royalty payments to RPI under the Funding Agreement;
- initiate preclinical studies and clinical trials for any additional indications for our current product candidates and any future product candidates that we may pursue;
- continue to build our portfolio of product candidates through the acquisition or in-license of additional product candidates or technologies;
- continue to develop, maintain, expand and protect our intellectual property portfolio;
- pursue regulatory approvals for our current and future product candidates that successfully complete clinical trials, including rimegepant and BHV-0223;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- hire additional clinical, medical, commercial, and development personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

Additionally, pursuant to the terms of our Series A Preferred Shares, we will be required to redeem our Series A preferred shares upon various circumstances, as described in greater detail below (see "-Contractual Obligations and Commitments") and in any event no later than December 31, 2024.

We expect that our existing cash, including net proceeds received from the January 2020 offering, and our available issuance of additional Series A Preferred Shares under the Preferred Share Agreement will be sufficient to fund our planned operating expenses, financial commitments and other cash requirements for at least the next 12 months.

We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional capital to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for rimegepant, troriluzole, or our other product candidates, we expect to

incur additional commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize or whether we commercialize jointly or on our own.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of manufacturing commercial-grade product and necessary inventory to support commercial launch;
- the costs associated with payment of milestones and royalties under existing contractual arrangements and/or in-licensing additional products candidates to augment our current pipeline; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, other third-party funding, strategic alliances, licensing arrangements or marketing and distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. Debt financing and preferred equity 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 or declaring dividends. If we raise additional funds through other third-party funding, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our 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 raise additional funds through equity or debt financings when needed, we will be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2019 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
	(in thousands)				
Commercial commitments[1]	$ 36,243	$ 18,239	$ 18,004	$ —	$ —
Research commitments[2]	14,672	13,829	843	—	—
Lease commitments[3]	9,772	2,887	4,232	1,493	1,160
Total	$ 60,687	$ 34,955	$ 23,079	$ 1,493	$ 1,160

(1) Amounts in the table represent commitments related to inventory and other commitments to prepare for a commercial launch of rimegepant, and license fees for software used by the commercial organization.

(2) Amounts in the table reflect commitments for costs associated with external CROs and CMOs engaged to conduct clinical development activities and clinical trials as well as to manufacture clinical trial materials.

(3) Amounts in the table reflect our future minimum lease payments under our leases for our Yardley office, including committed leasehold improvements, and approximately 15% of our expected commercial fleet. We expect the remaining commitments for our commercial fleet leases to occur in 2020.

Clinical development commitments in the preceding table include agreements that are enforceable and legally binding on us and that specify all significant terms, including fixed or minimum quantities to be purchased; fixed, minimum or variable price provisions; and the approximate timing of the transaction. For obligations with cancellation provisions, the amounts included in the preceding table are limited to the non-cancelable portion of the agreement terms or the minimum cancellation fee.

Under various agreements with third-party licensors and collaborators, we have agreed to make milestone payments and pay royalties and annual maintenance fees to third parties and to meet due diligence requirements based upon specified milestones. We have not included any contingent payment obligations, such as milestones, royalties, or due diligence, in the table above as the amount, timing and likelihood of such payments are not known. We have not included any of the annual maintenance fee payments in the above table, as although the amount and timing are known, we cannot currently determine the final termination dates of the agreements and, as a result, we cannot determine the total amounts of such payments we will be required to make under the agreements. We do not anticipate making material payments related to these arrangements in the next 12 months.

Pursuant to our Funding Agreement with RPI entered in June 2018, we have a commitment for repayments under the Revenue Participation Right due for sales of Products. A liability of $106.0 million represents the carrying value established on the date of the transaction. Actual payments to RPI may be significantly different than the carrying value based on future royalties that may become payable from the sale of Products.

In April 2019, we issued the Series A Preferred Shares for the aggregate original purchase price of $125 million. The holders of the Company's outstanding Series A Preferred Shares will have the right to require redemption of the shares in certain circumstances.

If the FDA approves rimegepant in the first quarter of 2020, starting in the first quarter of 2021 the Company will be obligated to redeem the Series A Preferred Shares for two times (2x) the original purchase price, payable in equal quarterly installments through December 31, 2024. If a Change of Control (as defined in the Company's memorandum and article of association) occurs prior to the first quarter of 2021 and the Series A Preferred Shares have not previously been redeemed, the Company must redeem the Series A Preferred Shares for two times (2x) the original purchase price of the Series A Preferred Shares payable in a lump sum at the closing of the Change of Control or in equal quarterly installments following the closing of the Change of Control through December 31, 2024.

In the event that the Company defaults on any obligation to redeem Series A Preferred Shares when required, the redemption amount shall accrue interest at the rate of eighteen percent (18%) per annum. If any such default continues for at least one year, the holders of such shares shall be entitled to convert, subject to certain limitations, such Series A Preferred Shares into common shares, with no waiver of their redemption rights.

In August 2019, the Company entered into a lease agreement for office space in Yardley, Pennsylvania. The lease will commence on March 1, 2020 and have a term of 88 months, with the ability to extend to 148 months. The lessor has provided the Company a temporary space to occupy while leasehold improvements are completed prior to commencement next year.

With the exception of the first month's rent payment made on execution of the lease, the Company is not required to pay rent until August 2020. The total lease payments due under the lease agreement is $5.1 million over the 88 months.

Under the 2018 AstraZeneca Agreement, we are obligated to pay milestone payments to AstraZeneca totaling up to $55.0 million upon the achievement of specified regulatory and commercial milestones and up to $50.0 million upon the achievement of specified sales-based milestones. In addition, we will pay AstraZeneca tiered royalties ranging from high single-digit to low double-digits based on net sales of specified approved products, subject to specified reductions.

Under our license agreement with BMS, we are obligated to make additional development milestone payments of up to $122.5 million for rimegepant or a derivative thereof and up to $74.5 million for other covered product candidates, as well as up to $150.0 million in commercial milestone payments for each licensed product and tiered royalties based on net sales of licensed products under the agreement at percentages in the low to mid-teens. As of December 31, 2019, we have paid $7.5 million in development milestones to BMS under the license agreement. If the FDA approves the rimegepant ODT NDA in connection with the PDUFA in the first quarter of 2020, we expect to pay BMS an additional $12.0 million in development milestones, currently accrued as of December 31, 2019, in 2020.

Under our license agreement with AstraZeneca, we are obligated to make development milestone payments of up to $30.0 million with respect to Rett syndrome and up to $60.0 million for any other indication, as well as commercial milestone payments of up to $120.0 million for all products licensed under the agreement and tiered royalties based on net sales of licensed products under the agreement at mid-single-digit to low double-digit percentages.

Under our license agreement with Yale, we are obligated to make regulatory milestone payments of up to $2.0 million, as well as royalties based on net sales of products from the licensed patents at a low single-digit percentage, subject to a minimum amount of up to $1.0 million per year.

Under our license agreement with Catalent U.K. Swindon Zydis Limited, a subsidiary of Catalent, Inc. ("Catalent") related to BHV-0223, we are obligated to pay up to $1.6 million upon the achievement of specified regulatory and commercial milestones, as well as royalties based on net sales of products licensed under the agreement at a low single-digit percentage. Under our license agreement with Catalent related to rimegepant, we are obligated to pay up to $1.6 million upon the achievement of specified regulatory and commercial milestones.

Under our license agreement with MGH, we are obligated to pay an annual license maintenance fee of up to $0.1 million, to make clinical and regulatory milestone payments of up to $0.8 million and commercial milestone payments of up to $2.5 million, and to pay royalties based on net sales at a low single-digit percentage.

Under our agreement with ALS Biopharma, LLC ("ALS Biopharma") and FCCDC, we are obligated to pay $3.0 million upon the achievement of a specified regulatory milestone with respect to the first licensed product and $1.0 million upon the achievement of a specified regulatory milestone with respect to subsequent products, as well as royalties based on net sales of products licensed under the agreement at a low single-digit percentage.

Under our license agreement with Rutgers, we are obligated to pay an annual license maintenance fee of up to less than $0.01 million per year, to make clinical and regulatory milestone payments of up to $0.8 million, and to pay royalties based on net sales of products at a low single-digit percentage, subject to a minimum amount of up to $100.0 million per year.

Under our commercial consulting agreement with R PHARM US, we are obligated to pay quarterly services fees, as well as milestones of up to $2.5 million based on commercial milestones related to BHV-0223.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis.

Our actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to our financial statements appearing at the end of this Annual Report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our 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 when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including central laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical and clinical studies; and
- CMOs in connection with drug substance and drug product formulation of preclinical and clinical trial materials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials 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. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, 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 reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Non-Cash Share-Based Compensation

We measure stock options and other share-based awards granted to employees, non-employees, and directors based on the fair value on the date of the grant and recognize the corresponding non-cash compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. We have only issued stock options with service-based vesting conditions and record the expense for these awards using the straight-line method.

Prior to the adoption of Accounting Standards Update ("ASU") No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Non-employee Share-based Payment Accounting ("ASU 2018-07"), which is discussed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, for share-based awards granted to consultants and non-employees, we recognized non-cash compensation expense over the period during which services were rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards was remeasured using the then-current fair value of our common shares and updated assumption inputs in the Black-Scholes option-pricing model.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common shares and assumptions we make for the volatility of our common shares, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

Valuation of Derivative Liability

The fair value of the derivative liability recognized in connection with contingent payments under the Preferred Share Agreement is determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability is determined using the with-and-without valuation method. As inputs into the valuation, we considered the type and probability of occurrence of certain events, the amount of the payments, the expected timing of certain events, and a risk-adjusted discount rate. In accordance with ASC 815, Derivatives and Hedging, the fair value of the derivative is recorded on the balance sheet as a derivative liability with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss. If factors change and different assumptions are used, the fair value of the derivative liability and related gains or losses could be materially different in the future.

Valuation of Warrant Liability

In connection with entering into the Credit Agreement, we issued warrants to purchase our common shares to the guarantor and co-guarantor of our obligations under the agreement. On January 26, 2018, the anti-dilution price protection provisions contained within the warrants expired. Due to the expiration of these provisions, we discontinued classification of

these warrants as a liability, and have accordingly reclassified them to additional paid-in capital within shareholders' equity. On expiration, the fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

We utilized the Black-Scholes option pricing model to value the warrant liability. The Black-Scholes option pricing model incorporated assumptions and estimates to value the warrant liability. Estimates and assumptions impacting the fair value measurement included the number of shares for which the warrants will be exercisable, the fair value per share of the underlying common shares issuable upon exercise of the warrants, the remaining contractual term of the warrants, the risk-free interest rate, the expected dividend yield, and the expected volatility of the price of the underlying common shares. The fair value per share of the common shares was based on the closing trading price of the shares on January 26, 2018, the day of expiration, and the increase in the fair value of the common shares during the time period from December 31, 2017 to expiration is the primary reason for the increase in the fair value of the warrant liability during the same period. We were a private company prior to the IPO in May 2017 and therefore lacked company-specific historical and implied volatility information of our shares. Therefore, we estimated the expected share volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. We estimated a 0% expected dividend yield based on the fact that we have never paid or declared dividends and do not intend to do so in the foreseeable future.

Equity method investment, including related impairment

An assessment of whether or not we have the power to direct activities that most significantly impact Kleo's economic performance and to identify the party that obtains the majority of the benefits of the investment was performed as of December 31, 2019 and December 31, 2018, and will be performed as of each subsequent reporting date. After each of these assessments, we concluded that the activities that most significantly impact Kleo's economic performance are the ability to direct its research activities, the ability to select vendors to perform the research, the ability to maintain research staff and the ability to raise additional funds, each of which are directed by Kleo. Based on the outcome of these assessments, we concluded that our investment in Kleo should be accounted for under the equity method. Changes related to this assessment could have a material impact on our financial statements.

We also periodically review the carrying value of our investment in Kleo to determine if there has been an other-than-temporary decline in carrying value. A variety of factors are considered when determining if a decline in carrying value is other than temporary, including, among other factors, Kleo's financial condition and business prospects, as well as our intent with regard to the investment. Changes related to the analysis of impairment of our investment in Kleo could have a material impact on our financial statements.

Non-Cash Interest Expense and Liability Related to Sale of Future Royalties

We have accounted for the Funding Agreement with RPI as a liability financing, primarily because it has significant continuing involvement in generating the future revenue on which the royalties are based (see Note 8). The liability related to sale of future royalties and the related non-cash interest expense are measured based on the Company's current estimate of the timing and amount of expected future royalties expected to be paid over the estimated term of the Funding Agreement with RPI Trust using a discounted cash flow model. The liability is amortized using the effective interest rate method, resulting in recognition of non-cash interest expense over the estimated term of the agreement. Each reporting period, the Company assesses the estimated timing and amount of future expected royalty payments over the estimated term. If there are changes to the estimate, the Company recognizes the impact to the liability's amortization schedule and the related non-cash interest expense prospectively. The Company's estimate of the amount of expected future royalties to be paid considers the probability of success of the compounds being approved for sale, market penetration rates of the compounds upon approval, compliance rate and net pricing. Additionally, the transaction costs associated with the liability will be amortized to non-cash interest expense over the estimated term of the Funding Agreement.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

Interest Rate Risk

The market risk inherent in our financial instruments and in our financial position has historically been the potential loss arising from adverse changes in interest rates. In August 2017, we repaid all outstanding amounts under the Credit Agreement and, as a result, we no longer have any exposure to interest rate risk related to indebtedness as of December 31, 2019. As of December 31, 2019 and 2018, we had cash of $316.7 million and $264.2 million, respectively. As of December 31, 2019, we held our cash in non-interest-bearing money market accounts and accordingly, the value of these accounts is not subject to fluctuation in interest rates.

Prior to the completion of our IPO in May 2017, we adopted an investment policy related to the use of the net proceeds from the sale of our common shares in our IPO, pursuant to which we hold such net proceeds in non-interest bearing accounts, with the goal of capital preservation and liquidity so that such funds are readily available to fund our operations.

We do not engage in any hedging activities against changes in interest rates or any other market risks. We do not have material foreign currency or any derivative financial instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and supplementary data of the Company required in this item are set forth beginning on page F-1.

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

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019 based on the framework in *Internal Control-Integrated Framework* (2013) issued by the Committee of Sponsoring

Organizations of the Treadway Commission (COSO). Based on that evaluation, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of our internal control over financial reporting as of December 31, 2019 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Changes in Internal Controls over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

We will file a definitive Proxy Statement for our 2020 Annual Meeting of Shareholders (the "2020 Proxy Statement") with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2020 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference to the information that will be contained in our 2020 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," "Executive Officers" and "Delinquent Section 16(a) Reports."

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the information that will be contained in the 2020 Proxy Statement under the captions "Executive Compensation" and "Director Compensation."

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

The information required by this Item is incorporated herein by reference to the information that will be contained in the 2020 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

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

The information required by this Item is incorporated herein by reference to the information that will be contained in the 2020 Proxy Statement under the captions "Transactions with Related Persons" and "Independence of the Board of Directors."

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated herein by reference to the information that will be contained in the 2020 Proxy Statement under the caption "Ratification of Selection of Independent Auditors."

PART IV

Item 15. Exhibits, Financial Statement Schedules

a. The following documents are filed as part of this report:

(1) Financial Statements:

The financial statements required by this item are submitted in a separate section beginning on page F-1 of this report.

(2) Financial Statement Schedules:

All other financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the consolidated financial statements or the notes thereto.

(3) Exhibits.

Exhibit Number*		Description of Document
2.1		Securities Purchase Agreement between Kleo Pharmaceuticals, Inc. and the Registrant, dated as of August 29, 2016 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on June 14, 2017).
2.2		First Subscription Agreement between Kleo Pharmaceuticals, Inc. and the Registrant, dated as of October 5, 2017 (incorporated by reference to Exhibit 2.2 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on October 12, 2017).
2.3		Second Subscription Agreement between Kleo Pharmaceuticals, Inc. and the Registrant, dated as of October 5, 2017 (incorporated by reference to Exhibit 2.3 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on October 12, 2017).
2.4		PRV Transfer Agreement, by and Between the Registrant and GW Research, LTD, dated as of March 15, 2019 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on March 18, 2019).
3.1		Amended and Restated Memorandum and Articles of Association (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on April 8, 2019).
4.1		Investors' Rights Agreement, dated as of October 31, 2016, by and among the Registrant and certain of its shareholders (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 7, 2017).
4.2		Warrant, dated August 15, 2015, issued to ALS Biopharma, LLC (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 7, 2017).
4.3		Description of Biohaven's Securities Registered under Section 12 of the Exchange Act.
10.1	#	License Agreement, by and between the registrant and Bristol-Myers Squibb Company, dated as of July 8, 2016 (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 7, 2017).
10.2	#	Amendment to License Agreement, by and between the Registrant and Bristol-Myers Squibb Company, dated as of March 9, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38080) filed with the Securities and Exchange Commission on March 14, 2018).
10.3	#	ALS Biopharma Agreement, by and among the registrant, ALS Biopharma, LLC and Fox Chase Chemical Diversity Center Inc., dated as of August 10, 2015, as amended to date (incorporated by reference to Exhibit 10.2 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 24, 2017).
10.4		Amendment and Assignment, by and among the Registrant, ALS Biopharma, LLC, Fox Chase Chemical Diversity Center and Biohaven Therapeutics Ltd, dated as of May 29, 2019 (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-3 (File No. 333-232167) filed with the Securities and Exchange Commission on June 17, 2019).

Exhibit Number*		Description of Document
10.5	#	License Agreement, by and between the registrant and AstraZeneca AB, dated as of October 5, 2016 (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 7, 2017).
10.6	#	License Agreement, by and between the Registrant and AstraZeneca AB, dated as of September 4, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38080) filed with the Securities and Exchange Commission on November 14, 2018).
10.7	#	Amended and Restated Agreement, by and between the Registrant and Yale University, dated as of May 6, 2019 (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-3 (File No. 333-232167) filed with the Securities and Exchange Commission on June 17, 2019).
10.8	#	Zydis® Development and License Agreement, by and between the registrant and Catalent U.K. Swindon Zydis Limited, dated as of March 9, 2015 (incorporated by reference to Exhibit 10.5 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 24, 2017).
10.9	#	Exclusive Patent License Agreement, by and between the registrant and The General Hospital Corporation d/b/a Massachusetts General Hospital, dated as of September 13, 2014 (incorporated by reference to Exhibit 10.6 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 24, 2017).
10.1	#	Exclusive License Agreement, by and between the registrant and Rutgers, the State University of New Jersey, dated as of June 15, 2016 (incorporated by reference to Exhibit 10.7 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 24, 2017).
10.1	#	Funding Agreement, by and between the Registrant and RPI Finance Trust, dated as of June 18, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's current report on Form 8-K (File No. 001-3808) filed with the Securities and Exchange Commission on June 25, 2018).
10.1		Common Stock Purchase Agreement, by and between the Registrant and RPI Finance Trust, dated as of June 18, 2018 (incorporated by reference to Exhibit 10.2 to the Registrant's current report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on June 25, 2018).
10.1		Series A Preferred Share Purchase Agreement, by and between the Registrant and RPI Finance Trust dated as of March 18, 2019 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38080) filed with the Securities and Exchange Commission on May 8, 2019).
10.1	+	2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 7, 2017).
10.15	+	Form of Share Option Agreement under 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 7, 2017).
10.16	+	2017 Equity Incentive Plan (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-8 (File No. 333-218193) filed with the Securities and Exchange Commission on May 23, 2017).
10.17	+	Form of Stock Option Grant Notice and Stock Option Agreement under 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.12 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 24, 2017).
10.18	+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under 2017 Equity Incentive Plan (incorporated by reference to Exhibit 10.13 to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on April 24, 2017).
10.19	+	2017 Employee Share Purchase Plan (incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form S-8 (File No. 333-218193) filed with the Securities and Exchange Commission on May 23, 2017).
10.20	+	Form of Indemnification Agreement with non-employee directors (incorporated by reference to Exhibit 10.15 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on May 1, 2017).

Exhibit Number*		Description of Document
10.21	+	Employment Agreement dated October 1, 2015 by and between Biohaven Pharmaceutical Holding Company Ltd. and Vlad Coric (incorporated by reference to Exhibit 10.19 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on May 1, 2017)).).
10.22	+	Employment Agreement dated May 9, 2017 by and between Biohaven Pharmaceuticals, Inc. and Vlad Coric (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-224123) filed with the Securities and Exchange Commission on April 3, 2018).
10.23	+	Employment Agreement dated May 2, 2016 by and between Biohaven Pharmaceutical Holding Company Ltd. and James Engelhart (incorporated by reference to Exhibit 10.21 to the Registrant's Amendment No. 2 to Registration Statement on Form S-1 (File No. 333-217214) filed with the Securities and Exchange Commission on May 1, 2017)).).
10.24	+	Employment Agreement dated May 5, 2017 by and between Biohaven Pharmaceuticals, Inc. and James Engelhart (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-224123) filed with the Securities and Exchange Commission on April 3, 2018).
10.25	+	Employment Agreement dated March 30, 2019 by and between Biohaven Pharmaceuticals, Inc. and William Jones, Jr.
10.26	+	Employment Agreement dated February 1, 2014 by and between Biohaven Pharmaceuticals, Inc. and Kimberly A. Gentile.
10.27	+	Offer Letter dated April 5, 2017 by and between Biohaven Pharmaceuticals, Inc. and Elyse Stock.
10.28	#	Zydis Commercial Supply Agreement, dated as of June 29, 2018, by and between Biohaven Pharmaceuticals, Inc. and Catalent U.K. Swindon Zydis Limited.
21.1		Subsidiaries of the Registrant.
23.1		Consent of PricewaterhouseCoopers LLP.
24.1		Power of Attorney (contained on signature page hereto).
31.1		Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.
31.2		Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.
32.1	@	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.
101		The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2019 formatted in Inline XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Comprehensive Loss, (iii) the Consolidated Statements of Convertible Preferred Shares and Shareholders' Equity (Deficit), (iv) the Consolidated Statements of Cash Flows, (v) Notes to Consolidated Financial Statements, and (vi) Cover Page, tagged as blocks of text.
104		The cover page from the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, formatted in Inline XBRL (included as Exhibit 101).

Portions of this exhibit (indicated by asterisks) have been omitted as such information is (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

+ Indicates management contract or compensatory plan.

@ These certifications are being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

Date: February 25, 2020

By: /s/ VLAD CORIC, M.D.
Vlad Coric, M.D.
Chief Executive Officer
(On behalf of the Registrant and as the Principal Executive Officer)

By: /s/ JIM ENGELHART
Jim Engelhart
Chief Financial Officer
(Principal Financial Officer)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Vlad Coric as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Biohaven Pharmaceutical Holding Company Ltd., and any or all amendments thereto, and to file the same, with all 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 or necessary to be done in and about the premises hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ VLAD CORIC, M.D. Vlad Coric, M.D.	Chief Executive Officer and Director (Principal Executive Officer)	February 25, 2020
/s/ JAMES ENGELHART James Engelhart	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	February 25, 2020
/s/ DECLAN DOOGAN, M.D. Declan Doogan, M.D.	Director	February 25, 2020
/s/ GREGORY H. BAILEY, M.D. Gregory H. Bailey, M.D.	Director	February 25, 2020
/s/ JOHN W. CHILDS John W. Childs	Director	February 25, 2020
/s/ JULIA P. GREGORY Julia P. Gregory	Director	February 25, 2020
/s/ MICHAEL HEFFERNAN Michael Hefferenan	Director	February 25, 2020

Biohaven Pharmaceutical Holding Company Ltd.

Financial Statements

For the Years Ended December 31, 2019, 2018 and 2017

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of
Biohaven Pharmaceutical Holding Company Ltd.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Biohaven Pharmaceutical Holding Company Ltd. and its subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, of convertible preferred shares and shareholders' equity (deficit) and of cash flows for each of the three years in the period ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Non-Cash Interest Expense and Liability Related to Sale of Future Royalties

As described in Notes 2 and 8 to the consolidated financial statements, the liability related to the sale of future royalties and the related non-cash interest expense are measured based on management's current estimate of the timing and amount of expected future royalties expected to be paid over the estimated term of the Funding Agreement with RPI Finance Trust using a discounted cash flow model. The liability is amortized using the effective interest rate method, resulting in the recognition of non-cash interest expense over the estimated term of the agreement. Each reporting period, management assesses the estimated timing and amount of future expected royalty payments over the estimated term. If there are changes to the estimate, management recognizes the impact to the liability's amortization schedule and the related non-cash interest expense prospectively. Management's estimate of the amount of expected future royalties to be paid considers the probability of success of the compounds being approved for sale, market penetration rates of the compounds upon approval, compliance rate and net pricing. The Company recognized non-cash interest expense on the liability related to the sale of future royalties of $26.6 million for the year ended December 31, 2019 and the liability related to the sale of future royalties, net was $144.1 million as of December 31, 2019.

The principal considerations for our determination that performing procedures relating to the non-cash interest expense and the liability related to sale of future royalties is a critical audit matter are there was significant judgment by management when developing the estimate of the timing and amount of future royalties to be paid and the implied effective interest rate in the arrangement. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and in evaluating audit evidence relating to management's estimate of the expected future royalties to be paid and the implied effective interest rate, including significant assumptions of the probability of success of the compounds being approved for sale, market penetration rates of the compounds upon approval, compliance rate and net pricing.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the financial statements. These procedures included testing the effectiveness of controls relating to management's process for estimating the non-cash interest expense and liability related to sale of future royalties, including controls over the development of the estimated amount of expected future royalties to be paid and the implied effective interest rate. These procedures also included, among others (i) testing management's process for estimating the non-cash interest expense and liability related to sale of future royalties, (ii) evaluating the reasonableness of significant assumptions used by management when developing the estimate of expected future royalties to be paid, including the probability of success of the compounds being approved for sale, market penetration rates of the compounds upon approval, compliance rate and net pricing, and (iii) evaluating the appropriateness of management's method used to estimate the implied effective interest rate and the resulting non-cash interest expense and liability recognized. Evaluating the reasonableness of management's assumptions related to the probability of success of the compounds being approved for sale, market penetration rates of the compounds upon approval, compliance rate and net pricing involved evaluating whether the assumptions used by management were reasonable considering (i) relevant industry forecasts and macroeconomic conditions, (ii) consistency with external market, research and industry data, and (iii) whether the assumptions were consistent with evidence obtained in other areas of the audit.

/s/ PricewaterhouseCoopers LLP
Hartford, Connecticut
February 25, 2020

We have served as the Company's auditor since 2017.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share amounts)

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash	$ 316,727	$ 264,249
Prepaid expenses and other current assets (Note 4)	11,554	8,090
Total current assets	328,281	272,339
Property and equipment, net (Note 6)	8,152	6,248
Equity method investment (Note 5)	5,338	11,414
Other assets	2,493	11
Total assets	344,264	$ 290,012
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	14,071	10,752
Accrued expenses (Note 7)	52,102	8,782
Total current liabilities	66,173	19,534
Liability related to sale of future royalties, net (Note 8)	144,111	117,515
Mandatorily redeemable preferred shares, net (Note 9)	103,646	—
Derivative liability (Note 9)	37,690	—
Other long-term liabilities	68	2,043
Total liabilities	351,688	139,092
Commitments and contingencies (Note 16)		
Shareholders' equity:		
Common shares, no par value; 200,000,000 shares authorized as of December 31, 2019 and 2018; 52,385,283 and 44,197,549 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	881,426	554,384
Additional paid-in capital	83,523	40,104
Accumulated deficit	(972,373)	(443,568)
Total shareholders' equity	(7,424)	150,920
Total liabilities and shareholders' equity	$ 344,264	$ 290,012

The accompanying notes are an integral part of these consolidated financial statements.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands, except share and per share amounts)

	Year Ended December 31,		
	2019	2018	2017
Operating expenses:			
Research and development	$ 344,673	$ 189,951	$ 89,441
General and administrative	134,449	34,603	18,141
Total operating expenses	479,122	224,554	107,582
Loss from operations	(479,122)	(224,554)	(107,582)
Other income (expense):			
Non-cash interest expense on mandatorily redeemable preferred shares	(12,711)	—	—
Non-cash interest expense on liability related to sale of future royalties	(26,580)	(11,726)	—
Change in fair value of warrant liability	—	(1,182)	(3,241)
Change in fair value of derivative liability	(3,875)	—	512
Change in fair value of contingent equity liability	—	—	(13,082)
Loss from equity method investment	(6,076)	(2,808)	(1,885)
Other	(22)	(185)	(906)
Total other income (expense), net	(49,264)	(15,901)	(18,602)
Loss before provision for income taxes	(528,386)	(240,455)	(126,184)
Provision for income taxes	419	467	1,006
Net loss and comprehensive loss	(528,805)	(240,922)	(127,190)
Accretion of beneficial conversion feature on Series A preferred shares	—	—	(12,006)
Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.	$ (528,805)	$ (240,922)	$ (139,196)
Net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.—basic and diluted	$ (10.91)	$ (6.15)	$ (5.00)
Weighted average common shares outstanding—basic and diluted	48,489,890	39,188,458	27,845,576

The accompanying notes are an integral part of these consolidated financial statements.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.
CONSOLIDATED STATEMENT OF CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)
(Amounts in thousands, except share and per share amounts)

	Series A Convertible Preferred Shares		Common Shares				
	Shares	Amount	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Total Shareholders' Equity (Deficit)
Balances as of December 31, 2016	4,948,369	$ 43,270	13,088,500	$ 19,944	$ 10,479	$ (75,456)	$ (45,033)
Issuance of Series A convertible preferred shares, net of offering costs of $1,334	4,305,182	38,666	—	—	—	—	—
Issuance of Series A convertible preferred shares as payment of offering costs	105,009	—	—	—	—	—	—
Beneficial conversion feature on Series A convertible preferred shares	—	(12,006)	—	—	12,006	—	12,006
Accretion of beneficial conversion feature on Series A convertible preferred shares	—	12,006	—	—	(12,006)	—	(12,006)
Issuance of common shares as payment for equity investment (Note 5)	—	—	32,500	352	—	—	352
Conversion of Series A convertible preferred shares to common shares	(9,358,560)	(81,936)	9,358,560	81,936	—	—	81,936
Issuance of common shares in settlement of contingent equity liability	—	—	1,883,523	32,020	—	—	32,020
Issuance of common shares upon completion of initial public offering, net of offering costs	—	—	11,385,000	176,128	—	—	176,128
Issuance of common share warrant as consideration for services	—	—	—	—	93	—	93
Exercise of stock options	—	—	309,665	681	(255)	—	426
Non-cash share-based compensation expense	—	—	—	—	13,239	—	13,239
Net loss	—	—	—	—	—	(127,190)	(127,190)
Balances as of December 31, 2017	—	$ —	36,057,748	$ 311,061	$ 23,556	$ (202,646)	$ 131,971
Issuance of common shares as payment for license agreement	—	—	109,523	4,080	—	—	4,080
Issuance of common shares upon completion of equity offerings, net of offering costs	—	—	6,970,171	230,339	—	—	230,339
Exercise of ALS Biopharma warrants, net settlement of shares	—	—	489,359	—	—	—	—
Reclassification of warrant liability to equity	—	—	—	—	5,203	—	5,203
Exercise of stock options	—	—	570,748	8,904	(5,580)	—	3,324
Non-cash share-based compensation expense	—	—	—	—	16,925	—	16,925
Net loss	—	—	—	—	—	(240,922)	(240,922)
Balances as of December 31, 2018	—	$ —	44,197,549	$ 554,384	$ 40,104	$ (443,568)	$ 150,920
Issuance of common shares upon completion of equity offering, net of offering costs	—	—	7,501,745	302,321	—	—	302,321
Exercise of related party warrants	—	—	215,000	7,201	(5,203)	—	1,998
Issuance of common shares as payment for TDP-43 asset	—	—	100,000	5,646	—	—	5,646
Issuance of common stock under equity incentive plan	—	—	370,989	11,874	(6,350)	—	5,524
Non-cash share-based compensation expense	—	—	—	—	54,972	—	54,972
Net loss	—	—	—	—	—	(528,805)	(528,805)
Balances as of December 31, 2019	—	$ —	52,385,283	$ 881,426	$ 83,523	$ (972,373)	$ (7,424)

The accompanying notes are an integral part of these consolidated financial statements.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands, except share and per share amounts)

	Year ended December 31,		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	$ (528,805)	$ (240,922)	$ (127,190)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash share-based compensation expense	54,972	16,925	13,239
Non-cash interest expense on mandatorily redeemable preferred shares	12,711	—	—
Non-cash interest expense on liability related to sale of future royalties	26,580	11,726	—
Non-cash interest expense	—	—	784
Non-cash issuance of common shares as payment for license agreement	5,646	4,080	—
Change in fair value of derivative liability	3,875	—	(512)
Change in fair value of warrant liability	—	1,182	3,241
Change in fair value of contingent equity liability	—	—	13,082
Loss from equity method investment	6,076	2,808	1,885
Deferred tax assets	—	—	9
Other non-cash items	646	269	64
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(3,464)	(2,893)	(4,730)
Other assets	(232)	21	(32)
Accounts payable	3,319	5,390	3,975
Accrued expenses	43,320	3,697	1,341
Other long-term liabilities	(1,975)	576	29
Net cash used in operating activities	$ (377,331)	$ (197,141)	$ (94,815)
Cash flows from investing activities:			
Purchases of property and equipment	(2,534)	(4,165)	(541)
Purchase of equity method investment	—	(6,375)	(6,627)
Payments for leasehold improvements	(1,250)	—	—
Net cash used in investing activities	$ (3,784)	$ (10,540)	$ (7,168)
Cash flows from financing activities:			
Proceeds from issuance of common shares	303,221	190,125	179,996
Proceeds from sale of future royalties	—	106,047	—
Proceeds from issuance of common stock related to sale of future royalties	—	43,953	—
Proceeds from issuance of mandatorily redeemable preferred shares	125,000	—	40,000
Proceeds from exercise of warrants	1,998	—	—
Payments of related party notes payable	—	—	(595)
Repayment of notes payable	—	—	(5,000)
Payments of issuance costs	(1,150)	(2,987)	(5,068)
Proceeds from exercise of stock options	5,524	3,324	426
Net cash provided by financing activities	$ 434,593	$ 340,462	$ 209,759
Net increase in cash and restricted cash	53,478	132,781	107,776
Cash and restricted cash at beginning of period	264,249	131,468	23,692
Cash and restricted cash at end of period	$ 317,727	$ 264,249	$ 131,468
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ —	$ —	$ 122
Cash paid for income taxes	$ 823	$ 333	$ 1,049
Supplemental disclosure of non-cash investing and financing activities:			
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 1,018	$ —
Beneficial conversion feature on Series A preferred shares	$ —	$ —	$ 12,006
Accretion of beneficial conversion feature on Series A preferred shares	$ —	$ —	$ 12,006
Issuance of Series A preferred shares as payment of offering costs	$ —	$ —	$ 1,242
Issuance of common shares as payment of equity investment	$ —	$ —	$ 352
Purchases of property and equipment under financing lease	$ —	$ —	$ 1,787

The accompanying notes are an integral part of these consolidated financial statements.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Amounts in thousands, except share and per share amounts)

1. Nature of the Business and Basis of Presentation

Biohaven Pharmaceutical Holding Company Ltd. (“we,” “us” or the “Company”) was incorporated in Tortola, British Virgin Islands in September 2013. We are a clinical-stage biopharmaceutical company with a portfolio of innovative, late-stage product candidates targeting central nervous system diseases, including neurological and rare disorders. Most of our product candidates are small molecules and based on three distinct mechanistic platforms—calcitonin gene-related peptide ("CGRP") receptor antagonists, glutamate modulators, and myeloperoxidase inhibitor—which we believe have the potential to significantly alter existing treatment approaches across a diverse set of indications with high unmet need in both large and orphan indications.

