# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

	FO	RM 10-K	
Mark One)  ANNUA	L REPORT PURSUANT TO SECTION 1	3 OR 15(d) OF THE SECUF	
	For the fiscal ye	ar ended December 31, 2021	
	•	or	
□ TRA	ANSITION REPORT PURSUANT TO SE	CTION 13 OR 15(d) OF TH	E SECURITIES EXCHANGE ACT OF 193
	For the transition	period from to	
	Commission	File Number: 001-38080	
	Biohaven Pharmaceut	istrant as Specified in its Charter)	Mot applicable S. Employer Identification No.)
	o Biohaven Pharmaceuticals, Inc. hurch Street, New Haven, Connecticut		06510
	ddress of principal executive offices)		(Zip Code)
	(2	203) 404-0410	
	(Registrant's telepho	one number, including area code)	
Securities registered pursuant	to Section 12(b) of the Act:		
Title of each	class Tradi	ng Symbol	Name of each exchange on which registered
Common Shares, with	nout par value	BHVN	New York Stock Exchange
Indicate by check mark if the r	to Section 12(g) of the Act: <b>None</b> egistrant is a well-known seasoned issuer, as defined in		

Indicate by check mark whether the registrant: (1) 12 months (or for such shorter period that the registrant		by Section 13 or 15(d) of the Securities Exchange Ac (2) has been subject to such filing requirements for the securities of the securities are the securities and the securities are the	
Indicate by check mark whether the registrant has this chapter) during the preceding 12 months (or for such		ve Data File required to be submitted pursuant to Rul required to submit such files). Yes $\boxtimes$ No $\square$	e 405 of Regulation S-T (§ 232.405 of
Indicate by check mark whether the registrant is a the definitions of "large accelerated filer," "accelerated f		filer, a non-accelerated filer, a smaller reporting comp "emerging growth company" in Rule 12b-2 of the Exc	
Large accelerated filer	$\boxtimes$	Accelerated filer	
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If an emerging growth company, indicate by check accounting standards provided pursuant to Section 13(		o use the extended transition period for complying wit	h any new or revised financial
Indicate by check mark whether the registrant has under Section 404(b) of the Sarbanes-Oxley Act (15 U.		nanagement's assessment of the effectiveness of its i accounting firm that prepared or issued its audit report	
Indicate by check mark whether the registrant is a	shell company (as defined in Rule 12b-	-2 of the Exchange Act). Yes □ No 🗷	
The aggregate market value of the registrant's cor fiscal quarter, June 30, 2021, based on the last reporter calculation does not reflect a determination that certain par value per share, outstanding.	d sale price of the registrant's common		2021 of \$97.08, was \$4.260 billion. The
	Documents Incor	porated by Reference	
Portions of the registrant's definitive Proxy Statem are incorporated by reference into Part III of this Annua		4A under the Securities Exchange Act of 1934 for its	2022 Annual Meeting of Shareholders

Unless the context requires otherwise, references in this report to "Biohaven," the "Company," "we," "our" or "us" refer to Biohaven Pharmaceutical Holding Company Ltd. and its subsidiaries.

## **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:

- the timing of and potential for U.S. Food and Drug Administration ("FDA") approval of, and our plans to develop and commercialize, our product candidates;
- our ongoing and planned clinical trials, including discovery and proof of concept trials, the status of our ongoing clinical trials, commencement dates for new clinical trials, and the timing of clinical trial results;
- · our plans to pursue research and development of other products;
- our ability to enter into additional collaborations with third parties;
- · anticipated future milestones, contingent and royalty payments and lease payments (and, in each case, their expected impact on liquidity);
- · the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- · our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position:
- the rate and degree of market acceptance of our products or product candidates, and our estimates regarding the potential market opportunity for our product candidates:
- · our competitive position, including our competitors and competing products (including biosimilars);
- · anticipated impact of interest rate changes on our financial statements;
- the timing and anticipated amounts of future tax payments and benefits (including the potential recognition of unrecognized tax benefits), as well as timing of conclusion of tax audits;
- · our estimates regarding future revenues, expenses and needs for additional financing; and
- the impacts of the COVID-19 pandemic on our business, operations, commercialization plans, clinical trials, regulatory timelines and other plans.

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.

# **Note Regarding Trademarks**

We have proprietary rights to a number of registered and unregistered trademarks worldwide that we believe are important to our business, including but not limited to NURTEC ODT. We have, in certain cases, omitted the ® and ™ designations for these and other trademarks used in this Annual Report on Form 10-K. Nevertheless, all rights to such trademarks are reserved. These and other trademarks referenced in this Annual Report on Form 10-K are the property of their respective owners.

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# **PART I**

#### Item 1. Business

#### Overview

We are a commercial-stage biopharmaceutical company with a portfolio of innovative, best-in-class therapies to improve the lives of patients with debilitating neurological and neuropsychiatric diseases, including rare disorders. Our Neuroinnovation portfolio includes FDA-approved NURTEC ODT (rimegepant) for the acute and preventive treatment of migraine and a broad pipeline of product candidates across five distinct mechanistic platforms: calcitonin gene related peptide ("CGRP") receptor antagonism, glutamate modulation, myeloperoxidase ("MPO") inhibition, Kv7 Ion Channel Activators ("Kv7"), and Myostatin.