The most advanced product candidate from our CGRP receptor antagonist platform is rimegepant, an orally available, potent and selective small molecule human CGRP receptor antagonist that we are developing for the acute and preventative treatment of migraine. During the second quarter of 2019, we submitted new drug applications ("NDAs") for the acute treatment of migraine to the United States Food and Drug Administration ("FDA") for the Zydis ODT and tablet formulations of rimegepant. The NDA submission of the Zydis ODT formulation of rimegepant was submitted using a FDA priority review voucher, purchased in March 2019, providing for an expedited 6-month review.

During the third quarter of 2019, we received communication from the FDA that our Zydis ODT and tablet formulation of rimegepant NDA submissions were accepted and we were given a Prescription Drug User Fee Act ("PDUFA") date in the first quarter of 2020 for our Zydis ODT submission. In December 2019, we also received a late-cycle communication update from the FDA in which no major issues were identified by the FDA. All comments from the FDA are preliminary and do not reflect a final decision on the review or approval of our NDA.

The Company is subject to risks and uncertainties common to clinical-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts may require additional capital, additional personnel and infrastructure, and further regulatory and other capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize revenue from product sales.

Subsequent to its May 2017 initial public offering, the Company has primarily raised funds through sales of equity in private placements and public offerings, as well as through the sale of a revenue participation right related to potential future royalties. The Company has incurred recurring losses since its inception, had an accumulated deficit as of December 31, 2019, and expects to continue to generate operating losses during the commercial launch of rimegepant. To execute its business plans, the Company will continue to require additional funding to support its continuing operations and pursue its growth strategy.

In June 2019, the Company issued and sold 6,976,745 common shares at a public offering price of $43.00 per share for net proceeds of approximately $281,100 after deducting underwriting discounts and commissions of approximately $18,000 and other offering expenses of approximately $900. In addition, in July 2019, the underwriters of the follow-on offering partially exercised their option to purchase additional shares, and the Company issued and sold 525,000 common shares for net proceeds of approximately $21,221 after deducting underwriting discounts and commissions of approximately $1,354. Thus, the aggregate net proceeds to the Company from the follow-on offering, after deducting underwriting discounts and commissions and other offering costs, were approximately $302,321.

In January 2020, the Company issued and sold 4,830,917 common shares at a public offering price of $51.75 per share for net proceeds of approximately $245,877 after deducting underwriting discounts and commissions of approximately $3,623 and other offering expenses of approximately $500. In addition, in February 2020, the underwriter of the January follow-on offering exercised its option to purchase additional shares, and the Company issued and sold 724,637 common shares for net proceeds of approximately $36,956 after deducting underwriting discounts and commissions of approximately $543. Thus, the aggregate net proceeds to the Company from the follow-on offering, after deducting underwriting discounts and commissions and other offering costs, were approximately $282,833.

Through the date of the issuance of this Form 10-K, the Company has funded its operations primarily with proceeds from sales of preferred and common shares. The Company has incurred recurring losses since its inception, including net losses of

(Amounts in thousands, except share and per share amounts)

1. Nature of the Business and Basis of Presentation (Continued)

$528,805, $240,922, and $127,190 during the years ended December 31, 2019, 2018 and 2017, respectively, and had an accumulated deficit of $972,373 as of December 31, 2019. As a result of the Company's commercial launch of rimegepant (if approved), the continued development of its product candidates, and other strategic investments, the Company expects to continue to generate operating losses for the foreseeable future. As of February 25, 2020, the issuance date of these consolidated financial statements, the Company expects that its cash as of December 31, 2019, along with the net proceeds received from the January 2020 offering, will be sufficient to fund its current forecast for operating expenses, planned commercialization of rimegepant (if approved), financial commitments and other cash requirements into the first quarter of 2021. The Company will need to raise additional capital until it is profitable. If no additional capital is raised through either public or private equity financings, debt financings, strategic relationships, alliances and licensing agreements, or a combination thereof, the Company will be required to delay, limit or reduce discretionary spending in areas related to research and development activities and other general and administrative expenses in order to fund its operating costs and working capital needs for at least one year from the date of the issuance of these financial statements.

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its subsidiaries after elimination of all significant intercompany accounts and transactions. Investments in companies in which the Company owns less than a 50% equity interest and where it exercises significant influence over the operating and financial policies of the investee are accounted for using the equity method of accounting.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of equity incentive awards, warrants, the fair value of derivative instruments, contingent equity instruments, non-cash interest related to the mandatorily redeemable preferred shares and non-cash interest expense on liability related to sale of future royalties. In addition, management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Restricted Cash

Restricted cash included in other assets in the consolidated balance sheets represents collateral held by a bank for a letter of credit ("LOC") issued in connection with the leased office space in Yardley, Pennsylvania. See Note 16 ''Commitments and Contingencies'' for additional information on the real estate lease. The following represents a reconciliation of cash in the consolidated balance sheets to total cash and restricted cash in the consolidated statements of cash flows:

	December 31, 2019	December 31, 2018
Cash	$ 316,727	$ 264,249
Restricted cash (included in other assets)	1,000	0
Total cash and restricted cash in the statement of cash flows	$ 317,727	$ 264,249

Equity Method Investments, Including Related Impairment

Investments in non-public companies in which the Company owns less than a 50% equity interest and where it has the ability to exercise significant influence over the operating and financial policies of the investee are accounted for using the equity method of accounting. The Company's proportionate share of the net income or loss of the equity method investment is included in other income (expense), net in the consolidated statement of operations and comprehensive loss and results in a

2. Summary of Significant Accounting Policies (Continued)

corresponding adjustment to the carrying value of the investment on the consolidated balance sheet. Dividends received reduce the carrying value of the investment.

An assessment of whether or not we have the power to direct activities that most significantly impact Kleo Pharmaceuticals, Inc. ("Kleo") economic performance and to identify the party that obtains the majority of the benefits of the investment was performed as of December 31, 2019 and December 31, 2018, and will be performed as of each subsequent reporting date. After each of these assessments, we concluded that the activities that most significantly impact Kleo's economic performance are the ability to direct its research activities, the ability to select vendors to perform the research, the ability to maintain research staff and the ability to raise additional funds, each of which are directed by Kleo. Based on the outcome of these assessments, we concluded that our investment in Kleo should be accounted for under the equity method. Changes related to this assessment could have a material impact on our financial statements.

We also periodically review the carrying value of our investment in Kleo to determine if there has been an other-than-temporary decline in carrying value. A variety of factors are considered when determining if a decline in carrying value is other than temporary, including, among other factors, Kleo's financial condition and business prospects, as well as our intent with regard to the investment. Changes related to the analysis of impairment of our investment in Kleo could have a material impact on our financial statements.

Property and Equipment

Property and equipment are recorded at cost and depreciated or amortized using the straight-line method over the estimated useful lives of the respective assets. As of December 31, 2019 and December 31, 2018, the Company's property and equipment consisted of an office building, office equipment and computer equipment.

The fixed assets have the following useful lives:

Building	30 years
Office equipment	3 - 5 years
Computer software	3 - 5 years
Computer equipment	3 years

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred. Property and equipment are monitored regularly for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable.

Fair Value Measurements

Certain assets of the Company are carried at fair value under GAAP. 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 on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

2. Summary of Significant Accounting Policies (Continued)

The Company's warrant liability was, and derivative liability is carried at fair value, based upon Level 3 inputs described above (see Note 3). The carrying values of other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Leases

Effective January 1, 2019, the Company determines if an arrangement contains a lease at the inception of a contract. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use assets and operating lease liabilities are recognized at the commencement date based on the present value of the remaining future minimum lease payments. As the interest rate implicit in the Company's leases is not readily determinable, the Company utilizes an estimate of its incremental borrowing rate based on market sources including interest rates for companies with similar credit quality for agreements of similar duration, determined by class of underlying asset, to discount the lease payments. The operating lease right-of-use assets also include lease payments made before commencement and exclude lease incentives. Leases with an initial term of 12 months or less are not recorded on the balance sheet, and lease expense is recognized on a straight-line basis over the term of the short-term lease.

For real estate leases, the Company elected to separately account for lease components and non-lease components. In addition, payments made by the Company for improvements to the underlying asset, if the payment relates to an asset of the lessor, are recorded as prepaid rent within other assets of the consolidated balance sheets and expensed as part of the amortization of the right-of-use asset. As of December 31, 2019, the Company had prepaid rent of $1,250 included in other assets in the consolidated financial statements, which consists of leasehold improvements related to leased office space in Yardley, Pennsylvania. As of December 31, 2019, the Company had restricted cash of $1,000 included in other assets in the consolidated financial statements, which represents collateral held by a bank for a letter of credit ("LOC") issued in connection with the leased office space in Yardley, Pennsylvania. The restricted cash is invested in a non-interest bearing account. See Note 16 ‘‘Commitments and Contingencies’’ for additional information on the real estate lease.

Segment Information

The Company manages its operations as a single segment, the development of therapies targeting neurological diseases, for the purposes of assessing performance and making operating decisions. Materially all of the Company's tangible assets are held in the United States.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including salaries, non-cash share-based compensation and benefits, third-party license fees, and external costs of vendors engaged to conduct clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-refundable prepayments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

The Company has entered into various research and development-related contracts. These agreements are cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Certain judgments and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Non-Cash Interest Expense and Liability Related to Sale of Future Royalties

The Company accounted for the Funding Agreement with RPI Finance Trust ("RPI") as a liability financing, primarily because it has significant continuing involvement in generating the future revenue on which the royalties are based (see Note 8). The liability related to sale of future royalties and the related non-cash interest expense are measured based on the Company's current estimate of the timing and amount of expected future royalties expected to be paid over the estimated term of the Funding Agreement with RPI Trust using a discounted cash flow model. The liability is amortized using the effective interest

2. Summary of Significant Accounting Policies (Continued)

rate method, resulting in recognition of non-cash interest expense over the estimated term of the agreement. Each reporting period, the Company assesses the estimated timing and amount of future expected royalty payments over the estimated term. If there are changes to the estimate, the Company recognizes the impact to the liability's amortization schedule and the related non-cash interest expense prospectively. The Company's estimate of the amount of expected future royalties to be paid considers the probability of success of the compounds being approved for sale, market penetration rates of the compounds upon approval, compliance rate and net pricing. Additionally, the transaction costs associated with the liability will be amortized to non-cash interest expense over the estimated term of the Funding Agreement.

Non-Cash Interest Expense on Mandatorily Redeemable Preferred Shares

The Company accounted for the Series A preferred shares (the "Series A Preferred Shares") sold to RPI as a liability financing because, under all redemption circumstances as defined in the Series A Preferred Shares agreement (the "Preferred Share Agreement"), the Series A Preferred Shares are required to be redeemed by December 31, 2024 (see Note 9). The mandatorily redeemable preferred shares liability was initially measured at fair value as of the transaction date, and will be amortized under the effective interest method. Accordingly, the Company is recognizing non-cash interest expense on the mandatorily redeemable preferred shares until December 31, 2024. The transaction costs associated with the mandatorily redeemable preferred shares liability will also be amortized to non-cash interest expense on mandatorily redeemable preferred shares until termination of the liability.

Derivative Liability

Certain scenarios as described in the Preferred Share Agreement were determined by the Company to result in a derivative liability (see Note 9). The with-and-without valuation method was used to determine the fair value of the embedded derivatives within the agreement. As inputs into the valuation, the Company considered the type and probability of occurrence of certain events, the amount of the payments, the expected timing of certain events, and a risk-adjusted discount rate. In accordance with ASC 815, Derivatives and Hedging, the fair value of the derivative was recorded on the balance sheet as a derivative liability with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss (see Note 3 for details on the fair value measurement). If factors change and different assumptions are used, the fair value of the derivative liability and related gains or losses could be materially different in the future.

Non-Cash Share-Based Compensation

The Company measures stock options and restricted share unit awards granted to employees, non-employees, and directors based on the fair value on the date of the grant and recognizes non-cash compensation expense of those awards, over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. Generally, the Company issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company also issues, from time to time, stock options with performance-based vesting conditions and records the expense for these awards when the Company concludes that it is probable that the performance condition will be achieved.

Effective July 1, 2018, the Company adopted Accounting Standards Update ("ASU") No. 2018-07, Compensation - Stock Compensation (Topic 718): Improvements to Non-employee Share-based Payment Accounting ("ASU 2018-07"), which sets out to simplify the accounting for non-employee share-based awards. The ASU expands the scope of Topic 718, Compensation-Stock Compensation, which currently only includes share-based payments issued to employees, to also include share-based payments issued to non-employees for goods and services. Consequently, the accounting for share-based payments to non-employees and employees is substantially aligned. ASU 2018-07 impacts the value at which share-based payments to non-employees is recognized.

Prior to the adoption of ASU 2018-07 for share-based awards granted to non-employees, including consultants, non-cash compensation expense was recognized over the period during which services were rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of the unvested awards were remeasured using the then-current fair value of the Company's common shares and updated assumption inputs in the Black-Scholes option-pricing model.

After adoption of ASU 2018-07, the measurement date for non-employee awards is the date of the grant. The non-cash compensation expense for non-employees is recognized, without changes in the fair value of the award, over the requisite service period, which is the vesting period of the respective award. The non-cash compensation expense for non-employees

2. Summary of Significant Accounting Policies (Continued)

was measured as of the adoption date of July 1, 2018, and this amount is the basis for prospective expense recognition. All of the Company's non-employee awards were previously measured as of June 30, 2018. Accordingly, no cumulative adjustment to beginning retained earnings was recorded as a result of the ASU 2018-07 adoption, as the measured value prior to adoption and the remeasured value on the date of adoption were materially the same.

The Company classifies non-cash share-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company lacks a sufficient history of company-specific historical and implied volatility information for its shares. Therefore, it estimates its expected share price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common shares and does not expect to pay any cash dividends in the foreseeable future.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the consolidated financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies. The provision for income taxes includes the effects of applicable tax reserves, or unrecognized tax benefits, as well as the related net interest and penalties.

Net Income (Loss) per Share

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common shareholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. Net income (loss) per share attributable to common shareholders is calculated based on net income (loss) attributable to Biohaven Pharmaceutical Holding Company Ltd. and excludes net income (loss) attributable to non-controlling interests for relevant periods.

Basic net income (loss) per share attributable to common shareholders is computed by dividing the net income (loss) attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) attributable to common shareholders is computed by adjusting net income (loss) attributable to common shareholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common shareholders is computed by dividing the diluted net income (loss) attributable to common shareholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding options, warrants to purchase common shares, convertible preferred shares and contingently issuable equity are considered potential dilutive common shares.

The Company's convertible preferred shares contractually entitled the holders of such shares to participate in dividends but contractually did not require the holders of such shares to participate in losses of the Company. In periods in which the Company reports a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders

2. Summary of Significant Accounting Policies (Continued)

is the same as basic net loss per share attributable to common shareholders, since potentially dilutive common shares are considered to be anti-dilutive.

Recently Adopted Accounting Pronouncements

Effective January 1, 2019, the Company adopted ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases. In July of 2018, the FASB issued ASU No. 2018-10, Codification Improvements to Topic 842, Leases ("ASU 2018-10"), and ASU No. 2018-11, Leases (Topic 842): Targeted Improvements ("ASU 2018-11"), both of which clarified and enhanced the certain amendments made in ASU 2016-02 and were adopted by the Company in conjunction with ASU 2016-02. The adoption required a modified retrospective transition approach, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. The Company has elected to adopt the standard using the effective date, January 1, 2019, as its date of initial application. Consequently, financial information was not updated, and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019. Given that the Company had no material outstanding leases as of the date of the adoption, the adoption of ASU 2016-02 did not have a material impact on the Company's financial position or results of operations.

Future Adoption of New Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-15, - Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, a new standard on a customer's accounting for implementation, set-up, and other upfront costs incurred in a cloud computing arrangement (CCA) that aligns the requirements for capitalizing implementation costs in a CCA service contract with existing internal-use software guidance. The standard also provides classification guidance on these implementation costs as well as additional quantitative and qualitative disclosures. The standard is effective for interim and annual periods beginning after December 15, 2019, with early adoption permitted, and can be adopted prospectively or retrospectively. We adopted the new standard on January 1, 2020 on a prospective basis and are continuing to establish new processes and internal controls that may be required to comply with the new cloud computing standard. We do not expect the adoption of this standard to have a significant impact on our financial statements.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement, which modifies the disclosure requirements on fair value measurements. The new guidance is effective for interim and annual reporting periods starting in fiscal year 2020 for the Company. Upon the effective date, certain provisions are to be applied prospectively, while others are to be applied retrospectively to all periods presented. An entity is permitted to early adopt any removed or modified disclosures upon issuance of this ASU and delay adoption of the additional disclosures until their effective date. We are currently evaluating the impact of the amendments on our consolidated financial statement disclosures. Since the amendments impact only disclosure requirements, we do not expect the amendments to have an impact on our consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in ASU 2019-12 are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption of the amendments is permitted. The Company is currently evaluating the impact that the adoption of ASU 2019-12 will have on its consolidated financial statements.

In January 2020, the FASB issued ASU No. 2020-01, Investments - Equity Securities (Topic 321), Investments - Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815) - Clarifying the Interactions between Topic 321, Topic 323, and Topic 815. The new standard addresses accounting for the transition into and out of the equity method and measurement of certain purchased options and forward contracts to acquire investments. The standard is effective for annual

(Amounts in thousands, except share and per share amounts)

2. Summary of Significant Accounting Policies (Continued)

and interim periods beginning after December 15, 2020, with early adoption permitted. Adoption of the standard requires changes to be made prospectively. We are currently assessing the impact of this standard on our financial condition and results of operations.

3. Fair Value of Financial Assets and Liabilities

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis on the consolidated balance sheet at December 31, 2019 and indicates the level of the fair value hierarchy utilized to determine such fair values:

	Fair Value Measurement as of December 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Derivative liability	$ —	$ —	$ 37,690	$ 37,690
	$ —	$ —	$ 37,690	$ 37,690

The Company held no financial assets or liabilities measured at fair value on a recurring basis as of December 31, 2018.

The following table provides a roll forward of the aggregate fair values of the Company's warrant liability and derivative liability at December 31, 2019 and 2018 for which fair value is determined by Level 3 inputs:

	Warrant Liability	Derivative Liability
December 31, 2017	$ 4,021	$ —
Change in fair value	1,182	—
Reclassification to equity	(5,203)	—
December 31, 2018	—	—
Transaction date balance	—	33,815
Change in fair value	—	3,875
Balance as at December 31, 2019	$ —	$ 37,690

Valuation of Warrant Liability

The warrant liability in the table above is composed of the fair value of warrants to purchase common shares that the Company issued to two of its directors in connection with a guarantee of its obligations under a credit agreement (see Note 10). On January 26, 2018, the anti-dilution price protection provisions contained within the warrants expired. Due to the expiration of these provisions, the Company discontinued classification of these warrants as a liability and reclassified $5,203, the fair value of the warrant liability at expiration of the anti-dilution price protection provisions, to additional paid-in capital within shareholders' equity. The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy.

The Company utilized the Black-Scholes option pricing model to value the warrant liability. The Black-Scholes option pricing model incorporated assumptions and estimates to value the warrant liability. Estimates and assumptions impacting the fair value measurement included the number of shares for which the warrants will be exercisable, the fair value per share of the underlying common shares issuable upon exercise of the warrants, the remaining contractual term of the warrants, the risk-free interest rate, the expected dividend yield, and the expected volatility of the price of the underlying common shares. The fair value per share of the Company's common shares was based on the closing trading price of the shares on January 26, 2018, the day of expiration, and the increase in the fair value of the common shares during the time period from December 31, 2017 to expiration is the primary reason for the increase in the fair value of the warrant liability during the same period. The Company was a private company prior to its IPO in May 2017 and therefore lacks company-specific historical and implied volatility information of its shares. Therefore, it estimated its expected share volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the

(Amounts in thousands, except share and per share amounts)

3. Fair Value of Financial Assets and Liabilities (Continued)

warrants. The Company estimated a 0% expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future.

Valuation of Derivative Liability

The fair value of the derivative liability in the table above was recognized in connection with the Series A Preferred Shares agreement with RPI, as described in Note 9, was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability relates to certain scenarios outlined in the agreement that would result in accelerated payments as compared to the agreement's host instrument. The with-and-without valuation method was used to determine the fair value of the embedded derivatives within the agreement. As inputs into the valuation, the Company considered the type and probability of occurrence of certain events, the amount of the payments, the expected timing of certain events, and a risk-adjusted discount rate. In accordance with ASC 815, Derivatives and Hedging, the fair value of the derivative was recorded on the balance sheet as a derivative liability with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss. If factors change and different assumptions are used, the fair value of the derivative liability and related gains or losses could be materially different in the future.

Valuation of Liability Related to Sale of Future Royalties

In June 2018, and as described in Note 8, the Company entered into a funding agreement with RPI, accounted for as a liability financing. As of December 31, 2019, the fair value of the liability related to sale of future royalties, used in determining the effective interest rate of the liability, is based on the Company's current estimates of future royalties expected to be paid to RPI over the life of the arrangement, which is considered Level 3.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2019	2018
Prepaid clinical trial costs	$ 6,101	$ 7,210
Due from broker for option exercises	2,978	22
Prepaid insurance	471	393
Other prepaid assets	2,000	458
Other current assets	4	7
	$ 11,554	$ 8,090

5. Equity Method Investment

On August 29, 2016, the Company executed a stock purchase agreement with Kleo, a privately held Delaware corporation, to purchase 3,000,000 shares of Kleo's common stock at an initial closing, with a commitment to purchase an aggregate of 5,500,000 additional shares of common stock, in each case at a share price of $1.00 per share (the "Kleo SPA"). Kleo is a development-stage biopharmaceutical company focused on advancing the field of immunotherapy by developing small molecules that emulate biologics. The Company purchased 3,000,000 shares upon the initial closing on August 31, 2016, and the remaining 5,500,000 shares were to be purchased in four equal tranches of 1,375,000 shares beginning six months from the initial closing and then every three months thereafter. In connection with the initial investment, the Company received the right to designate two of the members of Kleo's board of directors. The Company completed all four of remaining tranche purchases in March, June, October 2017 and January 2018, with each tranche purchase consisting of 1,375,000 shares for cash consideration of $1,375.

In March 2017, the Company purchased 500,000 shares of Kleo common stock directly from a co-founder of Kleo for consideration of $250 in cash and 32,500 common shares of the Company.

(Amounts in thousands, except share and per share amounts)

5. Equity Method Investment (Continued)

In addition to these purchases, in October 2017, the Company purchased an additional aggregate of 2,049,543 shares for cash consideration of $2,253 which allowed the Company to maintain its relative ownership interest in Kleo. As of December 31, 2017, the Company's ownership interest in the outstanding stock of Kleo was 43.3%. Upon completion of the fourth and final tranche investment in January 2018, the Company's ownership increased to 46.6%.

In November 2018, the Company participated in Kleo's Series B funding raise. The Company purchased 1,420,818 shares for cash consideration of $5,000. As of the close of the Series B funding raise, and as of December 31, 2019, the Company's ownership interest in the outstanding common stock of Kleo was approximately 42%.

The Company has a variable interest in Kleo through its equity investment. Kleo is a variable interest entity due to the equity investment at risk being insufficient to finance its activities. An assessment of whether or not the Company has the power to direct activities that most significantly impact Kleo's economic performance and to identify the party that obtains the majority of the benefits of the investment was performed as of December 31, 2019 and 2018, and will be performed as of each subsequent reporting date. After each of these assessments, the Company concluded that the activities that most significantly impact Kleo's economic performance are the ability to direct the research activities, the ability to select vendors to perform the research, the ability to maintain research staff and the ability to raise additional funds, each of which are directed by Kleo. Based on the outcome of these assessments, the Company concluded that the investment should be accounted for under the equity method.

The Company has recorded its investments in Kleo to date based on the costs of those investments, as adjusted for the Company's proportional share of Kleo's net income or loss in each period. The Company records future adjustments to the carrying value of its investment at each reporting date equal to its proportionate share of Kleo's net loss for the corresponding period. The Company recorded other expense and a corresponding reduction in the carrying value of its investment in Kleo of $6,076, $2,808 and $1,885 for its proportionate share of Kleo's net loss for the years ended December 31, 2019, 2018 and 2017, respectively.

The carrying value of the Company's investment in Kleo was $5,338 and $11,414 as of December 31, 2019 and 2018, respectively, and is reported as equity method investment on the consolidated balance sheet. The carrying value of the investment represents the Company's maximum loss exposure as of December 31, 2019.

The following table provides a roll forward of the carrying value of the Company's equity method investment:

	Carrying Value
Balance as at December 31, 2017	$ 7,847
Purchase of Kleo common stock	6,375
Loss recognized in connection with equity method investment	(2,808)
Balance as at December 31, 2018	11,414
Loss recognized in connection with equity method investment	(6,076)
Balance as at December 31, 2019	$ 5,338

(Amounts in thousands, except share and per share amounts)

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2019	2018
Building and Land	$ 2,140	$ 2,200
Building Improvements	4,718	3,210
Computer Hardware	1,206	420
Furniture & Fixtures	469	280
Office Equipment	441	441
	$ 8,974	$ 6,551
Accumulated depreciation	(932)	(303)
Construction in progress	110	—
	$ 8,152	$ 6,248

In August 2017, the Company entered into a lease agreement to consolidate our headquarters into a free standing building in New Haven, Connecticut, which we began occupying during the fourth quarter of 2018. The Company had the option to purchase the property for $2,700 and executed that option in December 2018.

Depreciation expense was $629, $261 and $35 for the years ended December 31, 2019, 2018 and 2017, respectively.

7. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2019	2018
Accrued development milestones payable (Note 16)	$ 12,000	$ —
Accrued employee compensation and benefits	3,521	108
Accrued clinical trial costs	16,476	6,753
Accrued commercialization and other professional fees	15,408	1,636
Other	4,697	285
	$ 52,102	$ 8,782

8. Liability Related to Sale of Future Royalties

In June 2018, pursuant to the Funding Agreement entered into by the Company and RPI, a Delaware statutory trust, the Company issued to RPI the right to receive certain revenue participation payments, subject to certain reductions, based on the future global net sales of the Products for each calendar quarter during the royalty term contemplated by the Funding Agreement ("Revenue Participation Right"), in exchange for $100,000 in cash. Specifically, the participation rate commences at 2.1% on annual global net sales of up to and equal to $1,500,000, declining to 1.5% on annual global net sales exceeding $1,500,000.

In addition, the Company had the option to repurchase 100% of the Revenue Participation Right from RPI for a purchase price of $155,000, if the Company entered into a definitive agreement to consummate a change of control (the "Buy-Back Option"). The Company did not exercise the Buy-Back Option which expired in July 2018.

Concurrent with the Funding Agreement, the Company entered into a Purchase Agreement with RPI. Pursuant to the Purchase Agreement, the Company sold 1,111,111 common shares of the Company to RPI at a price of $45.00 per share, for gross proceeds of $50,000.

8. Liabilities Related to Sale of Future Royalties (Continued)

The Company concluded that there were two units of accounting for the consideration received comprised of the liability related to sale of future royalties and the common shares. The Company accounted for the Funding Agreement with RPI as a liability financing, primarily because it has significant continuing involvement in generating the future revenue on which the royalties are based. The liability related to sale of future royalties and the related non-cash interest expense are measured based on the Company's current estimate of the timing and amount of expected future royalties expected to be paid over the estimated term of the Funding Agreement with RPI Trust using a discounted cash flow model. The liability is amortized using the effective interest rate method, resulting in recognition of non-cash interest expense over the estimated term of the agreement. Each reporting period, the Company assesses the estimated timing and amount of future expected royalty payments over the estimated term. If there are changes to the estimate, the Company recognizes the impact to the liability's amortization schedule and the related non-cash interest expense prospectively. The Company's estimate of the amount of expected future royalties to be paid considers the probability of success of the compounds being approved for sale, market penetration rates of the compounds upon approval, compliance rate and net pricing. Additionally, the transaction costs associated with the liability will be amortized to non-cash interest expense over the estimated term of the Funding Agreement.

The Company allocated the $100,000 from the Funding Agreement and $50,000 from the Purchase Agreement among the two units of accounting on a relative fair value basis at the time of the transaction. The Company allocated $106,047 in transaction consideration to the liability, and $43,953 to the common shares. The Company determined the fair value of the common shares based on the closing stock price on the transaction date, adjusted for the trading restrictions. The transaction costs incurred related to the transactions with RPI of $377 were allocated in proportion to the allocation of total consideration to the two units of accounting. The effective interest rate under the Funding Agreement, including transaction costs, as of December 31, 2019 is approximately 22%.

Biohaven recognized $26,580 and $11,726 in non-cash interest expense in the twelve months ended December 31, 2019 and 2018, respectively, related to the Funding Agreement.

9. Mandatorily Redeemable Preferred Shares, net

In April 2019, the Company sold 2,495 Series A Preferred Shares to RPI at a price of $50,100 per preferred share pursuant to a Series A preferred share purchase agreement (the "Preferred Share Agreement"). The gross proceeds from the transaction with RPI were $125,000, with $105,000 of the proceeds used to purchase a priority review voucher ("PRV") issued by the United States Secretary of Health and Human Services to potentially expedite the regulatory review of the new drug application ("NDA") for the ODT formulation of rimegepant and the remainder of the proceeds to be used for other general corporate purposes. Pursuant to the Preferred Share Agreement, the Company may issue additional Series A Preferred Shares to RPI in up to three additional closings for an aggregate amount of $75,000 subject to the acceptance by the FDA of both NDAs with respect to the tablet formulation of rimegepant and the NDA with respect to the ODT formulation of rimegepant. As a condition for the issuance of additional Series A Preferred Shares, one NDA must be accepted under the priority review designation pathway. Both of these conditions were met in 2019. The issuance of additional Series A Preferred Shares is also subject to customary closing conditions. The issuance of additional Series A Preferred Shares is entirely at the Company's option, and the Company is not obligated to issue any additional Series A Preferred Shares, subject to a fee up to $3,000 if not issued in total. The fee is reduced proportionally by the amount of additional Series A Preferred Shares issued up to the aggregate $75,000, in which the fee is reduced to zero.

The holders of the Company's outstanding Series A Preferred Shares, will have the right to require redemption of the shares in certain circumstances. If a Change of Control, as defined in the Company's memorandum and article of association, occurs after October 5, 2019 and the Series A Preferred Shares have not previously been redeemed, the Company must redeem the Series A Preferred Shares for two times (2x) the original purchase price of the Series A Preferred Shares payable in a lump sum at the closing of the Change of Control or in equal quarterly installments following the closing of the Change of Control through December 31, 2024.

If an NDA for rimegepant is not approved by December 31, 2021, the holders of the Series A Preferred Shares have the option at any time thereafter to require the Company to redeem the Series A Preferred Shares for one point two times (1.2x) the original purchase price of the Series A Preferred Shares.

If no Change of Control has occurred, the Series A Preferred Shares have not previously been redeemed and (i) rimegepant is approved on or before December 31, 2024, following approval and starting one-year after approval, the Company must redeem the Series A Preferred Shares for two times (2x) the original purchase price, payable in a lump sum or in equal quarterly

(Amounts in thousands, except share and per share amounts)

9. Mandatorily Redeemable Preferred Shares, net (Continued)

installments through December 31, 2024 (provided that if rimegepant is approved in 2024, the entire redemption amount must be paid by December 31, 2024) or (ii) rimegepant is not approved by December 31, 2024, the Company must redeem the Series A Preferred Shares for two times (2x) the original purchase price on December 31, 2024.

The Company may redeem the Series A Preferred Shares at our option at any time for two times (2x) the original purchase price, which redemption price may be paid in a lump sum or in equal quarterly installments through December 31, 2024.

In the event that the Company defaults on any obligation to redeem Series A Preferred Shares when required, the redemption amount shall accrue interest at the rate of eighteen percent (18%) per annum. If any such default continues for at least one year, the holders of such shares shall be entitled to convert, subject to certain limitations, such Series A Preferred Shares into common shares, with no waiver of their redemption rights.

Under all circumstances, the Series A Preferred Shares are required to be redeemed by December 31, 2024. Accordingly, the Company has concluded the Series A Preferred Shares are mandatorily redeemable instruments and classified as a liability. The Company initially measured the liability at fair value, and will subsequently accrete the carrying value to the redemption value through non-cash interest expense using the effective interest rate method. The effective interest rate under the Preferred Share Agreement, including transaction costs, was determined to be approximately 18%, and the Company recognized $12,711 in non-cash interest expense for the twelve months ended December 31, 2019. The Company had 2,495 and no Series A preferred shares issued and outstanding as of December 31, 2019 and 2018, respectively.

The following table shows the activity within the preferred share liability for the twelve months ended December 31, 2019:

	Carrying Value
Transaction date balance	$ 91,185
Non-cash interest expense recognized, net of transaction cost amortization	12,679
Gross balance at December 31, 2019	103,864
Less: Unamortized transaction costs	(218)
Net balance at December 31, 2019	$ 103,646

Certain scenarios as described in the Preferred Share Agreement were determined by the Company to result in a derivative liability. The with-and-without valuation method was used to determine the fair value of the embedded derivatives within the agreement. As inputs into the valuation, the Company considered the type and probability of occurrence of certain events, the amount of the payments, the expected timing of certain events, and a risk-adjusted discount rate. In accordance with ASC 815, Derivatives and Hedging, the fair value of the derivative was recorded on the balance sheet as a derivative liability with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss (see Note 3 for details on the fair value measurement). If factors change and different assumptions are used, the fair value of the derivative liability and related gains or losses could be materially different in the future.

The Company recorded the payment for the PRV as research and development expense in the consolidated statements of operations and comprehensive loss, and as an operating cash outflow in the consolidated statements of cash flows. During the second quarter of 2019, the Company submitted NDAs for the acute treatment of migraine to the FDA for the Zydis ODT and tablet formulations of rimegepant. The NDA submission of rimegepant Zydis ODT was submitted using the PRV.

10. Warrants

Guarantor and Co-Guarantor Warrants

On August 30, 2016, the Company entered into a one-year credit agreement (the “Credit Agreement”) with Wells Fargo Bank, National Association (“Wells Fargo”) providing for a term loan in the principal amount of $5,000 (the “Loan”) and borrowed the full $5,000 available under the Credit Agreement. The Credit Agreement was fully satisfied with a principal repayment to Wells Fargo of $5,000 on August 31, 2017. The Company recognized non-cash interest expense of $906 during the twelve months ended December 31, 2017 and $784 related to the accretion of the debt discount during the twelve December 31, 2017.

(Amounts in thousands, except share and per share amounts)

10. Warrants (Continued)

In connection with entering into the Credit Agreement, the Company issued warrants to purchase common shares to two of the Company's directors in connection with a guarantee of its obligations under the agreement. The Company previously classified the warrants as a liability on its consolidated balance sheet because each warrant represented a freestanding financial instrument that was not indexed to the Company's own shares. The warrant liability was initially recorded at fair value upon entering into the credit agreement and was subsequently remeasured to fair value at each reporting date.

On January 26, 2018, the anti-dilution price protection provisions contained within the warrants issued to each of the guarantor and co-guarantor of the Credit Agreement expired.

Changes in the fair value of the warrant liability, until expiration of the anti-dilution price protection provisions, were recognized as a component of other income (expense), net, in the Company's consolidated statement of operations and comprehensive loss. Upon expiration of the provision, the Company discontinued classification of these warrants as a liability, and has accordingly reclassified the fair value of $5,203 to additional paid-in capital within shareholders' equity.

The following table provides the income (expense) related to the warrant liability that the Company recorded net within other income (expense) in the consolidated statements of operations:

	Twelve Months Ended December 31,		
	2019	2018	2017
Expense from change in fair value of warrant liability	$ —	$ (1,182)	$ (3,241)

Both warrants, each to purchase 107,500 common shares at an exercise price of $9.2911 per share, were exercised in March 2019, resulting in proceeds to the Company of $1,998.

Fox Chase Chemical Diversity Center Inc.

In May 2019, the Company entered into an agreement with Fox Chase Chemical Diversity Center Inc. ("FCCDC") for FCCDC's TDP-43 assets (the "FCCDC Agreement"). The FCCDC Agreement provides the Company with a plan and goal to identify one or more new chemical entity candidates for preclinical development for eventual clinical evaluation for the treatment of one or more TDP-43 proteinopathies. As consideration, Biohaven issued 100,000 of its common shares to FCCDC valued at $5,646. As of the end of the second quarter of 2019, the payment was recorded in accounts payable and research and development expense as the shares had not settled during the quarter. Upon settlement of the shares in July 2019, the Company transferred the value of the common shares issued to FCCDC from accounts payable to common stock.

In addition to the common shares issued to FCCDC, Biohaven is obligated to pay FCCDC milestone payments totaling up to $4,500 with $1,000 for each additional NDA filing (See Note 13). The Company also issued a warrant to FCCDC, granting FCCDC the option to purchase up to 100,000 Biohaven common shares, at a strike price of $56.46 per share, subject to vesting upon achievement of certain milestones in development of TD-43. The warrant has standard terms and conditions for exercise and has accelerated vesting in the event of a change of control of Biohaven.

11. Shareholders' Equity

Issuance of Common Shares for the January 2020 Offering

In January 2020, the Company issued and sold 4,830,917 common shares at a public offering price of $51.75 per share for net proceeds of approximately $245,877 after deducting underwriting discounts and commissions of approximately $3,623 and other offering expenses of approximately $500. In addition, in February 2020, the underwriter of the January follow-on offering exercised its option to purchase additional shares, and the Company issued and sold 724,637 common shares for net proceeds of approximately $36,956 after deducting underwriting discounts and commissions of approximately $543. Thus, the aggregate net proceeds to the Company from the follow-on offering, after deducting underwriting discounts and commissions and other offering costs, were approximately $282,833.

11. Shareholders' Equity (Continued)

Issuance of Common Shares for the June 2019 Offering

In June 2019, the Company issued and sold 6,976,745 common shares at a public offering price of $43.00 per share for net proceeds of approximately $281,100 after deducting underwriting discounts and commissions of approximately $18,000 and other offering expenses of approximately $900. In addition, in July 2019, the underwriters of the follow-on offering partially exercised their option to purchase additional shares, and the Company issued and sold 525,000 common shares for net proceeds of approximately $21,221 after deducting underwriting discounts and commissions of approximately $1,354. Thus, the aggregate net proceeds to the Company from the follow-on offering, after deducting underwriting discounts and commissions and other offering costs, were approximately $302,321.

Exercise of Related Party Warrants

In connection with a guarantee of its obligations under the Credit Agreement, the Company issued warrants, each to purchase 107,500 common shares at an exercise price of $9.9211 per share, to two of its directors. Both warrants were exercised in March 2019, and common shares settled in the second quarter of 2019 (See Note 10).

Issuance of Common Shares for the December 2018 Offering

In December 2018, we closed on an underwritten public offering of 3,859,060 of common shares, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $37.25 per share. The aggregate gross proceeds to the Company from the offering, before deducting the underwriting discounts and commissions and offering expenses payable, were approximately $143,750.

2018 License Agreement with AstraZeneca

In September 2018, the Company entered into a License Agreement (the “2018 AstraZeneca Agreement”) with AstraZeneca AB (“AstraZeneca”). Under the 2018 AstraZeneca Agreement, the Company paid AstraZeneca an upfront cash payment of $3,000 and 109,523 shares valued at $4,080 on the settlement date (see Note 13).

Private Placements

In June 2018, pursuant to the Purchase Agreement between the Company and RPI (Note 8), the Company sold 1,111,111 common shares to RPI at a price of $45.00 per common share for net proceeds of $49,889 after deducting offering expenses of $111.

In March 2018, the Company sold an aggregate of 2,000,000 common shares in a private placement at a price of $27.50 per share, for net proceeds of $52,013 (“Private Placement”) after deducting underwriting discounts and commissions of $2,800 and other offering expenses of $187. Subsequent to the closing of the Private Placement, the Company paid BMS the $50,000 upfront payment under the BMS Amendment (see Note 13).

Agreement with ALS Biopharma, LLC

In April 2018, ALS Biopharma exercised a warrant for the purchase of 325,000 shares through a net share settlement, resulting in an issuance of 261,140 shares.

In January 2018, ALS Biopharma exercised a warrant for the purchase of 275,000 shares through a net share settlement, resulting in an issuance of 228,219 shares.

Issuance of Common Shares for the May 2017 Initial Public Offering

In connection with the completion of its IPO in May 2017, the Company amended its memorandum and articles of association to authorize the issuance of up to 200,000,000 no par value common shares. Each common share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Common shareholders are entitled to receive dividends, as may be declared by the board of directors.

On May 3, 2017, the Company's registration statement on Form S-1 relating to the IPO was declared effective by the SEC. The IPO closed on May 9, 2017 and the Company issued and sold 9,900,000 common shares at a public offering price of $17.00 per share for net proceeds of $152,651 after deducting underwriting discounts and commissions of $11,781 and other offering expenses of $3,868. Upon the closing of the IPO, all convertible preferred shares then outstanding converted into an aggregate of 9,358,560 common shares. In addition, on May 9, 2017, the underwriters of the IPO fully exercised their option to purchase additional shares, and on May 11, 2017, the Company issued and sold 1,485,000 common shares for net proceeds of

11. Shareholders' Equity (Continued)

$23,478 after deducting underwriting discounts and commissions of $1,767. The aggregate net proceeds to the Company from the IPO, after deducting underwriting discounts and commissions and offering expenses, were $176,128.

In connection with the completion of its IPO, the Company issued an aggregate of 1,883,523 common shares to BMS and AstraZeneca in satisfaction of obligations to contingently issue equity securities pursuant to the license agreements (see Note 13), for no additional consideration.

Convertible Preferred Shares

In February 2017, the Company completed the Series A Second Closing through the issuance and sale of an aggregate of 4,305,182 Series A preferred shares. The conversion option associated with the Series A preferred shares sold in the second closing met the definition of a BCF as the fair value of the underlying common shares exceeded the stated conversion price. Upon the sale and issuance of the Series A preferred shares, $2,406 of the BCF was immediately accreted, as this represented the difference between the stated conversion price and per share value of the common shares. The remaining portion of the BCF was being amortized using the effective interest method over the period from the date of issuance to the date of the earliest possible conversion, October 1, 2017.

In May 2017, upon the completion of the Company's IPO, all of the outstanding Series A preferred shares were automatically converted into an aggregate of 9,358,560 common shares. Upon conversion of the Series A preferred shares, the remaining unamortized BCF was reclassified to additional paid-in capital as a deemed dividend.

12. Share-Based Compensation

2014 Equity Incentive Plan

The Company's 2014 Equity Incentive Plan, as amended (the "2014 Plan"), provided for the Company to sell or issue common shares or restricted common shares, or to grant incentive stock options or nonqualified stock options for the purchase of common shares, to employees, members of the board of directors and consultants of the Company. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the common share on the date of grant and the term of stock option may not be greater than 10 years.

The total number of common shares that were issuable under the 2014 Plan was 4,000,000 common shares as of December 31, 2016. In January 2017, the Company effected an increase, effective October 28, 2016, in the number of common shares reserved for issuance under the 2014 Plan from 4,000,000 to 4,899,230 common shares.

Upon effectiveness of the 2017 Equity Incentive Plan, there are no further common shares authorized for grant under the 2014 Plan.

2017 Equity Incentive Plan

In April 2017, the Company's shareholders approved the 2017 Equity Incentive Plan (the "2017 Plan"), which became effective on May 3, 2017 in connection with the Company's IPO. The 2017 Plan provides for the grant of incentive share options, nonstatutory share options, share appreciation rights, restricted share awards, restricted share unit awards ("RSUs"), performance-based share awards and other share-based awards. Additionally, the 2017 Plan provides for the grant of performance cash awards. Upon the effectiveness of the 2017 Plan, there were 7,611,971 common shares reserved for issuance under the 2017 Plan, which consisted of 2,712,741 common shares reserved for future issuance under the 2017 Plan, 4,898,858 common shares reserved for issuance upon the exercise of outstanding options granted under the 2014 Plan, and 372 unallocated common shares remaining in the 2014 Plan share pool. In January 2018 and 2019, the board of directors approved an increase in the number of common shares reserved for future issuance under the 2017 Plan of 1,437,228 and 1,767,901, respectively. As of December 31, 2019, 37,328 common shares remained available for future issuance under the 2017 Plan. In January 2020, the Board of Directors approved an additional increase in the number of common shares reserved for future issuance under the 2017 Plan of 2,095,040.

Vesting periods are determined at the discretion of the board of directors. Stock options and RSUs typically vest over three or four years. The maximum contractual term for both stock options and RSUs is 10 years.

(Amounts in thousands, except share and per share amounts)

12. Share Based Compensation (Continued)

During the years ended December 31, 2019, 2018 and 2017, the Company granted options to purchase common shares to employees and directors of 2,168,950, 1,810,000 and 2,335,106, respectively. Also during the year ended December 31, 2019, the Company granted 118,600 RSUs. There were no RSUs granted during the years ended December 31, 2018 and 2017. The Company recorded non-cash share-based compensation expense for options and RSUs granted to employees and directors of $46,936, $11,246 and $5,210 during the years ended December 31, 2019, 2018 and 2017, respectively.

During the years ended December 31, 2019, 2018 and 2017 the Company granted options to purchase 212,625, 145,000 and 273,537 common shares to non-employees, respectively. There were no RSUs granted to non-employees during the years ended December 31, 2019, 2018 and 2017. The Company recorded non-cash share-based compensation expense for options granted to non-employees of $8,036, $5,679 and $8,029 during the years ended December 31, 2019, 2018 and 2017, respectively.

Non-Cash Share-Based Compensation Expense

Non-cash share-based compensation is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period of the award (generally three to four years) using the straight-line method. Non-cash share-based compensation expense, consisting of expense for both stock options and RSUs, was classified in the consolidated statements of operations and comprehensive loss as follows:

	Year Ended December 31,		
	2019	2018	2017
Research and development expenses	$ 26,284	$ 8,371	$ 6,933
General and administrative expenses	28,688	8,554	6,306
	$ 54,972	$ 16,925	$ 13,239

As of December 31, 2019, total unrecognized compensation cost related to the unvested share-based awards was $90,101, which is expected to be recognized over a weighted average period 2.6 years.

Stock Options

All stock option grants are awarded at fair value on the date of grant. The fair value of stock options is estimated using the Black-Scholes option pricing model and stock-based compensation is recognized on a straight-line basis over the requisite service period. Stock options granted generally become exercisable over a three-year or four-year period from the grant date. Stock options generally expire 10 years after the grant date.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common shares for those stock options that had exercise prices lower than the fair value of

(Amounts in thousands, except share and per share amounts)

12. Share Based Compensation (Continued)

the Company's common shares at December 31, 2019. The total intrinsic value of outstanding stock options for the years ended December 31, 2019, 2018 and 2017 was $284,300, $156,518 and $107,072, respectively.

The total fair value of options vested for the years ended December 31, 2019, 2018 and 2017 was $67,510, $25,876 and $15,494, respectively.

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors under the 2014 Plan and the 2017 Plan (collectively, the "Plans") were as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2019	2018	2017
Risk-free interest rate	1.90 %	2.91 %	2.10 %
Expected term (in years)	5.87	6.25	6.02
Expected volatility	72.10 %	73.03 %	73.26 %
Expected dividend yield	— %	— %	— %
Exercise price	$ 50.53	$ 32.35	$ 18.47

The assumptions that the Company used to determine the grant-date fair value of stock options granted to non-employees under the Plans were as follows, presented on a weighted average basis:

	Year Ended December 31,		
	2019	2018	2017
Risk-free interest rate	2.21 %	3.06 %	2.35 %
Expected term (in years)	10.00	10.00	10.00
Expected volatility	74.04 %	74.50 %	71.12 %
Expected dividend yield	— %	— %	— %
Exercise price	$ 49.73	$ 32.42	$ 18.23

As of December 31, 2019, unrecognized compensation expense related to unvested stock options totaled $85,163, which the Company expects to be recognized over a weighted-average period of 2.58 years. The Company expects approximately 3,893,495 of the unvested stock options to vest over the requisite service period.

The following table is a summary of the Company's stock option activity for the year ended December 31, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	
Outstanding at December 31, 2018	7,444,179	$ 15.99		
Granted	2,381,575	$ 50.46		
Exercised	(372,739)	$ 16.83		
Forfeited	(30,000)	$ 44.59		
Outstanding at December 31, 2019	9,423,015	$ 24.58	7.67	$ 284,300
Options exercisable at December 31, 2019	5,529,520	$ 15.48	6.81	$ 215,938
Vested at December 31, 2019 and expected to vest in the future	9,423,015	$ 24.58	7.67	$ 284,300

(Amounts in thousands, except share and per share amounts)

12. Share Based Compensation (Continued)

Restricted Share Units

The Company's RSUs are considered nonvested share awards and require no payment from the employee. For each RSU, employees receive one share of common stock at the end of the vesting period. The employee can elect to receive the one share of common stock net of taxes or pay for taxes separately and receive the entire share. Compensation cost is recorded based on the market price of the Company's common stock on the grant date and is recognized on a straight-line basis over the requisite service period.

As of December 31, 2019, there was $4,938 of total unrecognized compensation cost related to Company RSUs that are expected to vest. These costs are expected to be recognized over a weighted-average period of 2.90 years. The total fair value of RSUs vested during 2019 was $1,702.

The following table is a summary of the RSU activity for the year ended December 31, 2019:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested outstanding as of December 31, 2018	—	$ —
Granted	118,600	$ 57.40
Forfeited	—	$ —
Vested	(29,650)	$ 57.40
Unvested outstanding as of December 31, 2019	88,950	$ 57.40

13. License and Other Agreements

Amendment to License Agreement with Yale

In September 2013, the Company entered into an exclusive license agreement with Yale (the "Yale Agreement") to obtain a license to certain patent rights for the commercial development, manufacture, distribution, use and sale of products and processes resulting from the development of those patent rights, related to the use of riluzole in treating various neurological conditions, such as general anxiety disorder, post-traumatic stress disorder and depression. As part of the consideration for this license, the Company issued Yale 250,000 common shares and granted Yale the right to purchase up to 10% of the securities issued in specified future equity offerings by the Company, in addition to the obligation to issue shares to prevent anti-dilution. The obligation to contingently issue equity to Yale was no longer outstanding as of December 31, 2018.

The Yale Agreement was amended and restated in May 2019. As amended, the Company agreed to pay Yale up to $2,000 upon the achievement of specified regulatory milestones and annual royalty payments of a low single-digit percentage based on net sales of riluzole-based products from the licensed patents or from products based on troriluzole. Under the amended and restated agreement, the royalty rates are reduced as compared to the original agreement. In addition, under the amended and restated agreement, the Company may develop products based on riluzole or troriluzole. The amended and restated agreement retains a minimum annual royalty of up to $1,000 per year, beginning after the first sale of product under the agreement. If the Company grants any sublicense rights under the Yale Agreement, it must pay Yale a low single-digit percentage of sublicense income that it receives. To date, no milestone or royalty payments have been made under this agreement.

The Yale Agreement, as amended and restated, requires the Company to meet certain due diligence requirements based upon specified milestones relating to riluzole or troriluzole based products. The Company can elect to extend the deadline for its compliance with the due diligence requirements by a maximum of one year upon the payment to Yale of up to $150. The Company is also required to reimburse Yale for any fees that Yale incurs related to the filing, prosecution, defending and maintenance of patent rights licensed under the Yale Agreement. In the event that the Company fails to make any payments, commits a material breach, fails to maintain adequate insurance or challenges the patent rights of Yale, Yale can terminate the Yale Agreement. The Company can terminate the Yale Agreement (i) upon 90 days' notice to Yale, (ii) if Yale commits a material breach of the Yale Agreement or (iii) as to a specific country if there are no valid patent rights in such country. The Yale Agreement expires on a country-by-country basis upon the later of the date on which the last patent rights expire in such

13. License and Other Agreements (Continued)

country or ten years from the date of the first sale of a product incorporating the licensed patents or the Company's patents relating to troriluzole.

MGH Agreement

In September 2014, the Company entered into a license agreement (the "MGH Agreement") with The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH"), pursuant to which MGH granted the Company a license to certain patent rights for the commercial development, manufacture, distribution and use of any products or processes resulting from development of those patent rights, related to treating depression with a combination of ketamine and scopolamine. The Company was obligated to pay MGH annual license maintenance fees and future milestone payments of up to $750 upon the achievement of specified clinical and regulatory milestones and up to $2,500 upon the achievement of specified commercial milestones. The Company had also agreed to pay MGH royalties between zero and ten percent based on net sales of products licensed under the agreement. In July 2019, the Company elected to terminate the agreement. Upon termination, the Company is no longer subject to future milestone or royalty payments under the MGH Agreement.

ALS Biopharma Agreement

In August 2015, the Company entered into an agreement (the "ALS Biopharma Agreement") with ALS Biopharma and FCCDC, pursuant to which ALS Biopharma and FCCDC assigned the Company their worldwide patent rights to a family of over 300 prodrugs of glutamate modulating agents, including troriluzole, as well as other innovative technologies. Under the ALS Biopharma Agreement, the Company is obligated to use commercially reasonable efforts to commercialize and develop markets for the patent products. The Company is obligated to pay $3,000 upon the achievement of specified regulatory milestones with respect to the first licensed product and $1,000 upon the achievement of specified regulatory milestones with respect to subsequently developed products, as well as royalty payments of a low single-digit percentage based on net sales of products licensed under the agreement, payable on a quarterly basis. To date, no milestone or royalty payments have been made under this agreement.

In connection with the ALS Biopharma Agreement, the Company also issued to ALS Biopharma (i) 50,000 common shares; (ii) an immediately exercisable warrant to purchase 275,000 common shares at an exercise price of $5.60 per share; and (iii) a warrant to purchase 325,000 common shares at an exercise price of $5.60 per share, which warrant would become exercisable upon the Company's achievement of a specified regulatory milestone which was met in May 2016 (see Note 9). The ALS Biopharma Agreement terminates on a country-by-country basis as the last patent rights expire in each such country. If the Company abandons its development, research, licensing or sale of all products covered by one or more claims of any patent or patent application assigned under the ALS Biopharma Agreement, or if the Company ceases operations, it has agreed to reassign the applicable patent rights back to ALS Biopharma.

The Company recorded no research and development expenses during the years ended December 31, 2019, 2018 and 2017, as a result of the ALS Biopharma Agreement, which amounts consist of the fair value of the shares and warrants upon their issuance to ALS Biopharma.

Rutgers Agreement

In June 2016, the Company entered into an exclusive license agreement (the "Rutgers Agreement") with Rutgers, The State University of New Jersey ("Rutgers"), licensing several patents and patent applications related to the use of riluzole to treat various cancers. Under the Rutgers Agreement, the Company is required to pay Rutgers annual license maintenance fees until the first commercial sale of a licensed product, at which point the Company will pay Rutgers minimum annual royalties. The Company is also obligated to pay Rutgers up to $825 in the aggregate upon the achievement of specified clinical and regulatory milestones. The Company agreed to pay Rutgers royalties of a low single-digit percentage of net sales of licensed products sold by the Company, its affiliates or its sublicensees, subject to a minimum amount of up to $100 per year. If the Company grants any sublicense rights under the Rutgers Agreement, the Company must pay Rutgers a low double-digit percentage of sublicense income it receives.

Under the Rutgers Agreement, in the event that the Company experiences a change of control or sale of substantially all of its assets prior to the initiation of a Phase 3 clinical trial related to products licensed under the agreement, and such change of control or sale results in a full liquidation of the Company, the Company will be obligated to pay Rutgers a change-of-control fee equal to 0.30% of the total value of the transaction, but not less than $100. The Company determined that the change-of-control payment should be accounted for as a liability. The fair value of the obligation for all periods presented was $0 based on

13. License and Other Agreements (Continued)

the Company's assessment that the probability of a change-in-control event occurring prior to the initiation of a Phase 3 clinical trial related to products licensed under the agreement was remote.

The Rutgers Agreement also requires the Company to meet certain due diligence requirements based upon specified milestones. The Company can elect to extend the deadline for its compliance with the due diligence requirements by a maximum of one year upon payments to Rutgers of up to $500 in the aggregate. Under the Rutgers Agreement, the Company is required to reimburse Rutgers for any fees that Rutgers incurs related to the filing, prosecution, defending, and maintenance of patent rights licensed under the agreement. The Rutgers Agreement expires upon expiration of the patent rights under the agreement or ten years from the date of first commercial sale of a licensed product, whichever is later, unless terminated by either party.

BMS Agreement

In July 2016, the Company entered into an exclusive, worldwide license agreement with BMS (the "BMS Agreement") for the development and commercialization rights to rimegepant and BHV-3500, as well as other CGRP-related intellectual property. In exchange for these rights, the Company agreed to pay BMS initial payments, milestone payments and royalties on net sales of licensed products under the agreement.

The Company is obligated to make milestone payments to BMS upon the achievement of specified development and commercialization milestones. The development milestone payments due under the agreement depend on the licensed product being developed. With respect to rimegepant, the Company is obligated to pay up to $127,500 in the aggregate upon the achievement of the development milestones. For any product other than rimegepant, the Company is obligated to pay up to $74,500 in the aggregate upon the achievement of the development milestones. In addition, the Company is obligated to pay up to $150,000 for each licensed product upon the achievement of commercial milestones. If the Company receives revenue from sublicensing any of its rights under the agreement, it is also obligated to pay a portion of that revenue to BMS. The Company is also obligated to make tiered royalty payments to BMS based on annual worldwide net sales, with percentages in the low to mid-teens.

Under the BMS Agreement, the Company is obligated to use commercially reasonable efforts to develop licensed products and to commercialize at least one licensed product using the patent rights licensed from BMS and is solely responsible for all development, regulatory and commercial activities and costs. The Company is also required to reimburse BMS for any fees that BMS incurs related to the filing, prosecution, defending, and maintenance of patent rights licensed under the BMS Agreement. Under the BMS Agreement, BMS transferred to the Company manufactured licensed products, including certain materials that will be used by the Company to conduct clinical trials.