In November 2021, we entered into a strategic licensing and collaboration arrangement (the "Collaboration Agreement") with Pfizer Inc. pursuant to which Pfizer would gain rights to commercialize rimegepant and zavegepant in all countries worldwide outside of the United States. The Collaboration Agreement became effective January 4, 2022. Refer to Note 19 "Subsequent Events" of the Notes to Consolidated Financial Statements included in this report for additional information regarding the Collaboration Agreement.

# **Product Pipeline**

**Exclusive Commercial Product** 



The Migraine Research Foundation ranks migraine as the world's third most prevalent illness, with approximately 40 million individuals suffering from migraine attacks in the U.S., and 1 billion worldwide. While most sufferers experience migraine attacks once or twice per month, more than 4 million people in the U.S. alone 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 fewer than 15 migraine days per month. People with frequent episodes of migraine may progress to chronic migraine over time, thus migraine is a continuum disease.

Our exclusive commercial product, NURTEC ODT (rimegepant) for the acute treatment of migraine, was approved by the U.S. Food and Drug Administration ("FDA") on February 27, 2020 and became available by prescription in U.S. pharmacies on March 12, 2020. NURTEC ODT was also approved for the preventive treatment of migraine by the FDA on May 27, 2021. NURTEC ODT is the first and only medication proven to both treat and prevent migraine. We believe NURTEC ODT differentiates itself as a treatment in the migraine market because it allows patients and doctors to customize a single therapy to treat and prevent migraine attacks. It is further differentiated by its rapid onset and sustained efficacy for lasting migraine control.

In a study of people who took either NURTEC ODT (669 people) or placebo (682 people), more people taking NURTEC ODT experienced pain freedom and freedom from their most bothersome symptom (selected from light sensitivity, sound sensitivity, or nausea) at 2 hours vs placebo. Additionally, more people taking NURTEC ODT experienced freedom from functional disability and pain relief as early as 60 minutes vs placebo. These benefits were sustained through 48 hours for some people.

We have been successful at capturing the value of NURTEC ODT and bringing NURTEC ODT to migraine suffers and have exceeded the greater than 400% revenue growth in the United States ("U.S.") of the oral CGRP class with over 600% product revenue growth in 2021 versus 2020. As of January 28, 2022, NURTEC ODT leads the oral CGRP market in total prescriptions ("TRx") at 51.2% share (source: IQVIA SMART). In addition, we continue to expand payer coverage, with NURTEC ODT covered by insurance providers reflecting 89% coverage, and over 240 million covered lives in all channels.

NURTEC ODT is providing fast and lasting relief to more and more migraine patients each day. The entire oral CGRP class is outperforming initial launch expectations and reflects the importance of these medications to individuals with migraine. NURTEC ODT is now the number one migraine treatment in its class.

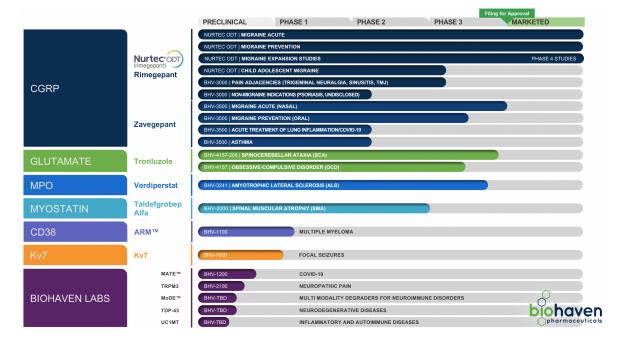
# Global Expansion of Rimegepant

We continue to aggressively expand the rimegepant franchise globally. Currently, there are four international regulatory approvals for rimegepant for the acute treatment of migraine, two international regulatory approvals for rimegepant for the preventive treatment of migraine and twelve regulatory submissions for rimegepant for the acute and preventive treatments of migraine. On November 9, 2021, we announced a strategic collaboration with Pfizer for markets outside the U.S. The collaboration combines our neuroscience research and development expertise with Pfizer's commercialization and marketing excellence to pave the way to bring rimegepant's dual therapy innovation to as many of the 1 billion migraine sufferers around the world as possible.



#### **Clinical Development Programs**

The following table summarizes our recent and expected future clinical development milestones for our product candidates. We hold the worldwide rights to all of our products and product candidates, including NURTEC ODT, which we have licensed to Pfizer to commercialize outside the United States for the treatment and prevention of migraine in accordance with the Collaboration Agreement.



## **CGRP Platform**

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 antimigraine 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 blocking neurogenic inflammation, decreasing artery dilation and inhibiting pain transmission.

# Rimegepant

Rimegepant is the most advanced product candidate from our CGRP receptor antagonist platform. It is an orally available, potent and selective small molecule human CGRP receptor antagonist that we developed for the acute and preventive treatment of migraine, and are developing for other non-migraine

indications as well such as trigeminal neuralgia, rhinosinusitis, temporomandibular disorder ("TMD") and psoriasis. The Zydis ODT formulation of rimegepant (NURTEC ODT) was approved by the FDA for the acute treatment of migraine on February 27, 2020. During the fourth quarter of 2020, we submitted a supplemental New Drug Application ("sNDA") to the FDA for the use of rimegepant in the preventive treatment of migraine, which was approved on May 27, 2021.