The BMS Agreement will terminate on a licensed product-by-licensed product and country-by-country basis upon the expiration of the royalty term with respect to each licensed product in each country. BMS has the right to terminate the agreement upon the Company's insolvency or bankruptcy, the Company's uncured material breach of the agreement, including the failure to meet its development and commercialization obligations, or if the Company challenges any of BMS's patent rights. The Company has the right to terminate the BMS Agreement if BMS materially breaches the agreement or if, after the Company provides notice, it chooses not to move forward with development and commercialization in a specific country.

The BMS Agreement required the Company to complete a financing transaction with gross proceeds of at least $30,000, of which a minimum of $22,000 was to be from investment in equity prior to October 17, 2016, unless extended by mutual agreement of the Company and BMS. The BMS Agreement was amended, effective October 14, 2016, to extend the deadline for completing the financing transaction to October 31, 2016, on which date the Series A First Closing was completed (see Note 12).

Under the BMS Agreement, the Company also agreed to issue BMS common shares in the amount of $12,500, which shares are contingently issuable upon the earliest to occur of (i) the initiation of a Phase 3 trial for the first licensed compound to reach such milestone, (ii) the Company's IPO or (iii) an event resulting in the change of control of the Company. Under the terms of the BMS Agreement, if the qualifying financing transaction involves the issuance of preferred shares, BMS is entitled to receive preferred shares instead of common shares, at its option. BMS also had the right to purchase up to 8%, on a fully diluted basis, of shares issued in a qualifying financing transaction (as defined in the BMS Agreement) on the same terms and rights as all other investors involved in the financing. The number of shares issuable to BMS under the agreement will be determined by dividing $12,500 by a price per share equal to the lower of (i) the price per share paid by investors in the

13. License and Other Agreements (Continued)

Series A First Closing, or $9.2911 (see Note 12), or (ii) the price per share paid by investors in any subsequent financing event that occurs prior to the events specified above.

The obligation to contingently issue equity to BMS is classified as a liability on the consolidated balance sheet because it represents an obligation to issue a variable number of shares for a fixed dollar amount. Upon entering into the BMS Agreement, the issuance-date fair value of the contingent equity liability of $13,125 was recognized as research and development expense in the consolidated statement of operations and comprehensive loss. The Company remeasured the fair value of the contingent equity liability at each reporting date since the date of issuance, recognizing changes in the fair value of the contingent equity liability as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. Changes in the fair value of the contingent equity liability continued to be recognized until the occurrence of a triggering event, which occurred in May 2017 with the completion of the IPO.

In May 2017, in connection with the completion of its IPO, the Company issued 1,345,374 common shares to BMS in satisfaction of its obligation to contingently issue equity securities pursuant to the license agreement and remeasured the contingent equity liability to fair value. The Company recognized expense of $0, $8,809 and $13,125 during the years ended December 31, 2019, 2018 and 2017, respectively, as a result of changes to the fair value of the contingent equity liability prior to its extinguishment in May 2017.

The Company recorded $17,500, $2,000 and $5,000 of research and development expense related to the BMS Agreement during the years ended December 31, 2019 , 2018 and 2017, respectively, for the achievement of specified milestones.

Amendment to License Agreement with BMS

In March 2018, the Company entered into an Amendment to License Agreement with BMS (the “BMS Amendment”), which amends the License Agreement between the Company and BMS from July 2016 (the “Original License Agreement” and, as amended by the BMS Amendment, the “BMS License Agreement”). Under the BMS Amendment, the Company paid BMS an upfront payment of $50,000 in return for a low single-digit reduction in the royalties payable on net sales of rimegepant and a mid single-digit reduction in the royalties payable on net sales of BHV-3500, recorded in Research and Development expense in the Consolidated Statements of Operations and Comprehensive Loss. Under the Original License Agreement, the Company was obligated to make tiered royalty payments based on annual worldwide net sales of licensed products upon their approval and commercialization, with percentages in the low- to mid-teens.

The BMS Amendment also removes BMS’s right of first negotiation to regain its intellectual property rights or enter into a license agreement with the Company following the Company’s receipt of topline data from its Phase 3 clinical trials with rimegepant, and clarifies that antibodies targeting CGRP are not prohibited as competitive compounds under the non-competition clause of the Original License Agreement.

The BMS License Agreement continues to provide the Company with exclusive global development and commercialization rights to rimegepant, BHV-3500 and related CGRP molecules, as well as related know-how and intellectual property. The Company’s obligations to make development and commercial milestone payments to BMS under the Original License Agreement remain unchanged.

2016 AstraZeneca Agreement

In October 2016, the Company entered into an exclusive license agreement (the "2016 AstraZeneca Agreement") with AstraZeneca, pursuant to which AstraZeneca granted the Company a license to certain patent rights for the commercial development, manufacture, distribution and use of any products or processes resulting from development of those patent rights, including BHV-5000 and BHV-5500. In exchange for these rights, the Company agreed to pay AstraZeneca an upfront payment, milestone payments and royalties on net sales of licensed products under the agreement. The regulatory milestones due under the agreement depend on the indication of the licensed product being developed as well as the territory where regulatory approval is obtained. Development milestones due under the agreement with respect to Rett syndrome total up to $30,000, and, for any indication other than Rett syndrome, total up to $60,000. Commercial milestones are based on net sales of all products licensed under the agreement and total up to $120,000. The Company has also agreed to pay tiered royalties based on net sales of all products licensed under the agreement of mid-single-digit to low double-digit percentages. If the Company receives revenue from sublicensing any of its rights under the 2016 AstraZeneca Agreement, the Company is also obligated to pay a portion of that revenue to AstraZeneca. To date, no payments have been made related to these milestones or royalties.

13. License and Other Agreements (Continued)

The Company is also required to reimburse AstraZeneca for any fees that AstraZeneca incurs related to the filing, prosecution, defending, and maintenance of patent rights licensed under the 2016 AstraZeneca Agreement.

The 2016 AstraZeneca Agreement expires upon the expiration of the patent rights under the agreement, unless earlier terminated by either party, or on a country-by-country basis ten years after the first commercial sale.

As part of the consideration under the 2016 AstraZeneca Agreement, the Company agreed to issue to AstraZeneca common shares in the amount of $10,000 if the Company completed a qualifying equity financing resulting in proceeds of at least $30,000 prior to December 29, 2016. Under the terms of the 2016 AstraZeneca Agreement, if the qualifying financing transaction involved the issuance of preferred shares, AstraZeneca would be entitled to receive preferred shares instead of common shares, at its option. The number of shares issued would be determined based on the price per share paid by investors in the qualifying financing transaction. Upon the occurrence of the qualifying financing transaction, 50% of the shares would be issuable upon the closing of the transaction (the "First Tranche") and the other 50% would become issuable upon the earlier of (i) the initiation of a Phase 2b or equivalent clinical trial of a product candidate based on the licensed patent rights or (ii) any liquidity event, including an IPO of the Company, any change of control of the Company or any assignment of the Company's rights and obligations under the 2016 AstraZeneca Agreement (the "Second Tranche"). The number of shares issuable to AstraZeneca in each of the First Tranche and the Second Tranche is determined by dividing $5,000 by the price per share paid by investors in the Company's Series A First Closing, or $9.2911 (see Note 10). In addition, AstraZeneca had the right to purchase up to 8%, on a fully diluted basis, of shares issued in such qualifying financing transaction, on the same terms and rights as all other investors involved in the financing.

In October 2016, upon completion of the Series A First Closing (see Note 10), the contingency associated with the First Tranche of contingently issuable equity related to the occurrence of a qualified financing was satisfied. As a result, the Company issued to AstraZeneca 538,150 Series A preferred shares with an aggregate fair value of $5,000, or $9.2911 per share. Upon issuance of the 538,150 Series A preferred shares to AstraZeneca, the Company reclassified the contingent equity liability associated with the First Tranche of $5,000 to the carrying value of Series A preferred shares.

The Company determined that the fair value of the contingent equity liability associated with the Second Tranche at each reporting date since the date of issuance, recognizing changes in the fair value of the contingent equity liability as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. Changes in the fair value of the contingent equity liability continued to be recognized until the occurrence of a triggering event, which occurred in May 2017 with the completion of the IPO.

In May 2017, in connection with the completion of its IPO, the Company issued 538,149 common shares to AstraZeneca in satisfaction of its obligation to contingently issue the Second Tranche of equity securities pursuant to the license agreement and remeasured the contingent equity liability to fair value. The Company recognized expense of $4,273 during the year ended December 31, 2017 as a result of changes to the fair value of the contingent equity liability prior to its extinguishment in May 2017.

RPharm Agreement

In November 2017, the Company entered into a consulting agreement with R PHARM US related to the commercial preparation for BHV-0223. In addition to fixed quarterly consulting expenses under the agreement, which are currently on hold pending resolution of the NDA filing status for BHV-0223, the Company agreed to pay up to $2,500 upon achievement of specific commercial milestones. The Company paid $22 and $1,400 to R PHARM US under this agreement during the years ended December 31, 2019 and 2018, respectively.

Catalent Agreements for Rimegepant

In January 2018, the Company entered into an exclusive world-wide license and development agreement with Catalent, Inc. pursuant to which the Company obtained certain license rights to the Zydis ODT technology for use with rimegepant. If the Company obtains regulatory approval or launches a rimegepant product that utilizes the Zydis ODT technology, the Company is obligated to pay Catalent up to $1,500 upon the achievement of specified regulatory and commercial milestones. If the Company commercializes a rimegepant product that utilizes the Zydis ODT technology, the agreement permits the Company to purchase the commercial product from Catalent at a fixed price, inclusive of a royalty. Under the agreement, Catalent will not develop or manufacture a formulation of any oral CGRP compound using Zydis ODT technology for itself or a third party until 2031, subject to certain minimum commercial revenues.

13. License and Other Agreements (Continued)

Under this agreement, the Company is responsible for conducting clinical trials and preparing and filing regulatory submissions. The Company has the right to sublicense its rights under the agreement subject to Catalent's prior written consent. Catalent has the right to enforce the patents covering the Zydis technology and to defend any allegation that a formulation using Zydis technology, such as rimegepant, infringes a third party's patent.

This agreement terminates on a country-by-country basis upon the later of (i) 10 years after the launch of the most recently launched product in such country and (ii) the expiration of the last valid claim covering each product in such country, unless earlier voluntarily terminated by the Company. This agreement automatically extends for one-year terms unless either party gives advance notice of intent to terminate. In addition, Catalent may terminate the agreement either in its entirety or terminate the exclusive nature of this agreement on a country-by-country basis if the Company fails to meet specified development timelines, which it may extend in certain circumstances.

In July 2018, the Company entered into a commercial supply agreement with Catalent pursuant to which Catalent will exclusively manufacture and supply the Company's worldwide requirements for rimegepant in the Zydis ODT delivery formulation, if the Company pursues and receives regulatory approval of this formulation of rimegepant, for an initial term of five years after its commercial launch with optional two-year renewal periods. Under the agreement, Catalent will supply the rimegepant Zydis ODT product at a fixed price, inclusive of a royalty, and will not develop or manufacture a formulation of any oral CGRP compound using Zydis ODT technology for itself or a third party for a specified period of time, subject to certain minimum commercial revenues.

Revenue Participation Right with RPI Finance Trust

In June 2018, pursuant to the Funding Agreement entered into by the Company and RPI (Note 7), the Company granted to RPI the right to receive certain revenue participation payments, subject to certain reductions, based on the future global net sales of the Products, for each calendar quarter during the royalty term contemplated by the Funding Agreement, in exchange for $100.0 million in cash. Specifically, the participation rate commences at 2.1 percent on annual global net sales of up to and equal to $1.5 billion, declining to 1.5 percent on annual global net sales exceeding $1.5 billion.

In addition, the Company had the option to repurchase 100% of the Revenue Participation Right from RPI for a purchase price of $155.0 million, if the Company entered into a definitive agreement to consummate a change of control. The Company did not exercise the Buy-Back Option which expired in July 2018.

2018 License Agreement with AstraZeneca

In September 2018, the Company entered into the 2018 AstraZeneca Agreement. Under the 2018 AstraZeneca Agreement, the Company paid AstraZeneca an upfront cash payment of $3,000 and 109,523 shares valued at $4,080 on the date of settlement, both of which are included in research and development expense, and is obligated to pay milestone payments to AstraZeneca totaling up to $55,000 upon the achievement of specified regulatory and commercial milestones and up to $50,000 upon the achievement of specified sales-based milestones. In addition, we will pay AstraZeneca tiered royalties ranging from high single-digit to low double-digits based on net sales of specified approved products, subject to specified reductions.

AstraZeneca granted Biohaven exclusive worldwide rights to develop and commercialize AZD3241, an oral myeloperoxidase ("MPO") inhibitor that AstraZeneca progressed through Phase 2 clinical trials. We plan to conduct a Phase 3 clinical trial of this product candidate, which will now be referred to as verdiperstat, for the treatment of multiple system atrophy ("MSA"), a rare, rapidly progressive and fatal neurodegenerative disease with no cure or effective treatments.

We are now solely responsible, and has agreed to use commercially reasonable efforts, for all development, regulatory and commercial activities related to verdiperstat. We may sublicense its rights under the Agreement and, if it does so, will be obligated to pay a portion of any milestone payments received from the sublicensee to AstraZeneca in addition to any milestone payments we would otherwise be obligated to pay. We are also now responsible for the prosecution and maintenance of the patents related to verdiperstat and has the first right to prosecute infringement of the patents and defend challenges to the validity or enforceability of the patents.

The Agreement terminates on a country-by-country basis and product-by-product basis upon the expiration of the royalty term for such product in such country. Each royalty term begins on the date of the first commercial sale of the licensed product in the applicable country and ends on the later of 10 years from such first commercial sale or the expiration of the last to expire of the applicable patents in that country. The Agreement may be terminated earlier in specified situations, including termination for uncured material breach of the Agreement by either party, termination by AstraZeneca in specified circumstances,

13. License and Other Agreements (Continued)

termination by us on a country-by-country basis with advance notice and termination upon a party's insolvency or bankruptcy.

License Agreement with the University of Connecticut

In October 2018, the Company announced it had signed an exclusive, worldwide option and license agreement (the "UConn Agreement") with the University of Connecticut ("UConn") for the development and commercialization rights to UC1MT, a therapeutic antibody targeting extracellular metallothionein. Under this agreement, we have the option to acquire an exclusive, worldwide license to UC1MT and its underlying patents to develop and commercialize throughout the world in all human indications. If the Company chooses to exercise the option, it would be obligated to pay UConn upon the achievement of specified regulatory and commercial milestones, and royalties of a low single-digit percentage of net sales of licensed products sold by the Company, its affiliates or its sublicensees.

Biotech Value Advisors Agreement

In March 2019, the Company entered into a master services agreement with Biotech Value Advisors, LLC related to the commercial preparation for several of the Company's late-stage product candidates. In addition to fixed quarterly consulting expenses under the agreement, the Company agreed to pay up to $2,000 upon achievement of specified commercial milestones.

Fox Chase Chemical Diversity Center Inc. Agreement

In May 2019, Biohaven entered into the FCCDC Agreement in which the Company purchased certain intellectual property relating to the TDP-43 protein from FCCDC. The FCCDC Agreement provides the Company with a plan and goal to identify one or more new chemical entity candidates for preclinical development for eventual clinical evaluation for the treatment of one or more TDP-43 proteinopathies. As consideration, Biohaven issued 100,000 of its common shares to FCCDC valued at $5,646. As of the end of the second quarter of 2019, the payment was recorded in accounts payable and research and development expense as the shares had not settled during the quarter. Upon settlement of the shares in July 2019, the Company transferred the value of the common shares issued to FCCDC from accounts payable to common stock.

In addition, Biohaven is obligated to pay FCCDC milestone payments totaling up to $4,500 with $1,000 for each additional NDA filing. The Company also issued a warrant to FCCDC, granting FCCDC the option to purchase up to 100,000 Biohaven common shares, at a strike price of $56.46 per share, subject to vesting upon achievement of certain milestones in development of TD-43 (see Note 10).

In connection with the FCCDC Agreement, Biohaven and FCCDC have established a TDP-43 Research Plan that provides for certain milestones to be achieved by FCCDC, and milestone payments to be made by the Company up to $1,500 over a period of up to 30 months as success fees for research activities by FCCDC. In addition to the milestone payments, the Company will pay FCCDC an earned royalty equal to zero to ten percent of net sales of any TD-43 patent products with a valid claim as defined in the FCCDC Agreement. The Company may also license the rights developed under the FCCDC Agreement and, if it does so, will be obligated to pay a portion of any payments received from such licensee to FCCDC in addition to any milestones payments it would otherwise be obligated to pay. The Company is also responsible for the prosecution and maintenance of the patents related to the TDP-43 assets.

The FCCDC Agreement can be terminated on a country-by-country basis and product-by-product basis upon expiration of the royalty term for such product in such country. Each royalty term begins on the date of the first commercial sale of the licensed product in the applicable country and ends on the expiration of the last to expire of the applicable patents in that country. The FCCDC Agreement may be terminated earlier in specified situations, including termination for uncured material breach of the FCCDC Agreement by either party, termination by FCCDC in specified circumstances, termination by the Company on a country-by-country basis with advance notice and termination upon a party's insolvency or bankruptcy.

14. Income Taxes

As a company incorporated in the British Virgin Islands ("BVI"), the Company is principally subject to taxation in the BVI. Under the current laws of the BVI, tax on a company's income is assessed at a zero percent tax rate. As a result, the Company has not recorded any income tax benefits from its losses incurred in the BVI during each reporting period, and no net operating loss carryforwards will be available to the Company for those losses. The Company has historically outsourced all of the research and clinical development for its programs under a master services agreement with Biohaven Pharmaceuticals, Inc., a Delaware corporation ("BPI"). As a result of providing services under this agreement, BPI was profitable during the years ended December 31, 2019, 2018 and 2017, and BPI is subject to taxation in the United States.

(Amounts in thousands, except share and per share amounts)

14. Income Taxes (Continued)

Our provision for income taxes has historically been comprised of Federal alternative minimum tax, and state taxes through December 31, 2017, and federal tax due to general business credit limitations and state taxes in 2018 and 2019.

As of December 31, 2019, we evaluated our deferred tax assets and determined that a full valuation allowance on these assets was appropriate due to excess credits.

Income (loss) before provision for income taxes consisted of the following:

	Year Ended December 31,		
	2019	2018	2017
BVI	$ (541,625)	$ (246,829)	$ (130,359)
Foreign (U.S.)	13,239	6,374	4,175
Loss before provision for income taxes	$ (528,386)	$ (240,455)	$ (126,184)

The provision for income taxes consisted of the following:

	Year Ended December 31,		
	2019	2018	2017
Current income tax provision:			
BVI	$ —	$ —	$ —
Foreign (U.S. federal and state)	419	467	997
Total current income tax provision	419	467	997
Deferred income tax provision (benefit):			
BVI	—	—	—
Foreign (U.S. federal and state)	—	—	9
Total deferred income tax provision (benefit)	—	—	9
Total provision for income taxes	$ 419	$ 467	$ 1,006

A reconciliation of the BVI statutory income tax rate of 0% to the Company's effective income tax rate is as follows:

	Year Ended December 31,		
	2019	2018	2017
BVI statutory income tax rate	0.0 %	0.0 %	0.0 %
Foreign tax rate differential	0.3	0.6	1.2
Tax Credits	(2.2)	(3.5)	(2.7)
Change in valuation allowance	1.9	3.4	2.2
Other	0.1	(0.3)	0.1
Effective income tax rate	0.1 %	0.2 %	0.8 %

Net deferred tax assets (liabilities) consisted of the following:

(Amounts in thousands, except share and per share amounts)

14. Income Taxes (Continued)

	December 31,	
	2019	2018
Deferred tax assets:		
Foreign net operating loss carryforwards	$ —	$ —
Tax credits	21,083	11,396
Other	1	1
Valuation allowance	(20,728)	(10,957)
Total deferred tax assets, net	356	440
Deferred tax liabilities:		
Other	(356)	(440)
Total deferred tax liabilities	(356)	(440)
Net deferred tax assets	$ —	$ —

As of December 31, 2019 and 2018, the Company had no remaining foreign net operating loss carryforwards. The Company had federal and state research and development credits of $14,845 and $1,214 which begin to expire in 2037. As of December 31, 2019 the Company had federal orphan drug credits of $5,279 which begin to expire in 2038.

On December 22, 2017, the Tax Cuts and Jobs Act ("The Act"), was signed into law, resulting in significant changes to the Internal Revenue Code of 1986, as amended. These changes include a federal statutory rate reduction from 35% to 21%, limitation on the amount of research and development expenses deductible per year beginning in years after 2021, reduction of the Orphan Drug Credit from 50% to 25% of qualified clinical testing expenditures, increased limitations on certain executive compensation, elimination of the Corporate Alternative Minimum Tax, and modifying or repealing other business deductions and credits. The revaluation of our deferred tax assets due to The Act was not material.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2019, 2018 and 2017 were due primarily to generation of excess credits and were as follows:

	Year Ended December 31,		
	2019	2018	2017
Valuation allowance as of beginning of year	$ 10,957	$ 2,784	$ —
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	9,771	8,173	2,784
Valuation allowance as of end of year	$ 20,728	$ 10,957	$ 2,784

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2019 or 2018. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2019 or 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company's statement of operations and comprehensive loss.

BPI files income tax returns in the U.S. and certain state jurisdictions. BPI's U.S. federal and state income tax returns are subject to tax examinations for the tax year ended December 31, 2016 and subsequent years. There are currently no income tax examinations pending.

(Amounts in thousands, except share and per share amounts)

15 . Net Loss per Share

Basic and diluted net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd. was calculated as follows:

	Year Ended December 31,		
	2019	2018	2017
Numerator:			
Net loss	$ (528,805)	$ (240,922)	$ (127,190)
Accretion of beneficial conversion feature on Series A preferred shares	—	—	(12,006)
Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.	$ (528,805)	$ (240,922)	$ (139,196)
Denominator:			
Weighted average common shares outstanding—basic and diluted	48,489,890	39,188,458	27,845,576
Net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.—basic and diluted	$ (10.91)	$ (6.15)	$ (5.00)

The Company's potential dilutive securities, which include stock options and warrants to purchase common shares, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,		
	2019	2018	2017
Options to purchase common shares	9,423,015	7,444,179	6,151,643
Warrants to purchase common shares	106,751	221,751	821,751
Restricted Share Units	88,950	—	—
	9,618,716	7,665,930	6,973,394

In January 2017, the Company issued warrants to purchase common shares to each of the Guarantor and Co-Guarantor of the Credit Agreement (see Note 10), pursuant to which each of the Guarantor and Co-Guarantor received a warrant to purchase 107,500 common shares at an exercise price of $9.2911 per share. These warrants are included in the table above for the year ended December 31, 2017. Both warrants were exercised in March 2019.

In January 2018, the anti-dilution price protection provisions contained within the warrants issued to each of the guarantor and co-guarantor of the Credit Agreement expired, and upon expiration of the provision, the Company discontinued classification of these warrants as a liability. As such, these warrants are excluded above for the year ended December 31, 2018.

(Amounts in thousands, except share and per share amounts)

16. Commitments and Contingencies

Notes Payable to Related Parties

On December 31, 2016, the Company entered into stock purchase agreements with each of the stockholders of Biohaven Pharmaceuticals, Inc. ("BPI"), acquiring 100% of the issued and outstanding shares of BPI for aggregate purchase consideration of $595. The Company funded the acquisition through the issuance of promissory notes to each of the former stockholders of BPI. The former stockholders of BPI are shareholders of the Company and also serve as the Company's Chairman of the board of directors, Chief Executive Officer, and Chief Medical Officer, respectively. The notes were payable in five annual payments, the first four of which were interest only, with the final payment to include the principal balance outstanding plus any accrued and unpaid interest. The notes bore interest at a rate of 4.5% per annum and had a maturity date of December 31, 2021. The notes became immediately due and payable upon specified events, including immediately prior to the consummation of an initial public offering of the Company's common shares or upon the occurrence of a change of control of the Company.

In connection with the closing of the Company's IPO in May 2017, the notes were paid in full.

Lease Agreements

Real Estate

In December 2016, the Company entered into an assignment agreement to assume an operating lease for its office space in New Haven, Connecticut. The lease agreement expired in October 2018. In addition, the Company entered into a lease agreement for additional space which expired on June 30, 2018. The Company recorded rent expense for these leases as follows:

	Year Ended December 31,	
	2018	2017
Rent expense	$ 114	$ 73

In August 2017, the Company entered into a lease agreement for office space and the related property for its United States ("US") headquarters in New Haven, Connecticut, which it began occupying during the fourth quarter of 2018. The lease commenced on January 1, 2018 and had a term of 85 months, with the ability to extend to 120 months. The Company had the option to purchase the property for $2,700 and executed that option in December 2018 and therefore has no remaining lease obligation related to its US headquarters building.

The Company recorded the following for the lease agreement for its US headquarters during the construction period:

	Year Ended December 31,	
	2018	2017
Rent expense	$ 43	$ 75
Capitalized costs	3,404	2,198

In August 2019, the Company entered into a lease agreement for office space in Yardley, Pennsylvania to support expansion of the Company's commercial operations in anticipation of the rimegepant commercial launch. The lease is expected to commence in the first quarter of 2020 and have a term of 88 months, with the ability to extend to 148 months. The Company has restricted cash of $1,000, as of December 31, 2019, included in other assets in the consolidated financial statements, which represents collateral held by a bank for a letter of credit issued in connection with the lease. The restricted cash is invested in a non-interest bearing account.

The lessor has provided the Company a temporary space to occupy while leasehold improvements are completed prior to the lease commencement date. With the exception of the first month's rent payment made on execution of the lease, the Company is not required to pay rent until August 2020. The Company determined there were two units of account for the lease, one for use of the temporary space, with a duration from the lease execution date to the lease commencement date and another

16. Commitments and Contingencies (Continued)

for the use of the premises, with a duration from the lease commencement date to the lease termination date. The two units of account are being treated as two separate operating leases.

Since the Company expects to occupy the temporary space for less than 12 months, the Company did not record a right-of-use asset and lease liability on its balance sheet for the temporary space. The rent expense for the temporary space recognized for the twelve months ended December 31, 2019 was $68 because there will be no cash payment for use of the temporary space, the rent expense recognized for the use of the temporary space is being treated as deferred rent payments.

The Company can begin occupying the premises after the landlord has substantially completed all agreed upon improvements to the office space. After substantial completion of the office space in the first half of 2020, the Company expects to record a right-of-use asset and operating lease liability on its balance sheet and straight-line the lease expense over the duration of the lease.

Commercial Fleet

During the fourth quarter of 2019 the Company took delivery of the first few vehicles related to our commercial car fleet. The remainder of these vehicles will become available for use during 2020.

License Agreements

The Company has entered into license agreements with various parties under which it is obligated to make contingent and non-contingent payments (see Note 13). License agreements generally require the Company to pay annual maintenance fees and future payments upon the attainment of agreed upon development and/or commercial milestones. These agreements may also require minimum royalty payments based on sales of products developed from the applicable technologies, if any.

The Company has submitted an investigational new drug application (“IND”) for vazegepant, it's third generation CGRP receptor antagonist, and received approval to proceed and subsequently commenced a Phase 1 clinical trial in October of 2018 to permit later stage clinical trials. Pursuant to the BMS License Agreement, the Company is required to pay $2,000 to BMS on commencement of a Phase 1 clinical trial, $4,000 on commencement of a Phase 2 clinical trial, and $6,000 on commencement of a Phase 3 clinical trial. Accordingly, the Company has recognized these liabilities when probable of occurrence in accrued expenses within the consolidated balance sheets in the fourth quarter of 2018, first quarter of 2019, and fourth quarter of 2019; respectively. The payment obligation under the agreement is deferred until the earlier of the first approval, or the discontinuation, of the development of rimegepant.

Pursuant to the BMS Agreement, the Company was required to pay $7,500 to BMS in relation to the NDA filing for rimegepant, and accordingly, the Company made the milestone payment in October 2019.

Research Commitments

The Company has entered into agreements with several contract research organizations to provide services in connection with its preclinical studies and clinical trials. The Company commits to minimum payments under these arrangements.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company's amended and restated memorandum and articles of association also provide for indemnification of directors and officers in specific circumstances. To date, the Company has not incurred any material costs as a result of such indemnification provisions. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2019 or 2018.

16. Commitments and Contingencies (Continued)

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of December 31, 2019, there were no matters which would have a material impact on the Company's financial results.

17. Related Party Transactions

Relationship with Yale University

Dr. Coric, the Company's Chief Executive Officer, previously served as an associate clinical professor of psychiatry at Yale. While previously employed by Yale, Dr. Coric was a co-inventor of some of the patents that the Company licenses from Yale. Under Yale's policies, as a co-inventor, Dr. Coric is entitled to receive a share of any royalties that the Company pays to Yale under the agreement with respect to the covered intellectual property and any proceeds from Yale's sale of the common shares the Company issued to Yale in connection with the license agreement. During 2017, Yale sold the common shares and, pursuant to Yale's policies, Dr. Coric received a payment from Yale of $600 in March 2018.

License Agreement with Yale

On September 30, 2013, the Company entered into the Yale Agreement with Yale (see Note 13). Yale is a related party because the Company's Chief Executive Officer is one of the inventors of the patents that the Company has licensed from Yale and, as such, is entitled to a specified share of the glutamate product-related royalty revenues that may be received by Yale under the Yale Agreement. As partial consideration for the license under the Yale Agreement, on September 30, 2013, the Company issued to Yale 250,000 common shares, representing 5.1% of the Company's then outstanding equity on a fully diluted basis. The fair value of the shares, totaling $152, was recognized as research and development expense at the time of issuance of the shares. During the years ended December 31, 2019, 2018 and 2017, the Company recognized no material research and development expense under the Yale Agreement, and as of December 31, 2019 and 2018, the Company owed no amounts to Yale.

Guarantor and Co-Guarantor Warrants

The Guarantor and Co-Guarantor of the Credit Agreement with Wells Fargo are each shareholders and members of the board of directors of the Company. The Company issued warrants to the Guarantor and Co-Guarantor in exchange for their respective guaranties (see Notes 10). The warrants were issued on January 26, 2017, pursuant to which each director received a warrant to purchase 107,500 common shares at an exercise price of $9.2911 per share. Both warrants were exercised in March 2019 and common shares settled in the second quarter of 2019.

Kleo Pharmaceuticals, Inc.

The Company has an investment in the common stock of Kleo (see Note 5). Kleo is a related party because the Company has determined that it exercises significant influence over the operating and financial policies of Kleo. In connection with its investment in Kleo, the Company received the right to designate two members of Kleo’s board of directors. The Company completed the last of four scheduled tranche purchases in January 2018, consisting of 1,375,000 shares for cash consideration of $1,375. In November 2018, the Company participated in Kleo's Series B funding raise. The Company purchased 1,420,818 shares for cash consideration of $5,000. As of December 31, 2019, the Company owned approximately 42% of Kleo's outstanding capital stock. The Company has also entered into a clinical development master services agreement with Kleo to assist Kleo with clinical development. As of December 31, 2019, the Company had not performed material services or received any payments under this agreement.

(Amounts in thousands, except share and per share amounts)

18. Quarterly Financial Data (Unaudited)

The following information has been derived from unaudited consolidated financial statements that, in the opinion of management, include all recurring adjustments necessary for a fair statement of such information.

	Three Months Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Operating expenses:				
Research and development[1]	$ 41,003	$ 175,977	$ 61,674	$ 66,019
General and administrative	13,462	23,235	28,782	68,970
Total operating expenses	54,465	199,212	90,456	134,989
Loss from operations	(54,465)	(199,212)	(90,456)	(134,989)
Other income (expense):				
Non-cash interest expense on mandatorily redeemable preferred shares	—	(3,955)	(4,378)	(4,378)
Non-cash interest expense on non-recourse debt related to sale of future royalties	(6,813)	(5,151)	(7,308)	(7,308)
Change in fair value of derivative liability	—	(1,263)	(1,717)	(895)
Loss from equity method investment	(900)	(1,415)	(1,993)	(1,768)
Other	(17)	(16)	8	3
Total other income (expense), net	(7,730)	(11,800)	(15,388)	(14,346)
Loss before provision for income taxes	(62,195)	(211,012)	(105,844)	(149,335)
Provision for income taxes	109	58	323	(71)
Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.	$ (62,304)	$ (211,070)	$ (106,167)	$ (149,264)
Net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd. — basic and diluted QTD	$ (1.41)	$ (4.67)	$ (2.04)	$ (2.85)
Weighted average common shares outstanding—basic and diluted QTD	44,242,070	45,226,434	52,077,240	52,285,999

(1) Includes one-time $105.0 million payment for a priority review voucher to expedite the regulatory review of the Zydis ODT version of rimegepant in the second quarter of 2019

(Amounts in thousands, except share and per share amounts)

18. Quarterly Financial Data (Unaudited) (Continued)

	Three Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Operating expenses:				
Research and development	$ 75,579	$ 29,052	$ 47,362	$ 37,958
General and administrative	7,857	9,064	7,574	10,108
Total operating expenses	83,436	38,116	54,936	48,066
Loss from operations	(83,436)	(38,116)	(54,936)	(48,066)
Other income (expense):				
Non-cash interest expense on non-recourse debt related to sale of future royalties	—	(501)	(5,633)	(5,592)
Change in fair value of warrant liability	(1,182)	—	—	—
Loss from equity method investment	(728)	(641)	(697)	(742)
Other	(29)	14	(14)	(156)
Total other income (expense), net	(1,939)	(1,128)	(6,344)	(6,490)
Loss before provision for income taxes	(85,375)	(39,244)	(61,280)	(54,556)
Provision for income taxes	87	25	161	194
Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.	$ (85,462)	$ (39,269)	$ (61,441)	$ (54,750)
Net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd. — basic and diluted QTD	$ (2.32)	$ (1.01)	$ (1.53)	$ (1.34)
Weighted average common shares outstanding—basic and diluted QTD	36,793,090	38,942,545	40,147,735	40,938,709

Exhibit 4.3

Description of Biohaven Pharmaceutical Holding Company Ltd.'s Securities Registered Under Section 12 of the Exchange Act

The following summary of the common shares of Biohaven Pharmaceutical Holding Company Ltd. ("Biohaven", "we" or "us") is based on and qualified by our amended and restated memorandum and articles of association ("memorandum and articles of association"). Please note that this summary is not intended to be exhaustive. For further information, please refer to the full version of our memorandum and articles of association, which is filed as an exhibit to this Annual Report on Form 10-K.

General

We are a company incorporated in the British Virgin Islands ("BVI") on September 25, 2013, and our affairs are governed by the provisions of our memorandum and articles of association, as amended and restated from time to time, and by the provisions of applicable BVI law.

Authorized Share Capital

As of December 31, 2019, we had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): common shares, no par value. Our memorandum and articles of association authorize us to issue up to 200,000,000 common shares. As of February 21, 2020, there were 58,282,598 common shares issued and outstanding, held of record by 57 shareholders.

Our memorandum and articles of association also authorize us to issue up to 3,992 Series A preferred shares, no par value (the "Series A Preferred Shares") and 9,996,008 preferred shares, no par value, but these classes of securities are not registered under Section 12 of the Exchange Act. Our board of directors may establish the rights and preferences of the preferred shares from time to time. As of February 21, 2020, there were 2,495 Series A Preferred Shares issued and outstanding, held of record by a single shareholder, RPI Finance Trust ("RPI") and no undesignated preferred shares issued and outstanding.

Common Shares

Voting. Holders of common shares are entitled to cast one vote for each share on all matters submitted to a vote of shareholders, including the election of directors. Holders of our common shares do not have cumulative voting rights.

Dividends. Holders of common shares are entitled to receive ratably such dividends, if any, as may be declared by the board of directors out of funds legally available therefor, subject to the preferential rights in respect of the Series A Preferred Shares or any other preferred shares. See "Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities—Dividend Policy" in this Annual Report on Form 10-K.

Liquidation. All holders of common shares are entitled to share ratably in any assets for distribution to shareholders upon the liquidation, dissolution or winding up of the company, subject to the preferential rights in respect of any preferred shares, including our Series A Preferred Shares.

Lability for Calls and Assessments. All outstanding common shares are fully paid and nonassessable.

Other. Holders of common shares do not have any preemptive or other rights to subscribe for additional shares pursuant to our memorandum and articles of association. Holders of common shares have no conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common shares.

Listing and Transfer Agent. Our common shares are listed on the New York Stock Exchange under the trading symbol "BHVN."

Transfer Agent and Registrar. The transfer agent and registrar for our common shares is American Stock Transfer & Trust Company, LLC.

The rights, preferences and privileges of the holders of common shares are subject to, and may be adversely affected by, the rights of the holders of shares of our Series A Preferred Shares and any other series of preferred shares that we may designate in the future.

Preferred Shares

Our board of directors has the authority, without further action by our common shareholders, but subject to certain matters reserved to the Series A Preferred shareholders, to issue up to 9,996,008 preferred shares in one or more other series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred shares with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common shares. The issuance of preferred shares, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common shares and the voting and other rights of the holders of our common shares. It is not possible to state the actual effect of the issuance of any preferred shares on the rights of holders of common shares until the board of directors determines the specific rights attached to the preferred shares.

Series A Preferred Shares

The terms of our Series A Preferred Shares that are material to the rights of our common shares include:

Voting. The Series A Preferred Shares are entitled to vote with the common shares on matters submitted to a vote of the holders of common shares on the basis of 1,000 votes per share.

Liquidation. The Series A Preferred Shares have a liquidation preference equal to two times (2x) the original purchase price therefor in the event of a voluntarily or involuntary liquidation, dissolution or winding up of the Company.

Protective Provisions. The Series A Preferred Shares have customary protective provisions which provide that, without the approval of holders of a majority of the Series A Preferred Shares, the Company may not adversely affect the rights of the Series A Preferred Shares or create, authorize or issue any class or series of equity securities of the Company senior to, or pari passu with, the Series A Preferred Shares. However, the Company is permitted to issue equity securities ranking junior to the Series A Preferred Shares, including common shares, as well as convertible and/or non-convertible debt.

Other. In the event the Company defaults on any obligation to redeem Series A Preferred Shares when required, the redemption amount shall accrue interest at the rate of eighteen percent (18%) per annum. If any such default continues for at least one year, the holders of such shares shall be entitled to convert, subject to certain limitations, such Series A Preferred Shares into common shares, with no waiver of their redemption rights. The Series A Preferred Shares are otherwise not convertible into common shares in any circumstances.

Anti-takeover Provisions in Our Memorandum and Articles of Association

Some provisions of our memorandum and articles of association may discourage, delay or prevent a change in control of our company or management that shareholders may consider favorable. Pursuant to our memorandum and articles of association:

- the board of directors is authorized to issue “blank check” preferred stock without shareholder approval;
- the board of directors is classified, with members serving staggered three-year terms;
- vacancies on the board of directors may be filled only by the board of directors;
- shareholders may remove directors only for cause by the affirmative vote of 66 2/3% of the outstanding common shares entitled to vote on the election of directors;
- the board of directors is expressly authorized to amend any provision of our memorandum and articles of association, other than those provisions which restrict the power of the shareholders or to amend the memorandum and articles of association, change the percentage of shareholders required to amend the memorandum and articles of association, or in circumstances where the memorandum and articles of association cannot be amended by the shareholders;
- shareholders may amend our memorandum and articles of association only with the affirmative vote of the holders of at least seventy-five percent (75%) of the then-outstanding shares entitled to vote on the matter;
- shareholders may not cumulate votes in the election of directors;
- shareholders may take action only at a duly called meeting of the shareholders, and shareholders are not permitted to act by written consent;

- shareholders holding less than 10$ of the votes of the outstanding shares entitled to vote at a meeting may not call a special meetings of the shareholders ;
- shareholders must satisfy advance notice procedures to submit proposals or nominate directors for consideration at a shareholder meeting; and
- we will indemnify officers and directors against losses that they may incur as a result of investigations and legal proceedings resulting from their services to us, which may include services in connection with takeover defense measures.

Under BVI law, however, our directors may only exercise the rights and powers granted to them under our memorandum and articles of association, as they believe in good faith to be in the best interests of our company and in accordance with directors' duties under BVI law, which are summarized below.

Directors' Fiduciary Duties

Under BVI law, our directors owe the company certain statutory and fiduciary duties including, among others, a duty to act honestly, in good faith, for a proper purpose and with a view to what the directors believe to be in the best interests of the company. Our directors are also required, when exercising powers or performing duties as a director, to exercise the care, diligence and skill that a reasonable director would exercise in comparable circumstances, taking into account without limitation, the nature of the company, the nature of the decision and the position of the director and the nature of the responsibilities undertaken. In the exercise of their powers, our directors must ensure neither they nor the company acts in a manner which contravenes the BVI Act or our memorandum and articles of association. A shareholder has the right to seek damages for breaches of duties owed to us by our directors in addition to other relief.

Exhibit 10.25

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the ***"Agreement")*** is entered into on this __ day of March 30, 2019 by and between **BIOHAVEN PHARMACEUTICALS, INC.,** a Delaware corporation (the ***"Company"***), and **WILLIAM JONES, JR.**, an individual resident of the Commonwealth of Pennsylvania (the ***"Executive"***).

WHEREAS, the Company is an indirect subsidiary of Biohaven Pharmaceutical Holding Company Ltd., a limited company formed under the laws of the Territory of the British Virgin Islands (the "***Parent***");

WHEREAS, the Parent, the Company and Executive desire to enter into this Agreement pursuant to which the Company will employ Executive, for the period and on the terms and conditions set forth herein;

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

1. EMPLOYMENT BY THE COMPANY.

(a) EMPLOYMENT AND DUTIES. The Company hereby agrees to employ Executive, and Executive hereby accepts such employment, in the capacity of Chief Commercial Officer, Migraine and Common Diseases of the Company, in accordance with the terms and conditions hereinafter set forth. During the Term (as defined below), Executive will report to the Chief Executive Officer of the Company (the ***"CEO"***) and agrees that he will devote time, attention and skills to the operation of the Business (as defined below) of the Company and that he will perform such duties, functions, responsibilities and authority in connection with the foregoing as are from time to time delegated to Executive by the CEO. These duties shall include, but shall not be limited to, responsibility for the Company's commercial launch, planning, implementation, management, developing strategies for sustainable value creation, implementing and monitoring effective internal control systems ensuring relevant and useful internal and external business development, networks, sales and reporting, and perform such duties, functions, responsibilities and authority in connection with the foregoing as are from time to time delegated to Executive by the CEO. For purposes of this Agreement, the ***"Business"*** of the Company shall be defined as the development and commercialization of migraine and common disease drug candidates and related technology-based products. Executive has disclosed to the Company that he is bound by the terms of an agreement with a previous employer or other party which could limit his abilities to perform his duties and obligations hereunder, and to the knowledge of Executive, Executive represents that his employment with the Company will not violate any noncompetition provisions contained in such agreements.

(b) TERM. The term of Executive's employment under this Agreement shall commence on April 1, 2019 (the "***Effective Date***") and shall continue until the Company or Executive terminates his employment under this Agreement, as set forth in Section 6(d) (the

"Term"); provided, however, if Executive does not commence employment by the Effective Date, this Agreement shall become null and void.

2. COMPENSATION. In consideration of all the services to be rendered by Executive to the Company hereunder, the Company hereby agrees to pay or otherwise provide Executive the following compensation and benefits. It is further understood that the Company shall have the right to deduct or withhold from any compensation or benefits payable under this Agreement all federal, state, city or other taxes as shall be required pursuant to any law or government regulation or ruling.

(a) BASE SALARY. The Executive shall be paid an annual base salary rate of Four Hundred Sixty Thousand Dollars ($460,000) (the "***Base Salary***"), which Base Salary shall be subject to an annual increase to the prior year's Base Salary; provided, however, that in no event shall such annual increase be less than cost of living increase. The applicable Base Salary will be paid in equal installments not less frequently than bi-monthly in accordance with the Company's salary payment practices in effect from time to time for senior executives of the Company.

(b) SIGN ON BONUS. In consideration of Executive executing this Agreement and in recognition of the other opportunities that executive is foregoing, on the Effective Date, the Company shall pay Executive a one-time cash bonus of Six Hundred Sixty Thousand Dollars ($660,000.00) (the "***Signing Bonus***"). In the event that Executive's employment is terminated by Executive without Good Reason (as defined below), or by the Company with Just Cause (as defined below), prior to the first anniversary of the Effective Date, Executive shall repay the Signing Bonus in full to the Company within two weeks of the termination of his employment.

(c) BONUS PAYMENT. In addition to the Base Salary then in effect, Executive shall be eligible to receive a bonus payment (the ***"Bonus Payment"***) with a target of fifty percent (50%) of the applicable year's Base Salary (the ***"Target Bonus"***), with the actual Bonus Payment based upon Executive achieving annual performance objectives established in advance by the CEO (except as provided below). The Bonus Payment will be paid in cash in accordance with the Company's bonus payment practices in effect from time to time for senior executives of the Company, but no later than February 1 of the calendar year immediately following the calendar year for which the bonus is being measured. The CEO shall review Executive's Target Bonus annually and may, with the approval by the sole discretion of the Board, increase the Target Bonus based upon the Company's and Executive's performance. In the event of less than a full year's employment, the Bonus Payment shall be prorated. The Company agrees that Executive will be entitled to a minimum Bonus Payment for fiscal years 2019 and 2020 that is at least equal to the Target Bonus. Executive shall have the opportunity to exceed the Target Bonus depending upon performance and at the recommendation of the CEO and the discretion of the Board of Directors of the Company (the ***"Board"***).

(d) EQUITY. On the Effective Date, Executive shall receive a ten-year option to purchase 80,000 common shares of the Parent which option has been approved by the board of directors of the Parent on March 22, 2019. The option shall: (i) have an exercise price that is equal to the closing price of a share of Parent on the Effective Date: (ii) be one-third (1/3) vested on the Effective Date, with an additional one-third (1/3) becoming vesting on each of the first two anniversaries of the Effective Date (and as provided below); and (iii) shall otherwise be governed by the Parent's 2017 Equity Incentive Plan and an award agreement consistent with this

Agreement. During the Term (beginning with the 2019 fiscal year), Executive shall be considered for additional long-term equity incentive awards that are made at the discretion of the Board, in each case at a level, and on terms and conditions, that are (i) commensurate with his positions and responsibilities at the Company; and (ii) appropriate in light of corresponding awards to other senior executives of the Company.

(e) FRINGE BENEFITS. The Executive shall be entitled to participate in those employee benefit plans that the Company may make generally available to its similarly-situated employees, provided that he otherwise meets the eligibility requirements of those plans. Executive will be able to participate in the Company's 401K plan with a Company contribution representing a 100% match of up to 4% of the employee contribution. In addition, Executive will receive an automobile allowance of One Thousand Dollars ($1,000.00) per month during the Term.

(f) EXPENSES. Executive shall be entitled to be reimbursed by the Company for all reasonable expenses incurred by him in connection with the fulfillment of his duties hereunder, including all necessary continuing education and certification costs and related expenses; provided, however, that Executive has obtained the Company's prior written approval of such expenses and has complied with all policies and procedures related to the reimbursement of such expenses as shall, from time to time, be established by the Company. The Company shall also promptly pay Executive's legal counsel for one-half (1/2) of his attorney fees incurred by him in connection with the negotiation and documentation of these arrangements, up to a maximum of $6,000. For the avoidance of doubt, to the extent that any reimbursements payable to Executive under this subsection 2(e) are subject to the provisions of Section 409A of the Code: (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(g) VACATIONS AND SICK LEAVE. Executive shall be entitled to participate in the Company's flexible paid vacation policy to be taken in accordance with the Company's vacation policy in effect from time to time and at such time or times as may be mutually agreed upon by the Executive and his supervisor. The Company also has nine (9) paid Company holidays; seven (7) standard holidays plus two (2) optional holidays to be taken at Executive's discretion. Executive shall also be entitled to sick leave according to the sick leave policy which the Company many adopt from time to time.

(h) LIVING EXPENSES. Executive shall be entitled to reasonable living expenses in the New Haven area, and reasonable commuting expenses, if employee does not move to Connecticut. These amounts are to be negotiated with and approved by the CEO, and living expenses may be in the form of a local hotel or a local apartment.

3. INDEMNIFICATION.

(a) COMPANY'S OBLIGATION TO INDEMNIFY. To the maximum extent allowable for the law of Delaware and the Bylaws and Certificates of Incorporation of the Company, the Company shall at all times during the Term and thereafter, indemnify and defend

and hold Executive harmless from and against all liability, loss, costs, claims, damages, expenses, judgments, awards, and settlements as well as attorneys' fees and expenses, personal or otherwise, whether in tort or in contract, law or equity, that Executive may incur by reason of or arising out of any claim, proceeding or investigation made by any third party (together, the ***"Losses"***), and relating to Executive's employment with the Company; provided, however, that the Company's foregoing indemnification obligations shall not apply to Losses incurred by the Company as a result of the Executive's willful misconduct, gross negligence, conviction of a felony (including entry of a plea of nolo contendere) for illegal or criminal behavior or engagement in activities unrelated to or beyond the scope of his employment. Indemnification shall include all costs, including actual attorneys' fees and expenses reasonably incurred in pursuing indemnity claims under or the enforcement of this Agreement, and prompt advancement of expenses incurred in connection with any proceeding or investigation, subject to an undertaking by Executive to repay amounts advanced if he is ultimately determined to not to be entitled to indemnification against such expenses.

(b) EXECUTIVE'S OBLIGATION TO INDEMNIFY. To the maximum extent allowable for the law of Delaware, Executive shall also at all times during the Term and thereafter, indemnify and defend and hold the Company, its founders, owners, directors, officers, employees, advisors, agents, partners, service providers and affiliates harmless from and against all Losses with respect to Executive's willful misconduct, gross negligence, conviction of a felony (including entry of a plea of *nolo contendere)* for illegal or criminal behavior or engagement in activities unrelated to or beyond the scope of his employment hereunder. Indemnification shall include all costs, including reasonable attorneys' fees and expenses reasonably incurred in pursuing indemnity claims under this Agreement.

4. LIMITATION OF LIABILITY. EXECUTIVE AGREES THAT REGARDLESS OF THE FORM OF ANY CLAIM, EXECUTIVES' SOLE REMEDY AND COMPANY OBLIGATION WITH RESPECT TO ANY CLAIMS MADE RELATED TO OR ARISING OUT OF THIS AGREEMENT SHALL BE GOVERNED BY THIS AGREEMENT, AND IN ALL CASES EXECUTIVE'S REMEDIES SHALL BE ENFORCEABLE ONLY AGAINST THE COMPANY AND NOT TO ASSETS OR PERSONAL AND BUSINESS INTERESTS OF COMPANY FOUNDERS, OTHER SHAREHOLDERS, DIRECTORS, OFFICERS, EMPLOYEES, ADVISORS, PARTNERS AND AFFILIATES. IT IS EXPRESSLY AGREED THAT IN NO EVENT SHALL THE COMPANY'S FOUNDERS, OTHER SHAREHOLDERS, DIRECTORS, OFFICERS, EMPLOYEES, ADVISORS, PARTNERS AND AFFILIATES BE LIABLE FOR PERSONAL, INCIDENTAL, DIRECT, INDIRECT, OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGE OR INJURY TO PROPERTY AND LOST PROFITS REGARDLESS OF WHETHER THE COMPANY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY.

5. INSURANCE. The Company may secure, in its own name, or otherwise, and at its own expense, life, health, accident and other insurance covering Executive or Executive and others. Executive agrees to assist the Company in procuring such insurance by submitting to the usual and customary medical and other examinations and by signing, as the insured, such applications and other instruments in writing as may be reasonably requires by the insurance companies to which application is made pursuant to such insurance. Executive agrees that he shall have no

right, title, or interest in or to any insurance policies or to the proceeds thereof which the Company many so elect to take out or to continue on the Executive's life.

6. TERMINATION OF EMPLOYMENT.

(a) TERMINATION BY THE COMPANY WITHOUT JUST CAUSE, BY VIRTUE OF DEATH OR DISABILITY OF THE EXECUTIVE, OR RESIGNATION BY THE EXECUTIVE FOR GOOD REASON.

(i) The Company shall have the right to terminate Executive's employment with the Company pursuant to this Section 6(a) at any time, in accordance with Section 6(d), without Just Cause (as defined in Section 6(c)(ii) below) or by virtue of the Executive's death or Disability (as defined in Section 6(a)(v) below) by giving notice as described in Section 9(a) of this Agreement. Executive shall have the right to terminate his employment for Good Reason in accordance with Section 6(a)(vi).

(ii) If the Company terminates Executive's employment at any time without Just Cause or by virtue of the death or Disability of Executive, or if Executive terminates his employment with the Company for "Good Reason" (as defined in Section 6(a)(vi) below), as soon as such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a ***"Separation from Service"***), then Executive shall be entitled to receive the Accrued Obligations (defined in Section 6(a)(iv) below). If Executive complies with the obligations in Section 6(a)(iii) below, Executive shall also be eligible to receive the following ***"Severance Benefits"***:

(1) an amount equal to two (2) times the sum of (a) Executive's then current Base Salary and (b) Executive's annual Target Bonus (the "***Severance Amount***"), paid to Executive in substantially equal installments over twenty four (24) months following his Separation from Service (the ***"Severance Period"),*** less all applicable withholdings and deductions; provided, however, that each such installment payable before the Release Effective Date (as defined in Section 6(a)(iii) below) shall not be paid until the first payroll following the Release Effective Date.

(2) If Executive timely elects continued coverage under COBRA or, if applicable, state insurance laws, for himself and his covered dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums or, if applicable, premiums for continuation coverage under state insurance laws, necessary to continue Executive's and his covered dependents' health insurance coverage in effect for himself (and his covered dependents) on the termination date until the earliest of: (i) eighteen (18) months following the termination date (the ***"COBRA Severance Period");*** (ii) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (iii) the date Executive ceases to be eligible for COBRA or state continuation coverage (or, with respect to his covered dependents, the date they cease to be eligible for COBRA or state continuation coverage) for any reason, including plan termination (such period from the termination date through the earlier of (i)-(iii), (the ***"COBRA Payment Period").*** Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums or, if applicable, premiums for continuation coverage under state insurance laws, on Executive's behalf would result in a violation of

applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying such premiums pursuant to this Section, the Company shall pay Executive on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium or, if applicable, premiums for continuation coverage under state insurance laws, for such month, subject to applicable tax withholding (such amount, the ***"Special Severance Payment"),*** for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive Executive of his rights under COBRA or ERISA for benefits under plans and policies arising under his employment by the Company.

(3) Payment of any earned but unpaid Bonus Payment for any Bonus Year completed prior to Executive's employment termination date;

(4) Payment, if any, of a pro-rata Bonus for the year that includes the Executive's termination date, determined and made in the sole discretion of the Board, equal to the actual Bonus Payment (if any) which would have been awarded to Executive if he had remained employed for the applicable performance period, multiplied by a fraction, the numerator of which is the number of days in the year of termination during which Executive was employed, and the denominator of which is 365 and payable at the time bonuses are paid to other similarly situated senior executives, but no later than March 15 of the year following the Executive's termination date;

(5) Notwithstanding anything to the contrary set forth in any applicable equity incentive plans or award agreements, effective as of Executive's employment termination date, the vesting and exercisability of all unvested stock options and other equity incentive award shall accelerate such that all stock options and other equity awards shall become immediately vested and, if applicable, exercisable by Executive upon such termination and all stock options shall remain exercisable until the earliest of (i) twenty-four months following Executive's termination, (ii) the 10th anniversary of the original date of grant, or (iii) the earliest it would have expired under its original term if employment had continued.

(iii) Executive will be paid all of his Accrued Obligations described in clause (i) of the definition thereof on the Company's first payroll date after Executive's date of termination from employment or earlier if required by law, and all other Accrued Obligations will be paid or provided in accordance with their applicable terms. Executive shall receive the Severance Benefits pursuant to Section 6(a)(ii) or Change in Control Severance Benefits pursuant to Section 6(b)(i) of this Agreement if, by the 60th day following the date of Executive's Separation from Service, he has signed and delivered to the Company a reasonable general release in favor of the Company that (x) does not require Executive to release any claims or rights provided under (or preserved by) this Agreement or any Accrued Obligations, (y) does not impose any additional post-employment restrictions not contained in this Agreement on Executive, and (z) is provided by the Company to Executive by the 15th day following the date of Executive's Separation from Service (the ***"Release"***), which cannot be revoked in whole or part by such 60th day (the date that the Release can no longer be revoked is referred to as the ***"Release Effective Date"***).

(iv) For purposes of this Agreement, ***"Accrued Obligations"*** are (i) any accrued but unpaid portion of the applicable Base Salary, plus any accrued but unused vacation time and unpaid expenses (in accordance with Section 2(d) and hereof) that have been earned by Executive as the date of such termination, and (ii) any other obligation to Executive under the then-applicable terms of this Agreement and any other written agreement, plan or arrangement with the Parent, the Company or any of their affiliates (e.g., indemnification rights, vested stock options, retirement plan accounts).

(v) For purposes of this Agreement, and subject to applicable state and federal law, termination of employment by the Company on account of the Executive's ***"Disability"*** shall mean termination because the Executive is unable due to a physical or mental condition to perform the essential functions of his position with or without reasonable accommodation for six (6) months in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. Whenever Severance Benefits or Change in Control Severance Benefits are payable to Executive hereunder during a time when Executive is partially or totally disabled, and such Disability would entitle him to disability income payments according to the terms of any plan or policy now or hereafter provided by the Company, the Severance Benefits or Change in Control Severance Benefits payable to Executive hereunder shall be inclusive of any such disability income and shall not be in addition thereto, even if such disability income is payable directly to Executive by an insurance company under a policy paid for by the Company.

(vi) For purposes of this Agreement, ***"Good Reason"*** shall mean the occurrence of any of the following events without Executive's consent: (1) a material reduction in Executive's Base Salary; (2) a material reduction in the Executive's duties, authority and responsibilities relative to the Executive's duties, authority, and responsibilities in effect immediately prior to such reduction; (3) the relocation of Executive's principal place of employment, without Executive's written consent, in a manner that lengthens his one-way commute distance by fifty (50) or more miles from his then-current principal place of employment immediately prior to such relocation; (4) any material breach by the Company (or any of their successors) of this Agreement or any other material written agreement of the Company or any successors; or (5) the liquidation, dissolution, merger, consolidation or reorganization of the Company or transfer of all or a significant portion of its business and/or assets, unless the successor or successors shall have assumed all duties and obligations of the Company under the Agreement; *provided, however,* that, any such termination by Executive shall only be deemed for Good Reason pursuant to this definition if: (a) Executive gives the Company written notice of his intent to terminate for Good Reason within thirty (30) days following the date that he first becomes aware of the first occurrence of the condition(s) that he believes constitute(s) Good Reason, which notice shall describe such condition(s); (b) the Company fails to remedy such condition(s) within thirty (30) days following receipt of the written notice (the ***"Cure Period");*** (c) the Company has not, prior to receiving such notice from Executive, already informed Executive that his employment with the Company is being terminated and (d) Executive voluntarily terminates his employment within thirty (30) days following the end of the Cure Period.

(b) TERMINATION BY THE COMPANY WITHOUT JUST CAUSE OR RESIGNATION BY THE EXECUTIVE FOR GOOD REASON COINCIDENT WITH A CHANGE IN CONTROL.

(i) If Executive's employment by the Company is terminated by the Company or any successor entity without "Just Cause" (as defined in Section 6(c)(ii)) (not including termination by virtue of death or Disability) or by Executive for Good Reason within twelve (12) months following the effective date of a "Change in Control" (as defined below), on the date that such termination constitutes a Separation from Service, without regard to any alternative definition thereunder, then in addition to paying or providing Executive with the Accrued Obligations and subject to compliance with Section 6(a)(iii), the Company will provide the following ***"Change in Control Severance Benefits":***

(1) The Company will pay the benefits as described in Sections 6(a)(ii)(1), 6(a)(ii)(2), 6(a)(ii)(3) and 6(a)(ii)(4).

(2) The Company will pay an additional amount equivalent to Executive's full Target Bonus, for the performance year in which Executive's termination occurs. This bonus will be payable subject to standard federal and state payroll withholding requirements and paid in equal installments beginning on the first day of the month following his Separation from Service; provided that any such payments payable before the Release Effective Date shall not be paid until the first payroll following the Release Effective Date; and

(3) Notwithstanding anything to the contrary set forth in any applicable equity incentive plans or award agreements, effective as of Executive's employment termination date, the vesting and exercisability of all unvested time-based vesting equity awards then held by Executive shall accelerate such that all awards become immediately vested and exercisable, if applicable, by Executive upon such termination and all stock options held by Executive shall remain exercisable, if applicable, for twelve (12) months following Executive's termination. With respect to any performance-based vesting equity award, such award shall continue to be governed in all respects by the terms of the applicable equity award documents.

(ii) For purposes of this Agreement, a "Change in Control means the occurrence of any of the events set forth in clauses (i), (ii) or (iii) with respect to either of the Company or the Parent, or the event set forth in clause (v) with respect to the Company, in each case in the definition of a Change in Control set forth in the Parent's 2017 Equity Incentive Plan, as may be amended from time to time.

(c) TERMINATION FOR JUST CAUSE OR VOLUNTARY TERMINATION.

(i) If Executive's employment is terminated prior to the expiration of the Term for Just Cause or if Executive's employment is terminated as set forth in Section 6(d)(ii) or (iii) hereof (not including a resignation for Good Reason), Executive shall NOT be entitled to receive any Severance Benefits (as defined in Section 6(a)(ii)) or Change in Control Severance Benefits (defined in Section 6(b)(i)) and he will only be entitled to receive any Accrued Obligations.

(ii) For the purposes hereof, the Company shall have "Just Cause" to terminate Executive's employment hereunder as a result of Executive's gross negligence, willful

misconduct, conviction of a felony (including the entry of a plea of nolo contendere) for illegal or criminal behavior in carrying out his duties as required pursuant to the terms of the Agreement. Notwithstanding any other provision contained herein, the Company shall have the right to terminate Executive's employment hereunder without Just Cause, and Executive's remedies hereunder in the event of such termination shall be limited to the Severance Benefits or Change in Control Severance Benefits, as applicable, set forth in Section 6(a)(ii) and 6(b)(i) hereof, and the Accrued Obligations.