In February 2022, we announced positive top-line results from an Asia-Pacific, Phase 3 clinical trial of NURTEC ODT in adults for the acute treatment of migraine. Led by BioShin Limited, our subsidiary in China and South Korea, the randomized, double-blind, placebo-controlled, regional, multi-center study met the co-primary endpoints evaluating the efficacy and safety of the ODT formulation of rimegepant, an oral CGRP receptor antagonist. This is the fifth positive pivotal study of rimegepant and the first to be conducted in Asia Pacific. The study met its co-primary endpoints of freedom from pain (p<0.0001) and freedom from most bothersome migraine-associated symptom ("MBS") including either nausea, phonophobia or photophobia (p<0.0001) at 2-hours following a single oral dose of rimegepant. The early onset and durable 48 hour efficacy observed in China and South Korea was consistent with previous clinical trial results. In addition

to the co-primary endpoints, NURTEC ODT demonstrated rapid onset efficacy that was superior to placebo on multiple clinically important outcomes, including: pain relief at 2 hours (p < 0.0001); normal functioning at 2 hours post-dose (p<0.0001); no need for rescue medication within 24 hrs of dosing (p < 0.0001), and showed lasting efficacy with sustained pain freedom from 2 through 24 hours (p < 0.0001) and sustained pain freedom from 2 through 48 hours (p < 0.0001). Initial analysis of topline data indicates NURTEC ODT was numerically advantaged compared to placebo on multiple early-onset measures, including: pain relief within 45 minutes and freedom from MBS within 45 minutes; return to normal function within 60 min; and pain freedom within 90 min. Rimegepant also showed a favorable safety and tolerability profile among study participants that was consistent with prior clinical trial results in the United States. Detailed data from the study will be presented at future medical meetings to help inform ongoing and future research. We expect to submit an NDA during the second half of 2022.

In February 2022, we were notified that the Committee for Medicinal Products for Human Use ("CHMP"), a committee of the European Medicines Agency, adopted a positive opinion, recommending the granting of a marketing authorization in the European Union ("EU") for rimegepant 75 mg (available as an orally dissolving tablet), intended for the prophylaxis and acute treatment of migraine. If approved, VYDURA (rimegepant) will be the commercial name for rimegepant in the EU. The full indication for VYDURA is the acute treatment of migraine with or without aura in adults and preventive treatment of episodic migraine in adults who have at least four migraine attacks per month. We expect to receive determination regarding our Marketing Authorization Application in the EU for rimegepant in the first half of 2022.

# Zavegepant

Zavegepant represents a novel chemical structure compared to other small molecule CGRP receptor antagonists in development (including rimegepant). We are developing zavegepant for the acute and preventive treatment of migraine as well as respiratory complications and non-migraine studies, with initial studies being conducted in acute treatment. We believe it has the potential to improve the existing standard of care based on its multiple potential routes of delivery, favorable safety profile, superior chemical attributes, higher value to patients and payors and potential for multiple indications.

In December 2021, we announced top-line results from our Phase 3 trial for the use of intranasal zavegepant for the acute treatment of migraine. The results of the study showed that zavegepant was statistically superior to placebo on the co-primary endpoints of pain freedom (24% vs 15%, p <.0001) and freedom from most bothersome symptom (40% vs 31%, p = 0.0012) at 2 hours. Zavegepant was superior to placebo demonstrating pain relief as early as 15 minutes, with patients achieving return to normal

function as early as 30 minutes after dosing (p < 0.006). The efficacy benefits of zavegepant were durable, including superiority versus placebo (p < 0.05) on: sustained pain freedom 2 to 24 hours; sustained pain freedom 2 to 48 hours; sustained pain relief 2 to 24 hours; and sustained pain relief 2 to 48 hours. Based upon these results, combined with our prior positive Phase 2/3 trial, we plan to proceed with regulatory submissions in the United States and other countries and expect to submit a New Drug Application ("NDA") for zavegepant with the FDA in the first half of 2022.

Our Phase 2/3 trial for the use of oral zavegepant for the preventive treatment of migraine is ongoing, with results expected in the second half of 2022.

# **Next Generation CGRP Receptor Antagonists**

In November 2020, we entered into a global collaboration and license agreement with Heptares Therapeutics Ltd. ("Sosei Heptares"), an international biopharmaceutical group focused on the discovery and early development of new medicines originating from their proprietary GPCR-targeted StaR technology and structure-based drug design platform capabilities. Under the agreement, Sosei Heptares will be eligible to receive development, regulatory and commercialization milestone payments, as well as tiered royalties on net sales of products resulting from the collaboration. In return, we will receive exclusive global rights to develop, manufacture and commercialize a portfolio of novel. small-molecule CGRP receptor antagonists discovered by Sosei Heptares for the treatment of CGRP-mediated disorders, including nonmigraine indications. The portfolio included the lead candidate HTL0022562, referred to as BHV-3100, which had advanced through preclinical development demonstrating promising and differentiated properties for further investigation in human trials. During the fourth quarter of 2021, we decided to stop development of BHV-3100 based upon its emerging preclinical profile and will instead advance one of the portfolio's backup compounds in its place.