(d) EVENTS OF TERMINATION. The Term shall terminate on the earliest to occur of the following events:

(i) the voluntary termination by Executive other than as a result of a resignation for Good Reason (as defined in Section 6(a)(vi));

(ii) the death of Executive or Executive's retirement;

(iii) termination on account of a Disability (as defined above);

(iv) the termination of the Executive by the Company with or without Just Cause (as defined in Section 6(c)(ii)) upon giving written notice to Executive; or

(v) for a termination for Good Reason, immediately upon Executive's full satisfaction of the requirements of Section 6(a)(vi)

(e) SECTION 409A.

(i) Notwithstanding anything to the contrary herein, the following provisions apply to the extent severance benefits provided herein are subject to Section 409A of the Internal Revenue Code (the ***"Code")*** and the regulations and other guidance thereunder and any state law of similar effect (collectively ***"Section 409A").*** Severance benefits shall not commence until the Executive has a "separation from service" (as defined under Treasury Regulation Section 1.409A- 1(h), without regard to any alternative definition thereunder, a "separation from service"). Each installment of severance benefits is a separate "payment" for purposes of Treas. Reg. Section 1.409A-2(b)(2)(i), and the severance benefits are intended to satisfy the exemptions from application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). However, if such exemptions are not available and the Executive is, upon separation from service, a "specified employee" for purposes of Section 409A, then, solely to the extent necessary to avoid adverse personal tax consequences under Section 409A, the timing of the severance benefits payments shall be delayed until the earlier of (i) six (6) months and one day after the Executive's separation from service, (ii) the Executive's death or (iii) such earlier date as permitted under Section 409A without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Section 409A period, all payments deferred pursuant to this paragraph shall be paid in a lump sum to Executive, and any remaining payments due shall be paid as otherwise provided herein or in the applicable agreement. No interest shall be due on any amounts so deferred. The parties acknowledge that the exemptions from application of Section 409A to severance benefits are fact specific, and any later amendment of this Agreement to alter the timing, amount or conditions

that will trigger payment of severance benefits may preclude the ability of severance benefits provided under this Agreement to qualify for an exemption. To the extent that any severance payments or benefits are deferred compensation under Section 409A, and are not otherwise exempt from the application of Section 409A, then, if the period during which Executive may consider and sign the Release spans two calendar years, the payment of such severance payments and benefits will not be made or begin until the later calendar year.

(ii) It is intended that this Agreement shall comply with the requirements of Section 409A, and any ambiguity contained herein shall be interpreted in such manner so as to avoid adverse personal tax consequences under Section 409A. Notwithstanding the foregoing, the Company shall in no event be obligated to indemnify the Executive for any taxes or interest that may be assessed by the Internal Revenue Service pursuant to Section 409A of the Code to payments made pursuant to this Agreement.

7. **RESTRICTIVE COVENANTS.**

(a) CIIA. As a condition of continued employment, Executive agrees to abide by the Confidential Information and Invention Assignment Agreement, attached as Exhibit A (the ***"CIIA"***). The CIIA may be amended from time to time in accordance with its terms without regard to this Agreement. The CIIA contains provisions that are intended by the parties to survive and do survive termination of the Term.

(b) NON-SOLICITATION AND NON-COMPETITION. Executive and the Company agree that the Company would suffer irreparable harm and incur substantial damage if Executive were to enter into Competition (as defined herein) with the Company. Therefore, in order for the Company to protect its legitimate business interests, Executive agrees as follows:

(i) Without the prior written consent of the Company, Executive shall not, during the period of employment with the Company, directly or indirectly, invest or engage in any business that is Competitive (as defined herein) with the Business of the Company or accept employment or render services to a Competitor (as defined herein) of the Company as a director, officer, agent, employee or consultant or solicit or attempt to solicit or accept business that is Competitive with the Business of the Company, except that Executive may own up to five percent (5%) of any outstanding class of securities of any company registered under Section 12 of the Securities Exchange Act of 1934, as amended; provided, however, the Company acknowledges that Executive currently engages in a number of activities set forth on Exhibit B as long as such permitted activities do not have a material adverse effect on the Executive's performance or this Agreement.

(ii) Without the prior written consent of the Company and upon any termination of Executive's employment with the Company and for a period of twelve (12) months thereafter, Executive shall not, either directly or indirectly, (x) invest or engage in any business that is Competitive (as defined herein) with the Business of the Company, except that Executive may own up to five percent (5%) of any outstanding class of securities of any company registered under Section 12 of the Securities Exchange Act of 1934, as amended, (y) accept employment with or render services to a Competitor of the Company as a director, officer, agent, employee or consultant unless he is serving in a capacity that has no relationship to that

portion of the Competitor's business that is Competitive with the Business of the Company, or (z) solicit, attempt to solicit or accept business Competitive with the Business of the Company from any of the customers of the Company at the time of his termination or within twelve (12) months prior thereto or from any person or entity whose business the Company was soliciting at such time.

(iii) Upon termination of his employment with the Company, and for a period of twelve (12) months thereafter, Executive shall not, either directly or indirectly, engage, hire, employ or solicit in any manner whatsoever the employment of an employee of the Company.

(iv) For purposes of this Agreement, a business or activity is in "Competition" or "Competitive" with the Business of the Company if it involves, and a person or entity is a "Competitor", if that person or entity is engaged in, or about to become engaged in, the research, development, design, manufacturing, marketing or selling of a specific product or technology that resembles, competes, or is designed to compete, with, or has applications similar to any product or technology for which the Company has obtained or applied for a patent or made disclosures, or any product or technology involving any other proprietary research or development engaged in or conducted by the Company during the Term of Executive's employment with the Company.

8. SECTION 280G; LIMITATIONS ON PAYMENT.

(a) If any payment or benefit Executive will or may receive from the Company or otherwise (a ***"280G Payment")*** would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the ***"Excise Tax"),*** then any such 280G Payment provided pursuant to this Agreement (a ***"Payment")*** shall be equal to the Reduced Amount. The ***"Reduced Amount"*** shall be either (x) the largest portion of the Payment that would result in no portion of the Payment (after reduction) being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount (i.e., the amount determined by clause (x) or by clause (y)), after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in a Payment is required pursuant to the preceding sentence and the Reduced Amount is determined pursuant to clause (x) of the preceding sentence, the reduction shall occur in the manner (the ***"Reduction Method")*** that results in the greatest economic benefit for Executive. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata (the ***"Pro Rata Reduction Method").***

(b) Notwithstanding any provision of Section 8(a) to the contrary, if the Reduction Method or the Pro Rata Reduction Method would result in any portion of the Payment being subject to taxes pursuant to Section 409A that would not otherwise be subject to taxes pursuant to Section 409A, then the Reduction Method and/or the Pro Rata Reduction Method, as the case may be, shall be modified so as to avoid the imposition of taxes pursuant to Section 409A as follows: (A) as a first priority, the modification shall preserve to the greatest extent possible, the greatest economic benefit for Executive as determined on an after-tax basis; (B) as a second

priority, Payments that are contingent on future events *(e.g.,* being terminated without Just Cause), shall be reduced (or eliminated) before Payments that are not contingent on future events; and (C) as a third priority, Payments that are "deferred compensation" within the meaning of Section 409A shall be reduced (or eliminated) before Payments that are not deferred compensation within the meaning of Section 409A.

(c) Unless Executive and the Company agree on an alternative accounting firm or law firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the change in control transaction shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change in control transaction, the Company shall appoint a nationally recognized accounting or law firm to make the determinations required by this Section 8. The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder. The Company shall use commercially reasonable efforts to cause the accounting or law firm engaged to make the determinations hereunder to provide its calculations, together with detailed supporting documentation, to Executive and the Company within fifteen (15) calendar days after the date on which Executive's right to a 280G Payment becomes reasonably likely to occur (if requested at that time by Executive or the Company) or such other time as requested by Executive or the Company.

(d) If Executive receives a Payment for which the Reduced Amount was determined pursuant to clause (x) of Section 8(a) and the Internal Revenue Service determines thereafter that some portion of the Payment is subject to the Excise Tax, Executive agrees to promptly return to the Company a sufficient amount of the Payment (after reduction pursuant to clause (x) of Section 8(a)) so that no portion of the remaining Payment is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount was determined pursuant to clause (y) of Section 8(a), Executive shall have no obligation to return any portion of the Payment pursuant to the preceding sentence.

9. GENERAL PROVISIONS.

(a) **NOTICES.** Any notices required hereunder to be in writing shall be deemed effectively given: (i) upon personal delivery to the party to be notified, (ii) when sent by electronic mail, telex or confirmed facsimile if sent during normal business hours of the recipient, and if not, then on the next business day, (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (iv) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company at its primary office location and to Executive at Executive's address as listed on the Company payroll or Executive's company-provided email address, or at such other address as the Company or the Executive may designate by ten (10) days advance written notice to the other.

(b) **ENTIRE AGREEMENT.** This Agreement, together with Exhibit A, constitutes the entire agreement between the parties hereto relating to the subject matter hereof, and supersedes all prior agreements and understandings, whether oral or written, with respect to the

same. No modification, alteration, amendment or revision of or supplement to this Agreement shall be valid or effective unless the same is in writing and signed by both parties hereto.

(c) **GOVERNING LAW.** This Agreement and the rights and duties of the parties hereunder shall be governed by, construed under and enforced in accordance with the laws of the State of Connecticut.

(d) **ASSIGNMENT.** The rights and obligations of the parties under this Agreement shall not be assignable without written permission of the other party.

(e) **SEVERABILITY.** The invalidity of any provision of this Agreement under the applicable laws of the State of Connecticut or any other jurisdiction, shall not affect the other provisions hereby declared to be severable from all other provisions. The intention of the parties, as expressed in any provision held to be void or ineffective shall be given such full force and effect as may be permitted by law.

(f) **SURVIVAL.** The obligations under Sections 3, 4, 6, 7, 8 and 9 shall survive the termination of the Term.

(g) **REMEDIES.** Executive and the Company recognize that the services to be rendered under this Agreement by Executive are special, unique, and of extraordinary character, and that in the event of the breach by Executive of the terms and conditions of Sections 2, 3, 4, and 7 hereof the Company shall be entitled, if it so elects, to institute and prosecute proceedings in any court of competent jurisdiction, to obtain damages for any breach thereof.

(h) **DISPUTE RESOLUTION.** Except for the right of either party to apply to a court of competent jurisdiction for a temporary restraining order, a preliminary injunction, or other equitable relief to preserve the status quo or prevent irreparable harm, any and all claims, disputes or controversies arising under, out of, or in connection with the Agreement, including any dispute relating to production, use or commercialization, which the parties shall be unable to resolve within sixty (60) days, shall be mediated in good faith. The party raising such dispute shall promptly advise the other party of such claim, dispute or controversy in a writing which describes in reasonable detail the nature of such dispute. By not later than five (5) business days after the recipient has received such notice of dispute, each party (other than Executive) shall have selected for itself a representative who shall have the authority to bind such party, and shall additionally have advised the other party in writing of the name and title of such representative. By not later than ten (10) business days after the date of such notice of dispute, the party against whom the dispute shall be raised shall select a mediation firm in Connecticut and such representatives shall schedule a date with such firm for a mediation hearing. The parties shall enter into good faith mediation, all the costs shall be shared equally. If Executive and the representatives of the other parties have not been able to resolve the dispute within fifteen (15) business days after such mediation hearing, the parties shall have the right to pursue any other remedies legally available to resolve such dispute in either the Courts of the State of Connecticut or in the United States District Court for the District of Connecticut, to whose jurisdiction for such purposes the Company and Executive each hereby irrevocably consents and submits.

[Signatures to follow on next page]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

Biohaven Pharmaceuticals, Inc.

By: /s/Vladimir Coric
Name: Vladimir Coric
Title: Chief Executive Officer

Executive

By: /s/William Jones, Jr.
Name: William Jones, Jr.

EXHIBIT A
CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT

Exhibit 10.26

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT ("Agreement") is made as of **February 1, 2014** by and between **Biohaven Pharmaceuticals, Inc., a Delaware corporation with an office at 234 Church Street, Suite 304, New Haven, Connecticut 06510** and its affiliates and subsidiaries (collectively the "Company") and **Ms. Kimberly A. Gentile** (the "Executive") of 7 Timber Lane Ellington, CT 06029 (telephone 860-871-1905 and email: kimberly.gentile@hotmail.com).

The parties are entering into this Agreement in order to set forth the terms and conditions under which the Executive shall be employed by the Company.

NOW, THEREFORE, the parties hereto, intending to be legally bound hereby, and in consideration of the mutual covenants contained herein, agree as follows:

1. Employment. The Company hereby agrees to employ the Executive and the Executive hereby accepts employment on the terms and conditions set forth herein. The Executive's employment with the Company shall commence on **February 3, 2014**.

2. Employment at Will. The Executive and the Company understand and agree that the Executive is an employee at will, and that the Executive may resign, or the Company may terminate the Executive's employment, at any time and for any or for no reason. Nothing in this Agreement shall be construed to alter the at-will nature of the Executive's employment, nor shall anything in this Agreement be construed as providing the Executive with a definite term of employment.

3. Position. During the Executive's employment with Company, the Executive shall serve as **Vice-President of Operations**. The Executive shall perform those duties generally required of persons in the position of **Vice-President of Operations**, including but not limited to those responsibilities listed in Appendix A (Employment Description), as well as such other duties, not inconsistent with this Agreement, as the Board may from time to time direct. The Executive shall report and be responsible to **Robert M. Berman, MD the Chief Medical Officer of the Company**.

4. Scope of Services. The Executive agrees to devote the Executive's full business time (which shall involve forty (40) hours per week or more as needed) and attention, skills and best efforts to the performance of the Executive's duties hereunder.

5. Salary, Compensation and Benefits.

5.1 Base Salary. During the Executive's employment, the Company agrees to pay, and the Executive agrees to accept, as the Executive's salary for all services to be rendered by the Executive hereunder, an annual salary of **$210,000** ("Base Salary"), payable at the same time that the Company pays its employees generally, but no less that once per month. The Base Salary is subject to annual increases in the sole discretion of the Board.

5.2 Incentives, Savings and Retirement Plans. The Executive shall be entitled to participate in all incentive, savings, and retirement plans, policies and programs made available by the Company to executive-level employees generally ("Plans") at the discretion of the Board.

5.3 Fringe Benefits. During the Executive's employment with the Company, the Executive shall be entitled to the benefits of such group medical, travel and accident, short and long-term disability and term life insurance, if any, as the Company shall make generally available from time to time to executive-level employees. The employee agrees that in lieu of Company provided medical insurance Executive will be compensated at a flat rate of $500/month.

5.4 Reimbursement. The Company shall reimburse the Executive (or, in the Company's sole discretion, shall pay directly), upon presentation of vouchers and other supporting documentation as the Company may reasonably require, for reasonable out-of-pocket expenses incurred by the Executive relating to the business or affairs of the Company or the performance of the Executive's duties hereunder, including, without limitation, reasonable expenses with respect to entertainment, travel and similar items, *provided* that the incurring of such expenses shall have been approved in accordance with the Company's regular reimbursement procedures and practices in effect from time to time.

5.5 Vacation. In addition to statutory holidays, the Executive shall be entitled to three (3) weeks paid vacation each calendar year during the Executive's employment, accruing ratably each month.

5.6 Withholding. The Company may withhold from the Executive's compensation all applicable amounts required by law.

6. Payments Upon Termination of Employment. In the event the Executive's employment with the Company terminates for any reason (including death or Disability (as hereinafter defined)), the Company shall pay to the Executive (i) any Base Salary including accrued vacation pay, expense reimbursements, compensation and benefits under any Plan, (as hereinafter defined), and any and all benefits and other similar amounts, accrued but unpaid as of the date of termination, and (ii) the awarded but unpaid portion, if any, of the Performance Bonus for any prior or current year. In addition, upon termination of the Executive's employment with the Company by the Company without Cause or upon the Executive's resignation from employment for Good Reason, contingent upon the Executive's execution and delivery of a general release reasonably satisfactory to the Company releasing the Company, its officers, agents, stockholders, and affiliates from any liability for any matter other than for payments under this Section 6 and contractual obligations under other written agreements, the Company shall pay to the Executive an amount equal to six (**6**) months portion of the Base Salary ("Severance"), to be paid over a like number of months consistent with the Company's normal payroll schedule; provided, however, that in the event of the Executive's material breach of any of the Related Agreements, which breach, if reasonably susceptible to cure, has not been cured to the satisfaction of the Company within ten (10) business days of the Executive's receipt of written notice of such breach, then the Company's obligation to pay Severance shall terminate and be of no further force or effect.

7. Non-Competition/Non-Solicitation. Executive acknowledges and recognizes the highly competitive nature of the businesses of the Company and its subsidiaries and affiliates and accordingly agrees as follows:

7.1 During the Employment Term and for a period of one year following the earlier of (A) the expiration of the Employment Term and (B) the date Executive ceases to be employed by the Company (the "'Restricted Period"), Executive will not directly or indirectly, (w) engage in any business for Executive's own account that competes directly or indirectly with the "Business of the Company" (defined below), (x) enter the employ of, or render any services to, any person engaged in any business that competes with the Business of the Company, or (y) interfere with business relationships (whether formed before or after the Effective Date) between the Company and customers or suppliers of, or consultants to, the Company. The "Business of the Company" shall mean the development and formulations of new pharmaceutical drugs to treat disorders of the central nervous systems using glutamates or (iii) any business which the Company conducts or has actively made plans to conduct (and Executive is aware of such plans) as of the date of termination of employment.

7.2 During the Restricted Period, Executive will not, directly or indirectly, (A) solicit or encourage to cease to work with the Company, or directly or indirectly hire, any person who is an employee of or consultant then under contract with the Company or who was an employee of or consultant then under contract with the Company within the six month period preceding such activity without the Company's written consent, (B) solicit any customer of the Company to cease doing business with the Company and (C) solicit any party in respect of projects which the Company is working on or actively considering at the time of termination of Executive's employment.

7.3 It is expressly understood and agreed that although Executive and the Company consider the restrictions contained in this Section 7 to be reasonable, if a judicial determination is made by a court of competent jurisdiction that the time or territory or any other restriction contained in the Agreement is an unenforceable restriction against Executive, the provisions of the Agreement shall not be rendered void but shall be deemed amended to apply as to such maximum time and territory and to such maximum extent as such court may judicially determine or indicate to be enforceable. Alternatively, if any court of competent jurisdiction finds that any restriction contained in this Agreement is unenforceable, and such restriction cannot be amended so as to make it enforceable, such finding shall not affect the enforceability of any of the other restrictions contained herein.

8. Executive's Representations and Warranties. The Executive represents and warrants that the Executive is not a party to any other employment, non-competition, or other agreement or restriction which could interfere with the Executive's employment with the Company or the Executive's or the Company's rights and obligations hereunder and that the Executive's acceptance of employment with the Company and the performance of the Executive's duties hereunder will not breach the provisions of any contract, agreement, or understanding to which the Executive is party or any duty owed by the Executive to any other person.

9. Definitions. Capitalized terms used in this Agreement but not otherwise defined herein shall have the meaning hereby assigned to them as follows:

9.1 "Cause" shall mean the Executive's: (i) dishonesty of a material nature (including, but not limited to, theft or embezzlement of Company funds or assets); (ii) conviction of, or guilty plea or no contest plea, to a felony charge or any misdemeanor involving moral turpitude, or the entry of a consent decree with any governmental body; (iii) noncompliance in any material respect with any laws or regulations, foreign or domestic, affecting the operation of the Company's business; (iv) violation of any express direction or any rule, regulation or policy established by the Board that is consistent with the terms of this Agreement, if such violation is likely to have a material adverse effect on the Company; (v) material breach of this Agreement or material breach of the Executive's fiduciary duties to the Company; (vi) gross incompetence, gross neglect, or gross misconduct in the performance of the Executive's duties; (vii) repeated and consistent failure to be present at work during normal business hours except during vacation periods or absences due to temporary illness; or (viii) abuse of alcohol or drugs which interferes with the Executive's performance of her duties. With respect to those circumstances of Cause set forth in the preceding clauses (iii) through (viii) that are reasonably susceptible to cure, Cause shall only exist where the Company has provided the Executive with written notice of the alleged problem and the Executive has failed to cure such condition to the satisfaction of the Company within ten (10) business days.

9.2 "Disability" The Executive shall be deemed to have a Disability for purposes of this Agreement either (i) if the Executive is deemed disabled for purposes of any group or individual disability policy paid for by the Company and at the time in effect, or (ii) if, in the good faith judgment of the Board, the Executive is substantially unable to perform the Executive's duties under this Agreement for more than [ninety (90)] days, whether or not consecutive, in any twelve (12) month period, by reason of a physical or mental illness or injury.

9.3 "Good Reason" shall mean, in the context of a resignation by the Executive, a resignation that occurs within thirty (30) days following the Executive's first having knowledge of any material adverse change in the Executive's compensation or any material breach of this Agreement by the Company, *provided* that in the case of a material breach, Good Reason shall only exist where the Executive has provided the Company with written notice of the breach, the breach is reasonably capable of being cured within a period often (10) business days, and the Company has failed to cure within ten (10) business days.

10. Waivers and Amendments. The respective rights and obligations of the Company and the Executive under this Agreement may be waived (either generally or in a particular instance, either retroactively or prospectively, and either for a specified period of time or indefinitely) or amended only with the written consent of a duly authorized representative of the Company and the Executive.

11. Successors and Assigns. The provisions hereof shall inure to the benefit of, and be binding upon, the Company's successors and assigns.

12. Entire Agreement. This Agreement constitutes the full and entire understanding and agreement of the parties with regard to the subjects hereof and supersede in their entirety all other or prior agreements, whether oral or written, with respect thereto.

13. Notices. All demands, notices, requests, consents and other communications required or permitted under this Agreement shall be in writing and shall be personally delivered or sent by facsimile machine (with a confirmation copy sent by one of the other methods authorized in this Section), reputable commercial overnight delivery service (including Federal Express and U.S. Postal Service overnight delivery service) or, deposited with the U.S. Postal Service mailed first class, registered or certified mail, postage prepaid, as set forth below:

If to the Company, addressed to:

Declan Doogan, M.D.
Executive Chairman
Biohaven Pharmaceuticals, Inc.
234 Church Street, Suite 301
New Haven, Connecticut 06510

If to the Executive, to the address set forth on the signature page of this Agreement or at the current address listed in the Company's records.

Notices shall be deemed given upon the earlier to occur of (i) receipt by the party to whom such notice is directed; (ii) if sent by facsimile machine, on the day (other than a Saturday, Sunday or legal holiday in the jurisdiction to which such notice is directed) such notice is sent if sent (as evidenced by the facsimile confirmed receipt) prior to 5:00 p.m. Eastern Time and, if sent after 5:00 p.m. Eastern Time, on the day (other than a Saturday, Sunday or legal holiday in the jurisdiction to which such notice is directed) after which such notice is sent; (iii) on the first business day (other than a Saturday, Sunday or legal holiday in the jurisdiction to which such notice is directed) following the day the same is deposited with the commercial courier if sent by commercial overnight delivery service; or (iv) the fifth day (other than a Saturday, Sunday or legal holiday in the jurisdiction to which such notice is directed) following deposit thereof with the U.S. Postal Service as aforesaid. Each party, by notice duly given in accordance therewith, may specify a different address for the giving of any notice hereunder.

14. Governing Law. This Agreement shall be construed and enforced in accordance with and governed by the laws of Connecticut (without giving effect to any conflicts or choice of laws provisions thereof that would cause the application of the domestic substantive laws of any other jurisdiction).

15. Consent to Jurisdiction

(a) EACH OF THE PARTIES HERETO HEREBY CONSENTS TO THE JURISDICTION OF ALL STATE AND FEDERAL COURTS LOCATED IN NEW VANEN, CONNECTICUT, AS WELL AS TO THE JURISDICTION OF ALL COURTS TO WHICH AN APPEAL MAY BE TAKEN FROM SUCH COURTS, FOR THE PURPOSE OF ANY SUIT, ACTION OR OTHER PROCEEDING ARISING OUT OF, OR IN CONNECTION

WITH, THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY, INCLUDING, WITHOUT LIMITATION, ANY PROCEEDING RELATING TO ANCILLARY MEASURES IN AID OF ARBITRATION, PROVISIONAL REMEDIES AND INTERIM RELIEF, OR ANY PROCEEDING TO ENFORCE ANY ARBITRAL DECISION OR AWARD. EACH PARTY HEREBY EXPRESSLY WAIVES ANY AND ALL RIGHTS TO BRING ANY SUIT, ACTION OR OTHER PROCEEDING IN OR BEFORE ANY COURT OR TRIBUNAL OTHER THAN THE COURTS DESCRIBED ABOVE AND COVENANTS THAT IT SHALL NOT SEEK IN ANY MANNER TO RESOLVE ANY DISPUTE OTHER THAN AS SET FORTH IN THIS SECTION, OR TO CHALLENGE OR SET ASIDE ANY DECISION, AWARD OR JUDGMENT OBTAINED IN ACCORDANCE WITH THE PROVISIONS HEREOF.

(b) EACH OF THE PARTIES HERETO HEREBY EXPRESSLY WAIVES ANY AND ALL OBJECTIONS IT MAY HAVE TO VENUE, INCLUDING, WITHOUT LIMITATION, THE INCONVENIENCE OF SUCH FORUM, IN ANY OF SUCH COURTS. IN ADDITION, EACH OF THE PARTIES CONSENTS TO THE SERVICE OF PROCESS BY PERSONAL SERVICE OR ANY MANNER IN WHICH NOTICES MAY BE DELIVERED HEREUNDER IN ACCORDANCE WITH SECTION 13 OF THIS AGREEMENT.

16. Equitable Remedies. The parties hereto agree that irreparable harm would occur in the event that any of the agreements and provisions of this Agreement were not performed fully by the parties hereto in accordance with their specific terms or conditions or were otherwise breached, and that money damages are an inadequate remedy for breach of this Agreement because of the difficulty of ascertaining and quantifying the amount of damage that will be suffered by the parties hereto in the event that this Agreement is not performed in accordance with its terms or conditions or is otherwise breached. It is accordingly hereby agreed that the parties hereto shall be entitled to an injunction or injunctions to restrain, enjoin and prevent breaches of this Agreement by the other parties and to enforce specifically such terms and provisions of this Agreement, such remedy being in addition to and not in lieu of, any other rights and remedies to which the other parties are entitled to at law or in equity.

17. Waiver of Jury Trial. EACH OF THE PARTIES HERETO HEREBY VOLUNTARILY AND IRREVOCABLY WAIVES TRIAL BY JURY IN ANY ACTION OR OTHER PROCEEDING BROUGHT IN CONNECTION WITH THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY.

18. Severability; Titles and Subtitles; Gender; Singular and Plural; Counterparts; Facsimile.

(a) In case any provision of this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected or impaired thereby.

(b) The titles of the sections and subsections of this Agreement are for convenience of reference only and are not to be considered in construing this Agreement.

(c) The use of any gender in this Agreement shall be deemed to include the other genders, and the use of the singular in this Agreement shall be deemed to include the plural (and vice versa), wherever appropriate.

(d) This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together constitute one instrument.

(e) Counterparts of this Agreement (or applicable signature pages hereof) that are manually signed and delivered by facsimile transmission shall be deemed to constitute signed original counterparts hereof and shall bind the parties signing and delivering in such manner.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the date first above specified.

COMPANY:

BIOHAVEN PHARMACEUTICALS, INC.

By:
Name: Declan Doogan M.D.
Title: Executive Chairman

EXECUTIVE:

/s/Kimberly Gentile
Kimberly Gentile

BIOHAVEN PHARMACEUTICALS, INC.

By: /s/Declan Doogan M.D.
Name: Declan Doogan M.D.
Title: Executive Chairman

By: /s/Kimberly Gentile
Kimberly Gentile

Exhibit 10.27

February 21, 2017

Elyse Stock M.D.

RE: LETTER OF OFFER OF EMPLOYMENT – **Chief of Strategy and Portfolio Development**

Dear Elyse,

Following our recent discussions, we are delighted to offer you the position of Chief of Strategy and Portfolio Development with Biohaven Pharmaceuticals, Inc. We are confident you will find this new opportunity both challenging and rewarding. The following points outline the terms and conditions we are proposing.

Title: Chief of Strategy and Portfolio Development
Start date: *April 5, 2017*
Base Salary: ***$325,000 per year + Benefits as described below:***

- As part of your employment, Biohaven will provide the following benefits:
  - *Health & Dental Insurance. Anthem Gold level health insurance (family plan) provided to the employee with no additional premium cost to the employee (program co-pays, deductibles, etc. will apply). Alternatively, at Biohaven's sole discretion, employee may continue with employee obtained program and Biohaven will reimburse employee for employee obtained program up to a total premium cost of $650/month for health, dental and vision.*
  - *Employer contribution to company 401k plan, representing a 100% company match of up to 4% of employee contribution.*
  - *Long-term disability insurance.*
  - *Incentive stock options based on performance will be awarded at the discretion of Biohaven Senior Management and upon approval of Board of Directors*
  - *Severance of 6 months regular salary if terminated by employer without "just cause." No severance will be paid if employee is terminated with "just cause" ("just cause" to terminate employment hereunder defined as a result of employee's gross negligence, willful misconduct, conviction of a felony (including the entry of a plea of nolo contendere) for illegal or criminal behavior in carrying out his duties).*
  - *Any relocation of workplace more than 30 miles from home address without approval of the employee will result in severance. Employee will work from home and travel to headquarters as needed upon mutual agreement. All pre-approved travel costs to headquarters, even from employee's second home in California, will be reimbursed by employer.*
  - *Cellphone and hotspot partial reimbursement of $100/month or if higher per approval of Chief Executive Officer.*

Annual Merit and Incentives:

- 3o% Annual Target Bonus payable in cash by February 1 of following year depending on employee performance (prorated for partial year employment) and at the discretion of the Board of Directors.
- Yearly salary increases based on performance will be awarded at the discretion of Biohaven Senior Management and upon approval of Board of Directors.
- One time issuance of 74,000 stock options granted upon employment ($9.2911 strike price valued at approximately $687,541) pursuant to the company's standard vesting schedule. Future incentive stock options based on performance will be awarded at the sole discretion of the Board of Directors.

Vacation/ Company Holidays / Sick Time:

- *Vacation time:* Four (4) weeks/per year of vacation time, accrued at 1.66 days per month or otherwise negotiated with your manager.
- *Company Holidays:* Nine (9) company holidays: 7 Standard Holidays + 2 Optional Holidays to be taken at employees discretion.
- *Sick Time:* To be managed at the discretion of the employees direct manager.

Reporting relationship: *Chief of Strategy and Portfolio Development reporting to the Chief Executive Officer.*

This arrangement may be terminated by either party upon notice in writing to either party with notice that complies with Employment Standards for Connecticut. We look forward to the opportunity to work with you in an atmosphere that is successful and mutually challenging and rewarding.

With the signature below, I accept this offer for employment.

/s/Elyse Stock
Elyse Stock M.D.

Sincerely,

Jim Engelhart, Chief Financial Officer, BIOHAVEN Pharmaceuticals, Inc.

Exhibit 10.28

Certain portions of this exhibit have been omitted pursuant to Rule 601(b)(10) of Regulation S-K The omitted information is (i) not material and (ii) would likely cause competitive harm to Biohaven Pharmaceutical Holding Company Ltd. if publicly disclosed. Information that has been omitted has been noted in this document with a placeholder identified by the mark "[***]".