#### **Glutamate Platform**

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.

## Troriluzole

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. We believe troriluzole offers potential advantages, compared to orally dosed riluzole including

improved bioavailability, no negative food effect, lower overall drug burden to the liver, optimized dosing regimen and compliance and potential for developing multiple formulations.

#### Spinocerebellar Ataxia

Our initial development has focused on the use of troriluzole in treating SCA, an orphan neurological disease characterized by problems with coordination, balance and movement. Currently there are no approved drug therapies for SCA. SCA was chosen as the lead indication based on a strong preclinical rationale as well as demonstration of preliminary efficacy of the active metabolite in troriluzole, riluzole, in two randomized controlled trials in patients with SCA and other ataxias conducted by third parties (Ristori 2010; Romano 2015). We have received both orphan drug designation and fast track designation from the FDA for troriluzole for the treatment of SCA.

Initially, we had conducted a Phase 2b/3, randomized, double-blind, placebo-controlled, parallel-group study to assess the safety and efficacy of troriluzole over 8 weeks in subjects with SCA. In October 2017, we announced that troriluzole at a dose of 140 mg QD did not differentiate from placebo on the primary endpoint of the mean change from baseline on the Scale for Assessment and Rating of Ataxia (SARA) total score after 8 weeks of treatment. During open-label treatment over the 48-week extension phase, however, troriluzole did show slowing of disease progression in troriluzole-treated subjects in contrast to the measurable decline expected for a cohort of untreated subjects based on the natural history of the disease. An expanded open-label extension phase for this study is ongoing. Based on our learnings from the Phase 2b/3 study, including analyses from the open-label extension phase, we are now conducting a Phase 3, randomized, double-blind, placebo-controlled, parallel-group study to assess the safety and efficacy of troriluzole over 48 weeks in subjects with SCA. We enriched this trial with specific SCA genotypes, extended the treatment period of this trial to 48 weeks. implemented the use of a modified SARA scale, and increased the dose of troriluzole to 200 mg QD. We believe that these changes may improve the ability of the trial to more accurately evaluate troriluzole's benefit in slowing disease progression in patients with SCA. In March 2019, we announced the initiation of the trial, which subsequently completed enrollment in the first quarter of 2021, with results expected in the first half of 2022.

# Obsessive Compulsive Disorder

We are developing troriluzole for OCD, which 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. In multiple case studies, the use of the active metabolite in troriluzole, riluzole, in patients with refractory OCD has commonly been associated with meaningful improvement of symptoms.

A Phase 2/3 double-blind, randomized, controlled trial to assess the efficacy of troriluzole in OCD commenced in December 2017. Enrollment in this study was completed in the first guarter of 2020. The Phase 2/3 study results were announced in June 2020. Troriluzole 200 mg administered once daily as adjunctive therapy in OCD patients with inadequate response to standard of care treatment showed consistent numerical improvement over placebo on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) at all study time points (weeks 4 to 12) but did not meet the primary outcome measure at week 12 (p = 0.22 at week 12) but was significant at week 8 (p < 0.05). Troriluzole was well tolerated with a safety profile consistent with past clinical trial experience. Given the strong signal in our Phase 2/3 proof of concept study and after receiving feedback from the FDA in an End of Phase 2 meeting, in December 2020 we initiated enrollment in the Phase 3 program. Two Phase 3 studies are currently ongoing with results expected in the second half of 2022.

#### Alzheimer's Disease

We conducted a clinical trial of troriluzole for Alzheimer's disease, 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, suggested the active metabolite of troriluzole, riluzole, protects from Alzheimer's-related pathology and cognitive dysfunction.

In January 2021, we announced top-line results from the study. Troriluzole did not statistically differentiate from placebo at 48 weeks on the study's prespecified co-primary endpoints on the ADAS-cog and the Clinical Dementia Rating Scale Sum of Boxes (CDR-SB) in study participants with mild-to-moderate AD. Troriluzole also did not differentiate from placebo on the key secondary measure of hippocampal volume assessed by MRI in the overall population. A subgroup analysis consisting only of mild AD patients did, however, reveal that troriluzole exhibited a nonsignificant numerical difference of a potential benefit at week 48 on both the ADAS-cog and hippocampal volumetric MRI. With regard to safety and tolerability, treatment with troriluzole at a dose of 280 mg once daily was relatively well tolerated and demonstrated a safety profile consistent with previous studies of troriluzole. In December 2021, we completed an ongoing long-term extension study of troriluzole in AD for mild AD patients.

#### 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/Stanford University). The oncology collaborations with Rutgers and Johns Hopkins/Stanford University 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.

In December 2021, the Global Coalition for Adaptive Research ("GCAR") selected troriluzole for evaluation in Glioblastoma Adaptive Global Innovative Learning Environment - NCT03970447 ("GBM AGILE"). GBM AGILE is a revolutionary patient-centered, adaptive platform trial for registration that tests multiple therapies for patients with newly-diagnosed and recurrent glioblastoma ("GBM"). Troriluzole will be evaluated in all patient subgroups of the trial which include newly-diagnosed methylated MGMT, newly-diagnosed unmethylated MGMT, and recurrent GBM. Troriluzole was selected for inclusion in GBM AGILE based on compelling evidence showing deregulation of glutamate in GBM. The therapeutic potential of troriluzole in GBM and other oncology indications is supported by several recent clinical and translational research studies conducted with troriluzole and its active moiety.

#### BHV-5000 and BHV-5500

An N-methyl-D-aspartate ("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. 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. Results from nonclinical studies limiting clinical dose of BHV-5000 have led us to focus on formulation development of BHV-5500 (lanicemine).

# Rett Syndrome

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. 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 standard of care is supportive.

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, and 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.

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.

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. Potential other conditions include depression, neuropathic pain and other disorders involving NMDA receptor dysfunction.

# 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. 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.

#### 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**

# Verdiperstat

Verdiperstat is a first-in-class, potent, selective, brain-permeable, irreversible MPO. MPO generates an array of cytotoxic oxidants and is a key driver of oxidative and inflammatory processes that underlie a broad range of disorders. MPO 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. In February 2019, we received orphan drug designation from the FDA for the treatment of Multiple System Atrophy ("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.

#### 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.

A Phase 3 randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of verdiperstat in participants with MSA began enrollment in July 2019. Ambulatory participants, 40-80 years of age, with possible or probable MSA,

including MSA-P or MSA-C, are randomized to 48 weeks of treatment with verdiperstat 600-mg BID or placebo. The primary efficacy endpoint is change from baseline to Week 48 in verdiperstat- vs. placebo-treated participants on a score derived from the Unified MSA Rating Scale, optimized based on FDA guidance to assess clinically meaningful change in ability to function. Between July 2019 and July 2020, 336 participants with MSA were enrolled at 48 sites across 6 countries (US, UK, France, Germany, Italy, Austria). In September 2021, we announced that Verdiperstat did not statistically differentiate from placebo on the prespecified primary efficacy measure, nor on the key secondary efficacy measures. Initial analysis of safety data was consistent with the overall profile of verdiperstat from prior clinical trial experience. Additional analyses are still pending, and full study results will be presented at an upcoming scientific meeting.

## Amyotrophic Lateral Sclerosis

Another potential target indication for verdiperstat is Amyotrophic Lateral Sclerosis ("ALS"). In September 2019, we announced that verdiperstat was selected to be studied in the pivotal 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. The HEALEY ALS Platform Trial is a perpetual multi-center, multi-regimen clinical trial evaluating the safety and efficacy of investigational products for the treatment of ALS. HEALEY ALS Platform Trial Regimen B is evaluating the safety and efficacy of verdiperstat in approximately 160 adults with ALS. Participants were randomized in a 3-to-1 ratio treated with verdiperstat 600 mg BID or placebo for 24 weeks. The study's primary efficacy endpoint measures the change in disease severity from baseline to week 24 on the ALS Functional Rating Scale-Revised in patients receiving treatment versus placebo. Secondary endpoints include change in respiratory function, muscle strength, and survival. In August 2020, we announced that the first patients were enrolled in the pivotal HEALEY ALS Platform Trial Regimen B. Enrollment in the trial was completed in November of 2021, with results expected mid-2022.

# Kv7 Platform

# **BHV-7000**

In February 2022, we announced that we entered into a definitive agreement with Channel Biosciences, LLC, a subsidiary of Knopp Biosciences, LLC, to acquire a Kv7 channel targeting platform, adding the latest advances in ion-channel modulation to our growing neuroscience portfolio. BHV-7000 (formerly known as KB-3061) is the lead asset from the Kv7 platform and is a potentially best-in-class potassium channel activator

with a profile suggestive of a wide therapeutic index, high selectivity, and significantly reduced GABA-ergic activity. We intend to bring BHV-7000 to the clinic in in 2022 in preparation for a development program in focal epilepsy.

# **Myostatin Platform**

# Taldefgrobep Alfa License Agreement

In February 2022, following the transfer of intellectual property we announced that we entered into a worldwide license agreement with Bristol-Myers Squibb Company ("BMS") for the development and commercialization rights to taldefgrobep alfa (also known as BMS-986089), a novel, Phase 3-ready anti-myostatin adnectin. Myostatin is a natural protein that limits skeletal muscle growth, an important process in healthy muscular development. However, in patients with neuromuscular diseases, active myostatin can critically limit the growth needed to achieve developmental and functional milestones. Myostatin inhibition is a promising therapeutic strategy for enhancing muscle mass and strength in a range of pediatric and adult neuromuscular conditions. Taldefgrobep is a muscle-targeted treatment for neuromuscular disease and offers the opportunity for combination therapy. We plan to initiate a Phase 3 clinical trial of taldefgrobep in Spinal Muscular Atrophy ("SMA") in 2022. SMA is a rare, progressively debilitating motor neuron disease in which development and growth of muscle mass are compromised, resulting in progressive weakness and muscle atrophy, reduced motor function, impaired quality of life and often death. The in-licensing of taldefgrobep expands our portfolio of innovative, late-stage product candidates for the treatment of neurologic, neuroinflammatory, and psychiatric indications.