ZYDIS® COMMERCIAL SUPPLY AGREEMENT(Rimegepant / BHV3000)

This **Zydis®** Commercial Supply Agreement is made as of this 29th day of June, 2018 ("**Effective Date**"), by and between Biohaven Pharmaceuticals, Inc., a Delaware corporation with a place of business at 234 Church Street, Suite 301, New Haven, CT 06510, USA ("**Client**"), and Catalent U.K. Swindon Zydis Limited, a company organized under the laws of Scotland (registered number SCO70961) with a place of business at Frankland Road, Blagrove, Swindon, Wiltshire, UK SN5 8YG ("**Catalent**").

RECITALS

A. Client develops, markets and sells pharmaceutical products;

B. Catalent is a leading provider of advanced technologies, and development, manufacturing and packaging services for pharmaceutical, biotechnology and consumer healthcare companies;

C. Catalent and its Affiliates have developed and licensed proprietary technology for the manufacture of the patented Zydis® Fast Dissolving Dosage Form ("**Zydis**") for the administration of pharmaceutical drugs (collectively, along with the Zydis Patents and all data, results and information relating to Zydis and the Zydis Patents (whether produced prior to or after the Effective Date), the "**Zydis Technology**");

D. Client and Catalent have entered into a Zydis Development and License Agreement dated November 20, 2017 (the "**Development Agreement**"), pursuant to which Catalent developed a Zydis formulation of the API (as defined below);

E. Client desires to have Catalent provide the services set forth in this Agreement (as defined below) in connection with Client's Product (as defined below), and Catalent desires to provide such services, all pursuant to the terms and conditions in this Agreement.

THEREFORE, in consideration of the circumstances described above and the mutual covenants, terms and conditions set forth below, the parties agree as follows:

ARTICLE 1
DEFINITIONS

The following terms have the following meanings in this Agreement:

1.1 "**Acknowledgement**" has the meaning set forth in Section 4.3(B).

1.2 “**Affiliate(s)**” means, with respect to Client or any Third Party, any Person, other than Client or such Third Party, that directly or indirectly controls, is controlled by or is under common control with Client or such Third Party; and with respect to Catalent, Catalent, Inc. and any corporation, firm, partnership or other entity controlled by it. For purposes of this definition, “**control**” means (a) the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a Person.

1.3 “**Agreement**” means this document, including all its Attachments and other appendices (all of which are incorporated by reference) and any amendment to any of the foregoing made in accordance with Section 18.1.

1.4 “**API**” means the compound (5 S,6S,9R)-5-amino-6-(2,3-difluorophenyl)-6, 7 ,8, 9-tetrahydro-5H-cyclohepta[b]pyridin-9-yl 4-(2-oxo-2,3-dihydro-l H-imidazo[4,5-b]pyridin-1-yl)piperidine-1-carboxylate, also known as rimegepant and BHV3000, or a salt thereof.

1.5 “**API Inventions**” has the meaning set forth in Article 11.

1.6 “**Applicable Laws**” means, with respect to Client, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of each jurisdiction in which API or Product is produced, marketed, distributed, used or sold; and with respect to Catalent, all laws, ordinances, rules and regulations, currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the jurisdiction in which Catalent Processes Product, including cGMP; provided, however, that with respect to cGMP, Catalent shall comply with the laws, ordinances, rules and regulations currently in effect or enacted or promulgated during the Term, and as amended from time to time, of the U.S, Europe and following its separation from the European Union, the United Kingdom.

1.7 “**Batch**” means a defined quantity of Product that has been or is being Processed in accordance with the Specifications.

1.8 “**Catalent**” has the meaning set forth in the introductory paragraph, or any successor or permitted assign. Catalent shall have the right to cause any of its Affiliates to perform any of its obligations hereunder, and Client shall accept such performance as if it were performance by Catalent.

1.9 “**Catalent Defective Processing**” has the meaning set forth in Section 5.2.

1.10 “**Catalent Indemnitees**” has the meaning set forth in Section 13.2.

1.11 “**Catalent IP**” has the meaning set forth in Article 11.

1.12 “**CGRP Compound**” means any molecule that is designed to bind to either calcitonin gene related peptide (“CGRP”) or a CGRP.

1.13 "**cGMP**" means current Good Manufacturing Practices promulgated by the Regulatory Authorities in the jurisdictions included in Applicable Laws (as applicable to Client and Catalent respectively). In the United States, this includes 21 C.F.R. Parts 210 and 211, as amended; and in the European Union, this includes 2003/94/EEC Directive (as supplemented by Volume 4 of EudraLex published by the European Commission), as amended, if and as implemented in the relevant constituent country.

1.14 "**Client**" has the meaning set forth in the introductory paragraph, or any successor or permitted assign.

1.15 "**Client Indemnitees**" has the meaning set forth in Section 13.1.

1.16 "**Client IP**" has the meaning set forth in Article 11.

1.17 "**Client-supplied Materials**" means any materials to be supplied by or on behalf of Client to Catalent for Processing, as provided in Attachment B, including API and reference standards.

1.18 "**Collaborator**" means, with respect to Client, any Person other than an Affiliate, that contractual privity with Client or an Affiliate of Client which is engaged in the research, development, commercialization, marketing, distribution, sales or support of drug substances or drug products on behalf of Client or its Affiliates.

1.19 "**Commencement Date**" means the first date upon which a Regulatory Authority approves Catalent as a manufacturer of any Product.

1.20 "**Confidential Information**" has the meaning set forth in Section 10.1.

1.21 "**Contract Year**" means each consecutive 12 month period beginning on the Commencement Date or anniversary thereof, as applicable.

1.22 "**Defective Product**" has the meaning set forth in Section 5.2.

1.23 "**Delayed Approval Fee**" has the meaning set forth in Section 7.3.

1.24 "**Development Agreement**" has the meaning set forth in Recital D.

1.25 "**Discloser**" has the meaning set forth in Section 10.1.

1.26 "**Effective Date**" has the meaning set forth in the introductory paragraph.

1.27 "**Exception Notice**" has the meaning set forth in Section 5.2.

1.28 "**Facility**" means Catalent's facility located in Swindon, UK; or such other facility as agreed by the parties in writing.

1.29 "**Firm Commitment**" has the meaning set forth in Section 4.2.

1.30 "**Invention**" has the meaning set forth in Article 11.

1.30.1 "**Launch Date**" means the date of first commercial sale of the Product made by the Client into the Territory

1.31 "**Losses**" has the meaning set forth in Section 13.1.

1.32 "**Minimum Requirement**" has the meaning set forth in Section 4.1.

1.33 **"Person"** shall mean an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.34 "**Process**" or "**Processing**" means (i) the qualification, validation and stability services for the Product and (ii) the compounding, filling or pressing, producing and bulk packaging (including initial blister packaging but not secondary or retail packaging) of Client-supplied Materials and Raw Materials into Product by Catalent, in accordance with the Specifications and under the terms of this Agreement and the Quality Agreement.

1.35 "**Processing Date**" means the day on which the first step of physical Processing is scheduled to occur, as identified in an Acknowledgement.

1.36 "**Process Inventions**" has the meaning set forth in Article 11.

1.37 "**Product**" means an orally disintegrating tablet pharmaceutical formulation containing the API which product falls within the claims of the Zydis® Patents or otherwise incorporates Zydis Technology, as more specifically described in the Specifications. A "unit" of Product is one tablet.

1.38 "**Product Maintenance Services**" has the meaning set forth in Section 2.3.

1.39 "**Purchase Order**" has the meaning set forth in Section 4.3(A).

1.40 "**Quality Agreement**" has the meaning set forth in Section 9.6.

1.41 "**Raw Materials**" means all raw materials, supplies, components and packaging necessary to manufacture and ship Product in accordance with the Specifications, as provided in Attachment B, but excluding Client-supplied Materials.

1.42 "**Recall**" has the meaning set forth in Section 9.5.

1.43 "**Recipient**" has the meaning set forth in Section 10.1.

1.44 "**Regulatory Approval**" means each approval, permit, product and/or establishment license, registration or authorization, including each approval pursuant to U.S. Investigational New Drug Applications, New Drug Applications and Abbreviated New Drug Applications (or equivalent non-U.S. filings, such as European marketing authorization applications), as applicable, of a Regulatory Authority that is necessary or advisable in connection with the

development, manufacture, testing, use, storage, exportation, importation, transport, promotion, marketing, distribution or sale of API or Product in the Territory.

1.45 "**Regulatory Authority**" means an international, federal, state or local governmental or regulatory body, agency, department, bureau, court or other entity in the Territory that is responsible for (A) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use or (B) health, safety or environmental matters generally. In the United States, this includes the United States Food and Drug Administration; and in the European Union, this includes the European Medicines Agency.

1.46 "**Representatives**" of an entity means such entity's duly authorized officers, directors, employees, agents, accountants, attorneys or other professional advisors.

1.47 "**Review Period**" has the meaning set forth in Section 5.2.

1.48 "**Rolling Forecast**" has the meaning set forth in Section 4.2.

1.49 "**Specifications**" means the procedures, requirements, standards, quality control testing and other data and the scope of services as set forth in Attachment B, as modified from time to time in accordance with Article 8.

1.50 "**Term**" has the meaning set forth in Section 16.1.

1.51 "**Territory**" means worldwide, but excluding any countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom, or the United States. Catalent shall not be obliged to Process Products for sale in any of such countries if it is prevented from doing so, or would be required to obtain or apply for special permission to do so, due to any restriction (such as an embargo) imposed on it by any governmental authority, including those imposed by the U.S. Department of the Treasury's Office of Foreign Assets Control.

1.52 "**Third Party**" means shall mean any Person other than Catalent and its Affiliates, and Client and its Affiliates and Collaborators.

1.53 "**Unit**" has the meaning set forth on Attachment C.

1.54 "**Unit Pricing**" has the meaning set forth in Section 7.1(B).

1.55 "**Validation Services**" has the meaning set forth in Section 2.1.

1.56 "**Vendor**" has the meaning set forth in Section 3.2(B).

1.57 "**Zydis**" has the meaning set forth in Recital C.

1.58 "**Zydis Patents**" has the meaning set forth in the Development Agreement.

1.59 "**Zydis Technology**" has the meaning set forth in Recital C.

ARTICLE 2
VALIDATION, PROCESSING & RELATED SERVICES

2.1 Validation Services. Catalent shall perform the Product qualification, validation and stability services described in Attachment A (the "**Validation Services**").

2.2 Supply and Purchase of Product. Catalent shall Process Product in accordance with the Specifications, Applicable Laws and the terms and conditions of this Agreement. During the Term, but no longer than for [***] from Commencement Date, Client and its Affiliates shall purchase exclusively from Catalent all of Client's and its Affiliates' requirements of Product in the Territory. Client shall have no right to self-manufacture or to have a Third Party manufacture Product unless Catalent is unable to supply Client with Client's Minimum Requirement for Product for a period of [***]. Catalent shall use commercially reasonable efforts to ensure continuous supply of Product. In case of limited manufacturing capacity, Catalent shall not disadvantage Processing of Product compared to other products. Promptly after execution of this Agreement, the parties shall develop a Product supply plan with the goal of ensuring a continuous supply of Product to Client during the Term.

2.3 Product Maintenance Services. Catalent shall provide and Client will receive those product maintenance services specified in Attachment D (the "**Product Maintenance Services**").

2.4 Other Related Services. Catalent shall provide other Product-related services, other than Validation Services, Processing or Product Maintenance Services, as either specified in Attachment D or agreed in writing by the parties from time to time. Such writing shall include the scope and fees for any such services and be appended to this Agreement. The terms and conditions of this Agreement shall govern and apply to such services.

ARTICLE 3
MATERIALS

3.1 Client-supplied Materials.

A. Client shall supply to Catalent for Processing, at Client's cost, Client-supplied Materials, in quantities sufficient to meet Client's requirements for Product. Client shall deliver such items and associated certificates of analysis to the Facility no later than [***] days (but not earlier than [***] days) before the Processing Date. Client shall be responsible at its expense for securing any necessary export, import or other governmental clearance, permit or certification required in respect of such supply. Catalent shall use Client-supplied Materials solely for Processing. Prior to delivery of any Client-supplied Materials, Client shall provide to Catalent a copy of all associated material safety data sheets, safe handling instructions and health and environmental information and any governmental certification or authorization that may be required under Applicable Laws relating to the API and Product, and thereafter shall provide promptly any update thereto.

B. Catalent shall inspect all Client-supplied Materials received to verify their identity. Unless otherwise expressly required by the Specifications, Catalent shall have no

obligation to test Client-supplied Materials it receives to confirm that they meet the associated specifications, certificate of analysis or otherwise; but in the event that Catalent detects a nonconformity with the Specifications, Catalent shall give Client prompt notice of such nonconformity. Catalent shall not be liable for any defect in Client-supplied Materials, or in Product as a result of defective Client-supplied Materials, unless Catalent failed to properly perform the foregoing obligations. Catalent shall follow Client's reasonable written instructions in respect of return or disposal of defective Client-supplied Materials, at Client's cost.

C. Client shall retain title to Client-supplied Materials at all times and shall bear the risk of loss of any such Client-supplied Materials unless as a result of gross negligence by Catalent.

3.2 Raw Materials.

A. Catalent shall be responsible for procuring, inspecting and releasing adequate Raw Materials as necessary to meet the Firm Commitment, unless otherwise agreed by the parties in writing. Catalent shall not be liable for any delay in delivery of Product if (i) Catalent is unable to obtain, in a timely manner, a particular Raw Material necessary for Processing and (ii) Catalent placed orders for such Raw Materials promptly following receipt of Client's Firm Commitment. In the event that any Raw Material becomes subject to purchase lead time beyond the Firm Commitment time frame, the parties will negotiate in good faith an appropriate amendment to this Agreement, including Section 4.2.

B. Client may require a specific supplier, manufacturer or vendor ("**Vendor**") to be used for Raw Material. In such an event, (i) such Vendor will be identified in the Specifications and (ii) the Raw Materials from such Vendor shall be deemed Client-supplied Materials for purposes of this Agreement. If the cost of the Raw Material from any such Vendor is greater than Catalent's costs for the same raw material of equal quality from other vendors, Catalent shall add the difference between Catalent's cost of the Raw Material and the Vendor's cost of the Raw Material to the Unit Pricing. Client will be responsible for all costs associated with qualification of any such Vendor that has not been previously qualified by Catalent.

C. In the event of (i) a Specification change for any reason, (ii) obsolescence of any Raw Material or (iii) termination or expiration of this Agreement, Client shall bear the cost of any unused Raw Materials (including packaging) unusable for Processing or Product and unused by Catalent for another customer, so long as Catalent purchased such Raw Materials in quantities consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations.

3.3 Artwork and Labeling. Client shall provide or approve, prior to the procurement of applicable Raw Material, all artwork, advertising and labeling information necessary for Processing, if any. Such artwork, advertising and labeling information is and shall remain the exclusive property of Client, and Client shall be solely responsible for the content thereof. Such artwork, advertising and labeling information or any reproduction thereof may not be used by Catalent in any manner other than performing its obligations hereunder without Client's written consent.

ARTICLE 4
MINIMUM COMMITMENT, PURCHASE ORDERS & FORECASTS

4.1 Minimum Requirement. [***].

4.2 Forecast. On or before the 10th day of each calendar month, beginning at least 6 months prior to the anticipated Commencement Date, Client shall furnish to Catalent a written 12 month rolling forecast of the quantities of Product that Client intends to order from Catalent during such 12-month period (the "**Rolling Forecast**). The first 3 months of each Rolling Forecast shall constitute a binding order for the quantities of Product specified in such Rolling Forecast (the "**Firm Commitment**") and the following 9 months of the Rolling Forecast shall be non-binding, good-faith estimates.

4.3 Purchase Orders.

A. From time to time as provided in this Section 4.3(A), Client shall submit to Catalent a binding, non-cancelable purchase order for Product specifying the number of Batches to be Processed, the Batch size (to the extent the Specifications permit Batches of different sizes) and the requested delivery date for each Batch (each, a "**Purchase Order**"); *provided*, that all Purchase Orders shall be in full batch quantities. Concurrently with the submission of each Rolling Forecast, Client shall submit a Purchase Order for the Firm Commitment. Purchase Orders for quantities of Product in excess of the Firm Commitment shall be submitted by Client at least 150 days in advance of the delivery date requested in the Purchase Order.

B. Promptly following receipt of a Purchase Order, Catalent shall issue a written acknowledgement (each, an "**Acknowledgement**") that it accepts or rejects such Purchase Order. Each acceptance Acknowledgement shall either confirm the delivery date set forth in the Purchase Order or set forth a reasonable alternative delivery date, and shall include the Processing Date. Catalent may reject any Purchase Order in excess of the Firm Commitment or otherwise not given in accordance with this Agreement.

C. Notwithstanding Section 4.3(B), Catalent shall use commercially reasonable efforts to supply Client with quantities of Product set forth in a Purchase Order which are up to [***]% in excess of the quantities specified in the Firm Commitment, subject to Catalent's other supply commitments and manufacturing, packaging and equipment capacity.

D. In the event of a conflict between the terms of any Purchase Order or Acknowledgement and this Agreement, the terms of this Agreement shall control.

4.4 Catalent's Cancellation of Purchase Orders. Notwithstanding anything in Section 4.3 and 4.5 to the contrary, Catalent reserves the right to cancel all, or any part of, a Purchase Order upon written notice to Client, and Catalent shall have no further obligations or liability with respect to such Purchase Order, if Client refuses or fails to supply conforming Client-supplied Materials prior to the deadline set forth in Section 3.1. [***]

4.5 Client's Modification or Cancellation of Purchase Orders.

A. Client may modify the delivery date or quantity of Product in a Purchase Order only by submitting a written change order to Catalent at least [***] days in advance of the earliest Processing Date covered by such change order. Such change order shall be effective and binding against Catalent only upon the written approval of Catalent, and notwithstanding any such written approval, Client shall remain responsible for the Firm Commitment.

B. Notwithstanding any amount due to Catalent under Section 4.1, if Client fails to place Purchase Orders sufficient to satisfy the Firm Commitment, Client shall pay to Catalent in accordance with Article 7 the Unit Pricing for all Units that would have been Processed if Client had placed Purchase Orders sufficient to satisfy the Firm Commitment.

C. [***]

4.6 Unplanned Delay or Elimination of Processing. Catalent shall use commercially reasonable efforts to meet the Purchase Orders, subject to the terms and conditions of this Agreement. Catalent shall provide Client with as much advance notice as practicable if Catalent determines that any Processing will be delayed or eliminated for any reason. If a delay in supply of Product, which is solely due the Catalent, is the sole cause that Client is unable to reach the Minimum Requirement, Client will only be obligated to pay for actual Product delivered.

ARTICLE 5
TESTING; SAMPLES; RELEASE

5.1 Batch Records and Data; Release. Unless otherwise agreed to by the parties during their ordinary course of dealings, after Catalent completes Processing of a Batch, Catalent shall provide Client with copies of Batch records prepared in accordance with the Specifications; *provided*, that if testing reveals an out-of-Specification result, Catalent shall provide such Batch records promptly following resolution of the out-of-Specification result. After Catalent completes Processing of a Batch, Catalent shall also provide Client or its designee with a certificate of analysis for such Batch. Issuance of a certificate of analysis constitutes release of the Batch by Catalent to Client. Client shall be responsible for final release of Product (including testing, at its cost) to the market.

5.2 Testing; Rejection. Following Client's receipt of a shipment of a Batch, Client or Client's designee may test samples of such Batch to confirm that the Specifications have been met. Unless within 20 days after Client's receipt of a Batch ("**Review Period**"), Client or its designee notifies Catalent in writing (an "**Exception Notice**") that such Batch does not meet the warranty set forth in Section 12.1 ("**Defective Product**"), and provides a sample of the alleged Defective Product, the Batch shall be deemed accepted by Client and Client shall have no right to reject such Batch. Upon timely receipt of an Exception Notice from Client, Catalent shall conduct an appropriate investigation in its discretion to determine whether it agrees with Client that Product is Defective Product and to determine the cause of any nonconformity. If Catalent agrees that Product is Defective Product and determines that the cause of nonconformity is attributable to Catalent's negligence or willful misconduct ("**Catalent Defective Processing**"), then Section 5.4 shall apply. For avoidance of doubt, where the cause of nonconformity cannot be determined or assigned, it shall be deemed not Catalent Defective Processing.

5.3 Discrepant Results. If the parties disagree as to whether Product is Defective Product and/or whether the cause of the nonconformity is Catalent Defective Processing, and this is not resolved within 30 days of the Exception Notice date, the parties shall cause a mutually acceptable independent third party to review records, test data and to perform comparative tests and/or analyses on samples of the alleged Defective Product and its components, including Client-supplied Materials. The independent party's results as to whether or not Product is Defective Product and the cause of any nonconformity shall be final and binding. Unless otherwise agreed by the parties in writing, the costs associated with such testing and review shall be borne by Catalent if Product is Defective Product attributable to Catalent Defective Processing, and by Client in all other circumstances.

5.4 Defective Processing. Catalent shall, at its option, either (A) re-Process (or if re-Processing is not permissible under cGMPs, then replace), at its cost any Batch of Defective Product attributable to Catalent Defective Processing (and Client shall be liable to pay for either the rejected Batch(es) or the replacement Batch(es), but not both), or (B) credit any payments made by Client for such rejected Batch. THE OBLIGATION OF CATALENT TO RE-PROCESS (OR REPLACE) DEFECTIVE PRODUCT IN ACCORDANCE WITH THE SPECIFICATIONS OR CREDIT PAYMENTS MADE BY CLIENT, IN EACH CASE WHICH DEFECTIVE PRODUCT IS ATTRIBUTABLE TO CATALENT DEFECTIVE PROCESSING, SHALL BE CLIENT'S SOLE AND EXCLUSIVE REMEDY UNDER THIS AGREEMENT FOR DEFECTIVE PRODUCT AND IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED. FOR CLARITY, NOTWITHSTANDING THE FOREGOING, TO THE EXTENT CLIENT HAS A RIGHT UNDER THIS AGREEMENT TO TERMINATE THIS AGREEMENT THAT DOES NOT ARISE FROM OR RELATE TO DEFECTIVE PROCESSING PURSUANT TO ARTICLE 5, SUCH RIGHT TO TERMINATE SHALL CONTINUE TO APPLY.

5.5 Supply of Material for Defective Product. In the event Catalent reprocesses (or if re-Processing is not permissible under cGMPs, then replaces) Defective Product pursuant to Section 5.4, Client shall supply, at its cost, Catalent with sufficient quantities of Client-supplied Materials in order for Catalent to complete such reprocessing or replacing.

ARTICLE 6
DELIVERY

6.1 Delivery. Catalent shall pack, label and deliver Product Ex Works (Incoterms 2010) the Facility promptly following Catalent's release of Product in accordance with Applicable Laws and Catalent's standard procedures. Catalent shall segregate and store all Product until tender of delivery. Title to Product shall transfer to Client upon Catalent's tender of delivery. Client shall qualify at least 1 carriers to ship Product and then designate the priority of such qualified carriers to Catalent.

6.2 Storage Fees. If Client fails to take delivery of any Product on any scheduled delivery date, Catalent shall store such Product and have the right to invoice Client monthly following such scheduled delivery for reasonable administration and storage costs.

6.3 Bill and Hold. From time to time, at the Client's request, the agreed delivery date of the Purchase Order may be extended under a bill and hold arrangement as more fully set forth below. For each such Batch of stored Product, Client agrees that: (A) Client has made a fixed commitment to purchase the Product, (B) risk of loss for such Product passes to Client upon placement into storage, (C) such Product shall be on a bill and hold basis for legitimate business purposes, (D) the Client shall identify a fixed delivery date for the Product and (E) Client agree to be invoiced and to pay such invoice in accordance with the Payment terms set forth in this Agreement. Upon making a request for a bill and hold arrangement, Client shall provide Catalent with a letter confirming items (A) through (E) of this Section for each Batch of stored Product.

6.4

ARTICLE 7
PAYMENTS

7.1 Fees. In consideration for Catalent performing services hereunder:

A. Client shall pay to Catalent the fees for Validation Services set forth on Attachment A. Catalent shall submit an invoice to Client for such fees upon the completion of the relevant phase of the Validation Services.

B. Client shall pay Catalent the unit pricing for Product set forth on Attachment C (together with any subsequent updates to pricing, the "**Unit Pricing**"). Catalent shall submit an invoice to Client for such fees upon tender of delivery of Product as provided in Section 6.1.

C. Client shall pay Catalent the annual fees for Product Maintenance Services set forth on Attachment D. Catalent shall submit an invoice to Client for such fees upon the Effective Date and upon each anniversary of the Effective Date during the Term.

D. Other Fees. Client shall pay Catalent for all other fees and expenses of Catalent owing in accordance with the terms of this Agreement, including pursuant to Sections 2.4, 4.1, 6.2 and 16.3, and Attachment D. Catalent shall submit an invoice to Client for such fees as and when appropriate.

7.2 Unit Pricing Increase. The Unit Pricing shall be adjusted on an annual basis, effective on each anniversary date of the Effective Date, upon 90 days' prior written notice from Catalent to Client, to reflect increases or decreases in, among other things, labor, utilities and overhead and shall be in an amount equal to the increase in the Producers Output Pricing Index (**"POPI"**) as defined in tables MM22 under category K3BI, as published on www.ons.gov.uk; provided, however, that no increase or decrease in Unit Pricing shall be made to the portion of Unit Pricing that represents royalties under the Development Agreement. In addition, in the event there are proposed price increases for Raw Materials, labor, utilities and components in excess of POPI, the parties shall use commercially reasonable efforts to minimize such price increases and Catalent shall pass such price increases through to Client, without mark-up, at the time of such price increase through an adjustment to the Unit Pricing.

7.3 Product Approval. If any Regulatory Approval necessary for Catalent to commence Processing at the Facility has not been obtained by Client within 12 months following the Effective Date, then Client shall pay to Catalent a fee as provided in Attachment C ("**Delayed Approval Fee**") until such Regulatory Approval has been obtained and Catalent is able to commence Processing.

7.4 Payment Terms. Payment of all Catalent invoices shall be due 30 days after the date of invoice. Client shall make payment in U.S. dollars, and otherwise as directed in the applicable invoice. If any payment is not received by Catalent by its due date, then Catalent may, in addition to other remedies available at equity or in law, charge interest on the outstanding sum from the due date (both before and after any judgment) at 2% per month until paid in full (or, if less, the maximum amount permitted by Applicable Laws).

7.5 Advance Payment. Notwithstanding any other provision of this Agreement to the contrary, if at any time Catalent determines that Client's credit is impaired, Catalent may require payment in advance before performing any further service under this Agreement, including any Processing, or making any further shipment of Product. If Client shall fail, within a reasonable time, to make such payment in advance, or if Client shall fail to make any payment when due, Catalent shall have the right, at its option, to suspend any further performance under this Agreement until such default is corrected, without such suspension releasing Client from its obligations under this Agreement.

7.6 Taxes. All taxes, duties and other amounts (excluding taxes based on net income and franchise taxes) assessed in respect of Client-supplied Materials, services or Product prior to or upon provision or sale, as the case may be, whether assessed on Catalent or Client, are the responsibility of Client, and either Client shall reimburse Catalent for all such taxes, duties or other amounts paid by Catalent or such sums will be added to invoices directed at Client. If any deduction or withholding in respect of tax or otherwise is required by law to be made from any of the sums payable hereunder, Client shall be obliged to pay to Catalent such greater sum as will leave Catalent, after deduction or withholding as is required to be made, with the same amount as it would have been entitled to receive in the absence of any such requirement to make a deduction or withholding.

7.7 Client and Third Party Expenses. Except as may be expressly covered by Product Maintenance Service fees, Client shall be responsible for 100% of its own and all third-party expenses associated with development, Regulatory Approval and commercialization of Product, including regulatory filings and post-approval marketing studies.

7.8 Development Batches. Each Batch produced under this Agreement, including those necessary to support the validation portion of Client's submissions for Regulatory Approvals, will be considered to be a "development batch" unless and until Processing has been validated. Client shall be responsible for the cost of each such Batch, even if such Batch fails to meet the Specifications, unless Catalent was grossly negligent in the Processing of the out-of-Specification Batch. Catalent and Client shall cooperate in good faith to resolve any problem causing the out-of-Specification Batch.

ARTICLE 8

CHANGES TO SPECIFICATIONS

All Specifications and any change to the Specifications agreed by the parties from time to time shall be in writing, dated and signed by the parties. Any change to the Process shall be deemed a Specification change. No change in the Specifications shall be implemented by Catalent, whether requested by Client or requested or required by any Regulatory Authority, until the parties have agreed in writing to such change, the implementation date of such change, and any increase or decrease in costs, expenses or fees associated with such change (including any change to Unit Pricing). Catalent shall respond promptly to any request made by Client for a change in the Specifications, and both parties shall use commercially reasonable, good-faith efforts to agree to the terms of such change in a timely manner. As soon as practicable after a request is made for any change in Specifications, Catalent shall notify Client of the costs associated with such change and shall provide such supporting documentation as Client may reasonably require. Client shall pay all costs associated with agreed changes to the Specifications. If there is a conflict between the terms of this Agreement and the terms of the Specifications, this Agreement shall control. Catalent reserves the right to postpone effecting changes to the Specifications until such time as the parties agree to and execute the required written amendment.

ARTICLE 9
RECORDS; REGULATORY MATTERS

9.1 Recordkeeping. Catalent shall maintain materially complete and accurate Batch, laboratory data and other technical records relating to Processing in accordance with Catalent standard operating procedures. Such information shall be maintained for a period of at least 2 years from the relevant finished Product expiration date or longer if required under Applicable Laws or the Quality Agreement.

9.2 Regulatory Compliance. Catalent shall obtain and maintain all permits and licenses with respect to general Facility operations required by any Regulatory Authority in the jurisdiction in which Catalent Processes Product. Client shall obtain and maintain all other Regulatory Approvals, authorizations and certificates with respect to Product or the services provided pursuant to this Agreement, including those necessary for Catalent to commence Processing. Client shall not identify Catalent in any regulatory filing or submission without Catalent's prior written consent, which consent shall not be unreasonably withheld and shall be memorialized in a writing signed by authorized Representatives of both Parties. Upon written request, Client shall provide Catalent with a copy of each Regulatory Approval required to distribute, market or sell Product in the Territory. If Client is unable to provide such information, Catalent shall have no obligation to deliver Product to Client, notwithstanding anything to the contrary in this Agreement. During the Term, Catalent will assist Client with all regulatory matters relating to Processing, at Client's request and expense. The parties intend and commit to cooperate to allow each party to satisfy its obligations under Applicable Laws relating to Processing under this Agreement.

9.3 Governmental Inspections and Requests. Catalent shall promptly advise Client if an authorized agent of any Regulatory Authority notifies Catalent that the agent intends to or does visit the Facility where at least one purpose relates to Processing. Upon request, Catalent shall

provide Client with a copy of any report issued by such Regulatory Authority received by Catalent following such visit, redacted as appropriate to protect any confidential information of Catalent or Catalent's other customers. Client acknowledges that it may not direct the manner in which Catalent fulfills its obligations to permit inspection by and to communicate with Regulatory Authorities. Client shall reimburse Catalent for all reasonable and documented costs associated with inspections by Regulatory Authorities in connection with Product, and pay the fees specified in Attachment D, to the extent applicable.

9.4 Client Facility Audits. During the Term, Client's Representatives shall be granted access upon at least 10 business days' prior notice, at reasonable times during regular business hours, to (A) the portion of the Facility where Catalent performs Processing, (B) relevant personnel involved in Processing and (C) Processing records described in Section 9.2, in each case solely for the purpose of verifying that Catalent is Processing in accordance with cGMPs, the Specifications and the Product master Batch records. Client may not conduct an audit under this Section 9.4 more than once during any 12-month period; *provided*, that additional inspections may be conducted in the event there is a material quality or compliance issue concerning Product or its Processing. Client's Quality Assurance Manager will arrange Client audits with Catalent Quality Management. Audits and inspections under this Section 9.4 shall be designed to minimize disruption of operations at the Facility. Such Representatives shall abide by all Catalent safety rules and other applicable employee policies and procedures, and Client shall be responsible for such compliance. Client shall indemnify and hold harmless Catalent for any action, omission or other activity of its Representatives while on Catalent's premises. Client's Representatives shall be required to sign Catalent's standard visitor confidentiality agreement prior to being allowed access to the Facility.

9.5 Recall. If a Regulatory Authority orders or requires the recall of any Product supplied pursuant to this Agreement or if Catalent believes a recall, field alert, Product withdrawal or field correction ("**Recall**") may be necessary with respect to any Product supplied under this Agreement, the party receiving the notice from the Regulatory Authority or that holds such belief shall promptly notify the other party in writing. Catalent will not act to initiate a Recall without the express prior written approval of Client, unless otherwise required by Applicable Laws. If Client believes a Recall may be necessary with respect to any Product supplied under this Agreement, Client shall promptly notify Catalent and Catalent shall provide all necessary cooperation and assistance to Client. Client shall provide Catalent with an advance copy of any proposed submission to a Regulatory Authority in respect of any Recall, and shall consider in good faith any comment from Catalent. The cost of any Recall shall be borne by Client, and Client shall reimburse Catalent for expenses incurred in connection with any Recall, in each case unless such Recall is caused solely by Catalent's breach of its obligations under this Agreement, violation of Applicable Laws or its negligence or willful misconduct, in which case Catalent shall bear the reasonable, actual and documented administrative costs incurred by Client for such Recall and, if applicable, the cost of replacing Product subject to Recall, both to the extent and as provided in Article 5.

9.6 Quality Agreement. Within 6 months after the Effective Date, and in any event prior to the first Processing of Product under this Agreement, the parties shall negotiate in good faith and enter into a quality agreement on Catalent's standard template (the "**Quality Agreement**"). The

Quality Agreement shall in no way determine liability or financial responsibility of the parties for the responsibilities set forth in that agreement. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any provision of this Agreement and the Quality Agreement with respect to any commercial matter, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

9.7 Regulatory Authority Fees. Catalent reserves the right to assess Client for any Regulatory Authority fees that may be established by any regulatory authority, which fees result directly from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of Client's product or Client-supplied materials. Without limiting the foregoing, Client shall reimburse Catalent for any Regulatory Authority fees Catalent may be required to pay pursuant to the Generic Drug User Fee Amendments of 2017, ("**GDUFA Fees**"), where such fees result directly from Catalent's formulation, development, manufacturing, processing, filling, packaging, storing or testing of Client's product or Client-supplied materials. A Catalent facility incurs GDUFA Fees when that Catalent facility is referenced in an approved ANDA. GDUFA Fees are assessed by the FDA on October 1st of each year and shall be paid by Client annually, where applicable. On or after October 1st of each year, Catalent will invoice Client for Client's pro-rata share of the annual GDUFA Fee Catalent incurs for each Catalent manufacturing or packaging facility identified in Client's approved ANDA(s). This includes, but is not limited to, any Catalent facility which manufactured or packaged Client's registration batches. Catalent will invoice Client for reimbursement of all other payments or fees at the time they are incurred by Catalent. Client shall pay all such invoices within 30 days from the date of such invoice.

ARTICLE 10
CONFIDENTIALITY AND NON-USE

10.1 Definition. As used in this Agreement, the term "**Confidential Information**" means all confidential information of the disclosing person of whatever type, including all information furnished by or on behalf of Catalent or Client (as the case may be, "**Discloser**"), its Affiliates or any of its or their respective Representatives, to the other party (for purposes of this Article 10, "**Recipient**"), its Affiliates or any of its or their respective Representatives, whether furnished before, on or after the Effective Date and furnished in any form, including written, verbal, visual, electronic or in any other media or manner and information acquired by observation or otherwise during any site visit at the other party's facility. Confidential Information includes all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), analyses, compilations, business or technical information and other materials prepared by either party, their respective Affiliates, or any of its or their respective Representatives, containing or based in whole or in part on any Confidential Information furnished by Discloser, its Affiliates or any of its or their respective Representatives. Confidential Information also includes the existence and terms of this Agreement.

10.2 Exclusions. Notwithstanding anything in Section 10.1 to the contrary, Confidential Information does not include information that (A) is or becomes generally available to the public

or within the industry to which such information relates other than as a result of a breach of this Agreement, (B) is already known by Recipient at the time of disclosure as evidenced by Recipient's written records, (C) becomes available to Recipient on a non-confidential basis from a source that is entitled to disclose it on a non-confidential basis or (D) was or is independently developed by or for Recipient without reference to Discloser's Confidential Information as evidenced by Recipient's written records.

10.3 Mutual Obligation. Recipient A) will keep confidential all Confidential Information, employing such protections as it would use for its own Confidential Information of a similar type but in no case less than reasonable protections under the circumstances, (B) will not use Discloser's Confidential Information except in connection with the performance of its obligations under this Agreement, and (C)will not disclose to any third party, without Discloser's prior written consent, Discloser's Confidential Information, except that Recipient may disclose Discloser's Confidential Information to any of its Affiliates and its or their respective Representatives that (I) need to know such Confidential Information for the purpose of performing under this Agreement, (II) are advised of the contents of this Article and (III) are bound to Recipient by obligations of confidentiality at least as restrictive as the terms of this Article. Each party shall be responsible for any breach of this Article by its Affiliates or any of its or their respective Representatives.

10.4 Permitted Disclosure. Recipient may disclose Discloser's Confidential Information to the extent required by law or regulation; *provided*, that prior to making any such legally required disclosure, Recipient shall give Discloser as much prior notice of the requirement for and contents of such disclosure as is practicable under the circumstances. Any such disclosure, however, shall not relieve Recipient of its obligations under this Agreement.

10.5 No Implied License. Except as expressly set forth in Section 10.1, Recipient will obtain no right of any kind or license under any of Discloser's Confidential Information, including any patent application or patent, by reason of this Agreement. Discloser's Confidential Information will remain Discloser's sole property, subject to Article 11.

10.6 Return of Confidential Information. Upon expiration or termination of this Agreement, Recipient will (and will cause its Affiliates and its and their respective Representatives to) cease its use and, upon written request, within 30 days either return or destroy (and certify as to such destruction) all of Discloser's Confidential Information, including any copy of such information, except for a single copy which may be retained for the sole purpose of ensuring compliance with its obligations under this Agreement.

10.7 Survival. The obligations of this Article will terminate 5 years from the expiration or termination of this Agreement, except with respect to trade secrets, for which the obligations of this Article will continue for so long as such information remains a trade secret under law.

ARTICLE 11
INTELLECTUAL PROPERTY

11.1 As used in this Agreement, "**Client IP**" means all intellectual property and related embodiments owned by or licensed to Client as of the Effective Date or developed by Client

other than in connection with this Agreement; "**Catalent IP**" means all intellectual property and related embodiments owned by or licensed to Catalent as of the Effective Date or developed by Catalent other than in connection with this Agreement; "**Invention**" means any intellectual property developed by either party or jointly by the parties in connection with this Agreement; "**API Inventions**" means any Invention that relates exclusively to the Client IP, Client's patented API or Client's proprietary Zydis® formulation of the API; and "**Process Inventions**" means any Invention, other than an API Invention, that relates exclusively to Catalent IP, Catalent's Confidential Information, improvements to the Zydis® Technology, Catalent's manufacturing processes or that relates to developing, formulating, manufacturing, filling, processing, packaging, analyzing or testing pharmaceutical products generally. All Client IP and API Inventions shall be owned solely by Client and no right therein is granted to Catalent under this Agreement, except that Catalent shall have a non-exclusive, royalty-free license to such items solely to the extent necessary to perform its obligations under this Agreement. All Catalent IP and Process Inventions shall be owned solely by Catalent and no right therein is granted to Client under this Agreement. The parties shall cooperate to achieve the allocation of rights to Inventions set forth in this Article 11, and each party shall be solely responsible for costs associated with the protection of its intellectual property. For avoidance of doubt, this Article 11 is intended to be in addition to, and not in lieu of, provisions regarding the allocation of rights in intellectual property set forth in the Development Agreement. In particular, this Article 11 shall not affect or impair Article 5 of the Development Agreement. In the event of a conflict between this Article 11 and Article 5 of the Development Agreement, Article 5 of the Development Agreement shall control.

ARTICLE 12
REPRESENTATIONS AND WARRANTIES

12.1 Catalent. Catalent represents, warrants and undertakes to Client that:

A. At the time of delivery by Catalent as provided in Section 6.1, Product shall have been Processed in accordance with Applicable Laws and cGMP and the Product shall be in conformity with the applicable Specifications and the Quality Agreement and shall not have been adulterated, misbranded or mislabeled within the meaning of Applicable Laws and cGMP; *provided*, that Catalent shall not be liable for defects attributable to Client-supplied Materials (including artwork, advertising and labeling);

B. To its knowledge, there are no patents owned by any Third Parties related to the Zydis Technology that are not owned by, or licensed to, Catalent or its Affiliates, that would be infringed or misused by Catalent's performance under this Agreement; and, to its knowledge, no trade secret, trademark, trade name, copyright or other proprietary rights of any Third Party would be infringed or misused by Catalent's performance of this Agreement; provided, however, that Catalent's representation under this Section 12.1 (B) shall not extend to activities conducted by Catalent due to Client's exercise of control over the Processing;

C it will not in the performance of its obligations under this Agreement use the services of any person debarred or suspended under 21 U.S.C. §335(a) or (b);

D Catalent will deliver Product to Client with unencumbered title;

E The Facility and its operation in Processing shall be in compliance with Applicable Laws, including health, safety and environmental permits and Regulatory Approvals, necessary for the operation of the Facility or conduct of the Processing;

F Catalent has not employed and does not employ, and will promptly take appropriate disciplinary actions against and immediately remove from any service, any individual who is or becomes debarred under 21 U.S.C. § 335(a) or (b) or any comparable provision of any other Applicable Laws, and will provide, upon request by Client, a certification that it has not employed and does not employ, and will promptly take appropriate disciplinary actions against and immediately cease using any such individual in the provision of any services under this Agreement; and

G Catalent has the right to use the Zydis Technology in the activities conducted by it in the performance of this Agreement.

12.2 Client. Client represents, warrants and undertakes to Catalent that:

A. [***];

B. The content of all artwork provided by or on behalf of Client to Catalent shall comply with all Applicable Laws;

C. All Product delivered to Client by Catalent shall be held, used and disposed of by or on behalf of the Client in accordance with all Applicable Laws, and Client will otherwise comply with Applicable Laws relating to Client's performance under this Agreement;

D. Client will not release any Batch of Product if the required certificates of conformance indicate that Product does not comply with the Specifications or if Client does not hold all necessary Regulatory Approvals to market and sell the Product;

E. Client has the right to permit Catalent to use in Catalent's performance of this Agreement all Client IP related to the Product, Client-supplied Materials (including artwork) or the Processing of Product and Client-supplied Materials; to its knowledge, there is no patent owned by a Third Party related to the Client IP used to Process Product that would be infringed or misused by Catalent's performance under this Agreement; and, to its knowledge, no trade secret trademark, trade name, copyright or other proprietary right of any Third Party would be infringed or misused by Catalent's performance under this Agreement; provided, however, that Client's representation under this Section 12.2 (E) shall not extend to activities conducted by Catalent except to the extent due to Client's exercise of control over the Processing; and

F. Client will supply Client-supplied Materials to Catalent with unencumbered title.

12.3 Mutual Representation. Furthermore, Catalent and Client both represent, warrant and undertake that no transaction or dealing under this Agreement shall be conducted with or for an

individual or entity that is designated as the target of any sanction, restriction or embargo administered by the United Nations, European Union, United Kingdom, or United States.

12.4 Limitations. THE REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS ARTICLE ARE THE SOLE AND EXCLUSIVE REPRESENTATIONS AND WARRANTIES MADE BY EACH PARTY TO THE OTHER PARTY, AND NEITHER PARTY MAKES ANY OTHER REPRESENTATION, WARRANTY OR GUARANTEE OF ANY KIND WHATSOEVER, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 13
INDEMNIFICATION

13.1 Indemnification by Catalent. Catalent shall indemnify, defend and hold harmless Client, its Affiliates, and their respective directors, officers, employees and agents (collectively, "**Client Indemnitees**") from and against any and all suits, claims, losses, demands, liabilities, damages, costs and expenses (including reasonable attorneys' fees and expenses and reasonable investigative costs) in connection with any suit, demand or action by any third party ("**Losses**") arising out of, relating to or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement; (B) any negligence or willful misconduct by Catalent; or (C) any actual or alleged infringement or violation of any Third Party patent, trade secret, copyright, trademark or other proprietary right by the Zydis Technology; in each case except to the extent that any of the foregoing arises out of or results from any Client Indemnitee's negligence, willful misconduct or breach of this Agreement.

13.2 Indemnification by Client. Client shall indemnify, defend and hold harmless Catalent, its Affiliates, and their respective directors, officers, employees and agents (collectively, "**Catalent Indemnitees**") from and against any and all Losses arising out of, relating to or resulting from (A) any breach of its representations, warranties or obligations set forth in this Agreement, (B) any manufacture, packaging, sale, promotion, distribution or use of or exposure to Product or Client-supplied Materials, including product liability or strict liability, (C) Client's exercise of control over the Processing to the extent that Client's instructions or directions violate Applicable Laws, (D) the conduct of any clinical trial utilizing Product or API, (E) any actual or alleged infringement or violation of any Third Party patent, trade secret, copyright, trademark or other proprietary right by intellectual property or other information provided by Client, including Client-supplied Materials, or (F) any negligence or willful misconduct by Client; in each case except to the extent that any of the foregoing arises out of or results from any Catalent Indemnitee's negligence, willful misconduct or breach of this Agreement. In addition, Client shall indemnify and hold harmless the Catalent Indemnitees from and against any and all Losses arising out of or resulting from any federal regulatory filings by or on behalf of Client or any of its Affiliates, including Losses incurred by Catalent arising from filings under 21 U.S.C. 355 and/or Section 505 of the Food and Drug Act (or non-U.S. equivalents) and related claims or proceedings (including Losses associated with Catalent's obligation to respond to third party subpoenas).

13.3 Indemnification Procedures. All indemnification obligations in this Agreement are conditioned upon the indemnified party (A) promptly notifying the indemnifying party of any

claim or liability of which the indemnified party becomes aware (including a copy of any related complaint, summons, notice or other instrument); *provided*, *however* , that failure to provide such notice within a reasonable period shall not relieve the indemnifying party of its obligations under this Article 13 except to the extent, if any, the indemnifying party is prejudiced by such failure, (B) allowing the indemnifying party, if the indemnifying party so requests, to conduct and control the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense), *provided*, that the indemnifying party shall promptly provide and continuously maintain such defense (C) cooperating with the indemnifying party in the defense of any such claim or liability and any related settlement negotiations (at the indemnifying party's expense) and (D) not compromising or settling any claim or liability without prior written consent of the indemnifying party.

ARTICLE 14
LIMITATIONS OF LIABILITY

14.1 CATALENT SHALL HAVE NO LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS FOR LOST, DAMAGED OR DESTROYED CLIENT-SUPPLIED MATERIALS, WHETHER OR NOT SUCH CLIENT-SUPPLIED MATERIALS ARE INCORPORATED INTO PRODUCT.

14.2 EXCEPT FOR CATALENT'S BREACH OF THE TERMS OF THIS AGREEMENT FOR WILLFUL MISCONDUCT OR GROSS NEGLIGENCE AND CATALENT'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 13 FOR THIRD PARTY DEATH OR BODILY HARM, CATALENT'S TOTAL LIABILITY UNDER THIS AGREEMENT SHALL IN NO EVENT EXCEED [***].

14.3 NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR LOSS OF REVENUES, PROFITS OR DATA ARISING OUT OF PERFORMANCE UNDER THIS AGREEMENT, WHETHER IN CONTRACT OR IN TORT, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE 15
INSURANCE

Each party shall, at its own cost and expense, obtain and maintain in full force and effect during the Term the following: (A) Commercial General Liability insurance with a per-occurrence limit of not less than [***]; (B) Products and Completed Operations Liability insurance with a per-occurrence limit of not less than [***]; (C) Workers' Compensation insurance with statutory limits and Employers Liability insurance with limits of not less than [***] per accident; and (D) All Risk Property insurance, including transit coverage, in an amount equal to the full replacement value of its property while in, or in transit to, the Facility as required under this Agreement. Each party may self-insure all or any portion of the required insurance as long as, together with its Affiliates, its US GAAP net worth is greater than [***] or its annual EBITDA (earnings before interest, taxes, depreciation and amortization) is greater than [***]. Each required insurance policy, other than self-insurance, shall be obtained from an insurance carrier with an A.M. Best rating of at least A- VII. If any required insurance policy is written on a

claims-made basis, such policy shall be maintained throughout the Term and for a period of at least 3 years thereafter. Each party shall obtain a waiver of subrogation clause from its property insurance carriers in favor of the other party. Each party shall be named as an additional insured within the other party's products liability insurance policies; provided, that such additional insured status will apply solely to the extent of the insured party's indemnity obligations under this Agreement. Such waivers of subrogation and additional insured status obligations will operate the same whether insurance is carried through third parties or self-insured. Upon the other party's written request from time to time, each party shall promptly furnish to the other party a certificate of insurance or other evidence of the required insurance or qualification to self-insurance in accordance with the requirements of this Article 15.

ARTICLE 16
TERM AND TERMINATION

16.1 Term. This Agreement shall commence on the Effective Date and shall continue until the later of (i) the expiration or termination of the Development Agreement or (ii) [***] from the commercial Launch of the Product in the Territory, unless earlier terminated in accordance with Section 16.2 (such term, including any extension in accordance with this Section 16.1, the "**Term**"). Unless this Agreement is terminated in accordance with Section 16.2, the Term shall automatically extend for successive 2-year periods unless and until one party gives the other party at least 12 months' prior written notice of its desire to terminate as of the end of the then-current Term.

16.2 Termination. This Agreement may be terminated immediately without further action:

A. by either party if the other party files a petition in bankruptcy, or enters into an agreement with its creditors, or applies for or consents to the appointment of a receiver, administrative receiver, trustee or administrator, or makes an assignment for the benefit of creditors, or suffers or permits the entry of any order adjudicating it to be bankrupt or insolvent and such order is not discharged within 30 days, or takes any equivalent or similar action in consequence of debt in any jurisdiction; or

B. by either party if the other party materially breaches this Agreement and such breach is not cured within 60 days after the giving of written notice requiring the breach to be remedied; *provided*, that in the case of a failure of Client to make payments in accordance with the terms of this Agreement, Catalent may terminate this Agreement if such payment breach is not cured within 10 days of receipt of notice of non-payment from Catalent.

16.3 Effect of Termination. Expiration or termination of this Agreement shall be without prejudice to any right or obligation that accrued to the benefit of either party prior to such expiration or termination. In the event of a termination of this Agreement:

A. Catalent shall promptly return to Client, at Client's expense and direction, any remaining inventory of Product or Client-supplied Materials; *provided*, that all outstanding invoices have been paid in full;

B. Client shall pay Catalent all invoiced amounts outstanding hereunder, plus, upon receipt of invoice therefor, for any (i) Product that has been shipped pursuant to Purchase Orders but not yet invoiced, (ii) Product Processed pursuant to Purchase Orders that has been completed but not yet shipped, and (iii) in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), all Product being Processed pursuant to Purchase Orders (or, alternatively, Client may instruct Catalent to complete such work in process, and the resulting completed Product shall be governed by clause (ii));

C. in the event that this Agreement is terminated for any reason other than by Client pursuant to Section 16.2(A) or (B), Client shall pay Catalent for all costs and expenses incurred, and all noncancellable commitments made, in connection with Catalent's performance of this Agreement, so long as such costs, expenses or commitments were made by Catalent consistent with Client's most recent Firm Commitment and the vendor's minimum purchase obligations.

16.4 Survival. The rights and obligations of the parties shall continue under Articles 11 (Intellectual Property), 13 (Indemnification), 14 (Limitations of Liability), 17 (Notice), 18 (Miscellaneous); under Articles 10 (Confidentiality and Non-Use) and 15 (Insurance), in each case to the extent expressly stated therein; and under Sections 7.4 (Payment Terms), 7.6 (Taxes), 7.7 (Client and Third Party Expenses), 9.1 (Recordkeeping), 9.5 (Recall), 12.4 (Limitations), 16.3 (Effect of Termination) and 16.4 (Survival), in each case in accordance with their respective terms if applicable, notwithstanding expiration or termination of this Agreement.

ARTICLE 17
NOTICE

All notices and other communications under this Agreement shall be in writing and shall be deemed given: (A) when delivered personally or by hand; (B) when delivered by electronic mail (e-mail); (C) when delivered by facsimile transmission (receipt verified); (D) when received or refused, if sent by registered or certified mail (return receipt requested), postage prepaid; or (E) when delivered, if sent by express courier service; in each case to the parties at the following addresses (or at such other address for a party as shall be specified by like notice; *provided*, that notices of a change of address shall be effective only upon receipt thereof):

To Client: Biohaven Pharmaceuticals, Inc.
234 Church Street, Suite 301
New Haven, CT 06510 USA
Attn: Robert Berman, M.D. Chief Medical Officer
email: robert.berman@biohavenpharma.com

With a copy to: IPraxus Legal, LLC
67 Sterling Hill Road
P.O. Box 689
Lyme, CT 06371 US
Attn: Warren K. Volles
Email: mail@ipraxuslegal.com

To Catalent: Catalent U.K. Swindon Zydis Limited
Frankland Road
Blagrove
Swindon
Wiltshire SN5 8RU
United Kingdom
Attn: VP/GM Modified Release Technologies
Facsimile: +44 1793 886998]

With a copy to: Catalent Pharma Solutions, LLC
14 Schoolhouse Road
Somerset, NJ 08873
USA
Attn: General Counsel (Legal Department)
E-Mail: GenCouns@catalent.com
Facsimile: +1 (732) 537-6491

ARTICLE 18
MISCELLANEOUS

18.1 Entire Agreement; Amendments. This Agreement, together with the Quality Agreement and the Development Agreement, constitutes the entire understanding between the parties, and supersedes any contract, agreement or understanding (oral or written) of the parties, with respect to its subject matter. For the avoidance of doubt, this Agreement does not supersede any existing generally applicable confidentiality agreement between the parties as it relates to periods prior to the Effective Date or to business dealings not covered by this Agreement. No term of this Agreement may be amended except upon written agreement of both parties, unless otherwise expressly provided in this Agreement.

18.2 Captions; Certain Conventions. The captions in this Agreement are for convenience only and are not to be interpreted or construed as a substantive part of this Agreement. Unless otherwise expressly provided in this Agreement or the context of this Agreement otherwise requires, (A) words of any gender include each other gender, (B) words such as "herein", "hereof", and "hereunder" refer to this Agreement as a whole and not merely to the particular provision in which such words appear, (C) words using the singular include the plural, and vice versa, (D) the words "include(s)" and "including" shall be deemed to be followed by the phrase "but not limited to", "without limitation" or words of similar import, (E) the word "or" shall be deemed to include the word "and" (*e.g.*, "and/or"), (F) references to "Article," "Section," "subsection," "clause" or other subdivision, or to an Attachment or other appendix, without reference to a document are to the specified provision or Attachment of this Agreement, and (G) subject to Applicable Laws, all references to liabilities or obligations of Catalent shall be subject to Article 14, regardless of whether the particular provision includes a cross-reference to Article 14. This Agreement shall be construed as if it were drafted jointly by the parties.

18.3 Further Assurances. The parties shall execute, acknowledge and deliver such further instruments and take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

18.4 No Waiver. Failure by either party to insist upon strict compliance with any term of this Agreement in any one or more instances will not be deemed a waiver of its rights to insist upon such strict compliance with respect to any subsequent failure.

18.5 Severability. If any term of this Agreement is declared invalid or unenforceable by a court or other body of competent jurisdiction, the remaining terms of this Agreement will continue in full force and effect.

18.6 Independent Contractors. The relationship of the parties is that of independent contractors, and neither party will incur any debt or make any commitment for the other party except to the extent expressly provided in this Agreement. Nothing in this Agreement is intended to create or will be construed as creating between the parties the relationship of joint venturers, co-partners, employer/employee or principal and agent. Neither party shall have any responsibility for the hiring, termination or compensation of the other party's employees or contractors or for any employee benefits of any such employee or contractor.

18.7 Successors and Assigns. This Agreement will be binding upon and inure to the benefit of the parties, their successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other party, except that either party may, without the other party's consent (but subject to prior written notice), assign its rights and delegate its duties under this Agreement to an Affiliate (and in the case of Client, to a Collaborator, upon Catalent's written consent, which shall not be unreasonably withheld) or to a successor that acquires (through the purchase of assets, stock or otherwise) substantially all of the business or assets of the assigning party to which this Agreement relates and any assignment in violation of this Section 18.7 shall be void *ab initio*.

18.8 No Third Party Beneficiaries. This Agreement shall not confer any right or remedy upon any individual or entity other than the parties and their respective successors and permitted assigns, except that the Client Indemnitees and the Catalent Indemnitees may invoke the benefits of the indemnification provisions of this Agreement.

18.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware, USA, excluding its conflicts of law provisions. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

18.10 Alternative Dispute Resolution. Any dispute arising between the Parties in connection with this Agreement shall first be presented to the respective senior executives of the Parties for their consideration and resolution. If such Parties' executives cannot resolve such dispute within ninety (90) days, then such dispute may submitted be either Party to arbitration by the International Institute for Conflict Prevention and Resolution, 575 Lexington Avenue, 21st Floor, New York, NY 10022 ("**CPR**") by one arbitrator selected by the Parties. If no agreement on an arbitrator can be reached within thirty (30) days after the CPR offers names of potential arbitrators, then the CPR will choose one arbitrator having reasonable experience in commercial

transactions of the type described in this Agreement. The arbitration shall take place in the English language in New York City, New York, in accordance with the CPR administered arbitration rules then in effect, and judgment upon any award rendered in such arbitration will be binding and may be entered in any court having jurisdiction of the matter. The arbitration shall commence within sixty (60) days of the date on which a written demand for arbitration is filed. The arbitrator's decision shall set forth a reasoned basis for any award of damages or finding of liability. The arbitrator shall not have power to award damages in excess of actual compensatory damages and shall not multiply actual damages or award punitive damages. The arbitrator shall award to the prevailing party, if any, its costs and attorneys' fees and expenses reasonably incurred in connection with the arbitration, including any subsequent or related enforcement proceeding.

18.11 Prevailing Party. In any dispute resolution proceeding between the parties in connection with this Agreement, the prevailing party will be entitled to recover its reasonable attorney's fees and costs in such proceeding from the other party.

18.12 Publicity. Neither party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other party's express prior written consent, except as required under Applicable Laws, by any governmental agency or by the rules of any stock exchange on which the securities of the disclosing party are listed, in which case the party required to make the press release or public disclosure shall use commercially reasonable efforts to obtain the approval of the other party as to the form, nature and extent of the press release or public disclosure prior to issuing the press release or making the public disclosure.

18.13 Right to Dispose and Settle. If Catalent requests in writing from Client direction with respect to disposal of any inventories of Product, Client-supplied Materials, equipment, samples or other items belonging to Client and is unable to obtain a response from Client within a reasonable period after making reasonable efforts to do so, Catalent shall be entitled in its sole discretion to (A) dispose of all such items and (B) set-off any and all amounts due to Catalent or any of its Affiliates from Client against any credits Client may hold with Catalent or any of its Affiliates.

18.14 Force Majeure. Except as to payments required under this Agreement, neither party shall be liable in damages for, nor shall this Agreement be terminable or cancelable by reason of, any delay or default in such party's performance hereunder if such default or delay is caused by events beyond such party's reasonable control, including acts of God, law or regulation or other action or failure to act of any government or agency thereof, war or insurrection, civil commotion, destruction of production facilities or materials by earthquake, fire, flood or weather, labor disturbances, epidemic or failure of suppliers, vendors, public utilities or common carriers; *provided*, that the party seeking relief under this Section 18.14 shall promptly notify the other party of such cause(s) beyond such party's reasonable control. The party that may invoke this Section 18.14 shall use commercially reasonable efforts to reinstate its ongoing obligations to the other party as soon as practicable. If the cause(s) shall continue unabated for 180 days, then both parties shall meet to discuss and negotiate in good faith what modifications to this Agreement should result from such cause(s).

18.15 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Any photocopy, facsimile or electronic reproduction of the executed Agreement shall constitute an original.

[Signature page follows]

IN WITNESS WHEREOF, the parties have caused their respective duly authorized representatives to execute this Agreement effective as of the Effective Date.

CATALENT U.K. SWINDON ZYDIS LIMITED

By: /s/ Peter Allen
Name: Peter Allen
Title: General Manager

Biohaven Pharmaceuticals, Inc.

By: /s/ Vlad Coric
Name: Vlad Coric
Title: CEO and Director

Exhibit 21.1

SUBSIDIARIES OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

Name	Jurisdiction of Incorporation
Biohaven Pharmaceuticals, Inc.	Delaware
Biohaven Asia Pacific Ltd.	British Virgin Islands
BioShin Hong Kong Limited	Hong Kong
Biohaven Therapeutics Ltd.	British Virgin Islands
Biohaven Ireland Limited	Ireland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333-232167) and on Form S-8 (Nos. 333-233197, 333-225224 and 333-218193) of Biohaven Pharmaceutical Holding Company Ltd. of our report dated February 25, 2020 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut
February 25, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Vlad Coric, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2019 of Biohaven Pharmaceutical Holding Company Ltd. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: February 25, 2020

/s/ VLAD CORIC, M.D.

Vlad Coric, M.D.
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James Engelhart, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2019 of Biohaven Pharmaceutical Holding Company Ltd. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: February 25, 2020

/s/ JAMES ENGELHART

James Engelhart
Chief Financial Officer
(principal financial officer)

Exhibit 32.1

CERTIFICATIONS OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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), Vlad Coric, M.D., Chief Executive Officer of Biohaven Pharmaceutical Holding Company Ltd. (the "Company"), and James Engelhart, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2019, to which this Certification is attached as Exhibit 32.1 (the "Periodic 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 Periodic 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 25 day of February 2020.

/s/ VLAD CORIC, M.D.	/s/ JAMES ENGELHART
Vlad Coric, M.D.	James Engelhart
Chief Executive Officer	*Chief Financial Officer*
(principal executive officer)	*(principal financial officer)*

***** This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.