#### **Biohaven Labs**

# Kleo Pharmaceuticals, Inc. and Biohaven Labs

In January 2021, we acquired the remaining approximately 58% of Kleo Pharmaceuticals, Inc. ("Kleo") that we did not previously own. We have assumed Kleo's laboratory facilities located in Science Park in New Haven, Connecticut and formed Biohaven Labs to serve as the integrated chemistry and discovery research arm of Biohaven. Biohaven Labs will continue several existing Kleo discovery partnerships, including one with the Bill and Melinda Gates Foundation for the development of a Hyperimmune Globulin Mimic for COVID-19 and PeptiDream for the development of immuno-oncology therapeutics.

Our proprietary Multimodal Antibody Therapy Enhancer ("MATE") conjugation technology uses a new class of synthetic peptide binders to target the spike protein of SARS-CoV-2 that are then selectively conjugated to commercially available intravenous immunoglobulin. The Biohaven synthetic binders for SARS-CoV2 were designed to establish a much wider area and number of contacts with the spike protein that

other agents like monoclonal antibodies. In February 2021, we announced that BHV-1200 developed with our proprietary MATE platform has demonstrated functional binding and neutralization of the SARS-CoV-2 virus, including the strains known as the "English" and "South African" variants (also known as B.1.1.7 and B.1.351, respectively). The preliminary experiments conducted by Biohaven Labs and an academic collaborator demonstrated that BHV-1200 substantially reduced viral entry into cells. We intend to advance BHV-1200 into a full clinical development program. Accelerated development of the COVID-19 MATE program has been supported by the Bill and Melinda Gates Foundation. In addition, the in vitro data indicated that BHV-1200 may activate important immune system components including antibody-dependent cellular phagocytosis and antibody dependent cellular cytotoxicity. We believe our proprietary MATE-conjugation technology could also be used against other infectious diseases by changing the targeting moiety of its antibody binders.

# TDP-43

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 us 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 Biohaven.

# 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.

# Artizan Biosciences Inc License Option

In December 2020, we entered into an Option and License Agreement with Artizan Biosciences Inc ("Artizan"), a biotechnology company focused on addressing inflammatory diseases involving the human intestinal microbiota. Pursuant to the agreement, we acquired an option to obtain a royalty-based license from Artizan to manufacture, use and commercialize certain products. Artizan will use the proceeds to continue advancing the preclinical research and development of its lead program for inflammatory bowel

disease, which is anticipated to enter the clinic in 2022, as well as to explore additional disease targets.

#### BHV-1100

In the fourth quarter of 2021, we initiated a Phase 1a/1b trial in multiple myeloma patients using its antibody recruiting molecule ("ARM") BHV-1100 in combination with autologous cytokine induced memory-like ("CIML") natural killer (NK) cells and immune globulin ("IG") to target and kill multiple myeloma cells expressing the cell surface protein CD38. BHV-1100 is the lead clinical asset from our ARM™ Platform developed from a strategic alliance with PeptiDream Inc. (TYO: 4587). This clinical trial will assess the safety and tolerability as well as exploratory efficacy endpoints in newly diagnosed multiple myeloma patients who have tested positive for minimal residual disease ("MRD+") in first remission prior to autologous stem cell transplant ("ASCT").

# Reliant Glycosciences, LLC

In July 2021, we entered into a development and license agreement with Reliant Glycosciences, LLC ("Reliant") for collaboration on a program with Biohaven Labs' multifunctional molecules to develop and commercialize conjugated antibodies for therapeutic uses relating to IgA nephropathy and other diseases and conditions. Under the Agreement, Reliant was entitled to an upfront payment and will be eligible to receive development milestone payments and royalties on net sales of licensed products.

# KU Leuven

In January 2022, Biohaven and Katholieke Universiteit Leuven ("KU Leuven") entered into an Exclusive License and Research Collaboration Agreement (the "KU Leuven Agreement") to develop and commercialize first-in-class TRPM3 antagonists to address the growing proportion of people worldwide living with chronic pain disorders. The TRPM3 antagonist platform was discovered at the Centre for Drug Design and Discovery ("CD3") and the Laboratory of Ion Channel Research ("LICR") at KU Leuven. Under the KU Leuven Agreement, Biohaven receives exclusive global rights to develop, manufacture and commercialize KU Leuven's portfolio of small-molecule TRPM3 antagonists. The portfolin includes the lead candidate, henceforth known as BHV-2100, which has demonstrated promising efficacy in preclinical pain models and will be the first to advance towards Phase 1 studies. Biohaven will support further basic and translational research at KU Leuven on the role of TRPM3 in pain and other disorders.

# 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.

# 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.

Biohaven Pharmaceutical Ireland DAC ("Biohaven Ireland") will be the supplier for Pfizer sales of rimegepant and zavegepant ("the Licensed Products") in all countries worldwide outside the U.S. ("the Territory"). As part of our Collaboration Agreement, Pfizer was granted a co-exclusive, royalty-bearing license for patent rights and know-how to develop and manufacture the Licensed Products in the Territory.

# **Commercialization Strategy**

We have commercialized NURTEC ODT for the acute and preventive treatment of migraine in the United States, and we intend to commercialize our product candidates if approved by regulators. In November 2021, we signed a collaboration and license agreement with Pfizer pursuant to which Pfizer has the exclusive right to commercialize product candidates containing rimegepant and may elect to commercialize zavegepant in territories outside the United States. In the future, we may enter into additional distribution or licensing arrangements for commercialization rights for other product candidates.

With respect to commercializing NURTEC ODT and zavegepant in the United States, we recruited a seasoned team of sales specialists, account directors and field medical professionals who are focused on targeting health care professionals and institutions serving patients with migraine, including neurologists, headache centers/specialists and primary care. Our commercial organization has grown as expected following our first full year of NURTEC ODT net sales in 2021 to meet the increasing sales demands of NURTEC ODT.

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

#### **Customers**

Our customers are primarily comprised of pharmaceutical wholesale distributors. Our net product sales to three customers, AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc., each accounted for more than 10.0% of our total net product sales for the years ended December 31, 2021 and 2020 and on a combined basis, accounted for approximately 92% and 98%, respectively.

In connection with our Collaboration Agreement with Pfizer, Pfizer agreed to, among other things, provide us with tiered, escalating royalties from the upper teens to twenty percent of net sales of the Licensed Products in the Territory. In general, Pfizer's obligation to pay royalties continues on a product-by-product and country-by-country basis until the latest of ten years after the first commercial sale of such product in such country, or the expiration of the patent rights covering such product in such country or the expiration of the period of exclusivity applicable to such product in such country. The Collaboration Agreement did not result in the recognition of revenue during the year ended December 31, 2021.

# Intellectual Property

We own or license patents in the U.S. and foreign countries that protect our products, their methods of

use and manufacture, as well as other innovations relating to the advancement of our science to help bring new therapies to patients. We also develop brand names and trademarks for our products to differentiate them in the marketplace. We consider the overall protection of our patents, trademarks, licenses and other intellectual property rights to be of material value and act to protect these rights from infringement. 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 other 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 development programs.

In the biopharmaceutical industry, a substantial portion of an innovative product's commercial value is usually realized during the period in which the product has market exclusivity. A product's market exclusivity is generally determined by two forms of intellectual property: patent rights held by the innovator company and any regulatory forms of exclusivity to which the innovative drug is entitled.

Patents are a key determinant of market exclusivity for most pharmaceuticals. Patents provide the innovator with the right to exclude others from practicing an invention related to the medicine. Patents may cover, among other things, the active ingredient(s), various uses of a drug product, discovery tools, pharmaceutical formulations, drug delivery mechanisms and processes for (or intermediates useful in) the manufacture of products. Protection for individual products extends for varying periods in accordance with the expiration dates of patents in the various countries. The protection afforded, which may also vary from country to country, depends upon the type of patent, its scope of coverage and the availability of meaningful legal remedies in the country.

Market exclusivity can also be influenced by regulatory data protection ("RDP"). Many developed countries provide certain non-patent incentives for the development of medicines. For example, in the U.S., the EU, United Kingdom, Japan, and certain other countries, RDP intellectual property rights are offered to: (i) provide a time period of data protection during which a generic company is not allowed to rely on the innovator's data in seeking approval; (ii) restore patent term lost during drug development and approval; and (iii) provide incentives for research on medicines for rare diseases, or orphan drugs, and on medicines useful in treating pediatric patients. These incentives can extend the market exclusivity period on a product beyond the patent term.

#### Patents and Patent Applications

We have over 1,000 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, South Korea, China, Hong Kong and Australia.

# Rimegepant and Zavegepant

The intellectual property rights related to rimegepant and zavegepant include patents and patent applications in-licensed from BMS, with expiration dates of February 22, 2031 for rimegepant, and October 7, 2031 for zavegepant, not including eligible patent term extensions, 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 an expiration date of February 22, 2031, including patent term adjustment but not including any potential patent term extension. Based on the FDA's approval of NURTEC ODT (rimegepant sulfate) orally disintegrating tablets on February 27, 2020, a request for Patent Term Extension under 35 U.S.C.156 of the United States Code was filed for U.S. Patent 8,314,117. If the application is granted as filed, the term of U.S. Patent 8,314,117 will be extended to February 27, 2034, not including a potential additional six month period of pediatric exclusivity. On August 10, 2021, the U.S. Patent and Trademark Office issued U.S. Patent 11,083,724 which, among other things, is directed to ODT forms of CGRP antagonists, including rimegepant. This patent has an expiration date of March 25, 2039 in the U.S. and is pending in other countries. U.S. Patent 8,481,546 covers the composition of matter of zavegepant, and has an expiration date of October 7, 2031, including patent term adjustment but not including any potential patent term extension. These and other patents and applications cover rimegepant and zavegepant and their use in treating migraine and 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.

# Troriluzole

We own a portfolio of patents and patent applications in the U.S. and foreign countries directed to prodrugs of riluzole, including among others 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 patents and patent applications. We own these patent applications subject to an agreement with ALS Biopharma and FCCDC. In addition, we have filed patent applications relating to drug product formulations containing trorilizole and methods of using the formulations to treat various diseases.

# Next Generation CGRP Receptor Antagonists

We have in-licensed patents and patent applications in the U.S. and foreign countries directed to CGRP receptor antagonists developed by Sosei Heptares pursuant to a Collaboration and License Agreement dated November 30, 2020. The patents and patent applications disclose novel compounds, pharmaceutical compositions and methods of treating various diseases including those other than migraine such as pain, hot flashes, cluster headache and other CGRP-mediated cerebrovascular and vascular disorders. The patents and patent applications include, for example, U.S. Patents 9,808,457 and 10,300,056 which expire on October 28, 2036 not including eligible patent term extensions.

#### BHV-5000

We have also in-licensed patents and patent applications directed to BHV-5000 from AstraZeneca. They contain claims directed to the prodrug form of lanicemine, BHV-5000, as well as the use of the prodrug in treating a variety of neurological diseases including Rett syndrome and depression. Three U.S. patents have been granted that are directed to BHV-5000 and its composition and uses and have a statutory expiration date in 2034. Corresponding foreign patents are granted in Europe, Japan, China, and other countries.

#### Verdiperstat

In September 2018, we in-licensed 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.

# **Licensing and Other Agreements**

In addition to our independent efforts to develop and market products, we enter into agreements such as licensing agreements, option-to-license agreements and strategic collaborations. The licensing and other agreements typically include, among other terms and conditions, non-refundable upfront license fees, option fees and option exercise payments, milestone payments and royalties. See Note 14, "Licensing and Other Agreements," to the Consolidated Financial Statements included in this report for additional information regarding our licenses and other agreements.

# **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 investigational new drug ("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 gather information on the 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 have used in our zavegepant 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 an application if they determine that the data are 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 and 6 months from the date that the FDA accepts the application for filing for priority review NDAs. 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, as well as the Sponsor of the NDA, 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 post approval. 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 Complete Response Letter ("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.

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 program for troriluzole for the treatment of SCA and the treatment of OCD is 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.

# **Product Exclusivity - United States**

In the United States, biopharmaceutical products are protected by patents with varying terms depending on the type of patent and the filing date. A significant portion of a product's patent life, however, is lost during the time it takes an innovative company to develop and obtain regulatory approval of a new drug. As compensation at least in part for the lost patent term due to regulatory review periods, the innovator may, depending on a number of factors, apply to the government to restore lost patent term by extending the expiration date of one patent up to a maximum term of five years, provided that the extension cannot cause the patent to be in effect for more than 14 years from the date of drug approval. A company seeking to market an innovative pharmaceutical in the U.S. must submit a complete set of safety and efficacy data to the FDA. If the innovative pharmaceutical is a chemical product, the company files an NDA. If the medicine is a biological product, a Biologic License Application ("BLA") is filed. The type of application filed affects RDP exclusivity rights.

# Small Molecule Products

A competitor seeking to launch a generic substitute of small molecule drug in the U.S. must file an Abbreviated New Drug Application ("ANDA") with the FDA. In the ANDA, the generic manufacturer needs to demonstrate only "bioequivalence" between the generic substitute and the approved NDA drug. The ANDA relies upon the safety and efficacy data previously filed by the innovator in its NDA. An innovator company is required to list certain of its patents covering the medicine with the FDA in what is commonly known as the FDA's Orange Book. The FDA cannot approve an ANDA until after the innovator's listed patents expire unless there is a successful patent challenge. However, after the

innovator has marketed its product for four years, a generic manufacturer may file an ANDA and allege that one or more of the patents listed in the Orange Book under an innovator's NDA is either invalid or not infringed (a Paragraph IV certification). The innovator then must decide whether to file a patent infringement suit against the generic manufacturer. From time to time, ANDAs, including Paragraph IV certifications, could be filed with respect to certain of our products.

In addition to patent protection, certain innovative pharmaceutical products can receive periods of regulatory exclusivity. An NDA that is designated as an orphan drug can receive seven years of exclusivity for the orphan indication. During this time period, neither NDAs nor ANDAs for the same drug product can be approved for the same orphan use. A company may also earn six months of additional exclusivity for a drug where specific clinical studies are conducted at the written request of the FDA to study the use of the medicine to treat pediatric patients, and submission to the FDA is made prior to the loss of basic exclusivity. Medicines approved under an NDA can also receive several types of RDP. An innovative chemical pharmaceutical product is entitled to five years of RDP in the U.S., during which the FDA cannot approve generic substitutes. If an innovator's patent is challenged, as described above, a generic manufacturer may file its ANDA after the fourth year of the fiveyear RDP period. A pharmaceutical drug product that contains an active ingredient that has been previously approved in an NDA, but is approved in a new formulation, but not for the drug itself, or for a new indication on the basis of new clinical studies, may receive three years of RDP for that formulation or indication.

#### Biologic products

The U.S. healthcare legislation enacted in 2010 created an approval pathway for biosimilar versions of innovative biological products that did not previously exist. Prior to that time, innovative biologics had essentially unlimited regulatory exclusivity. Under the new regulatory mechanism, the FDA can approve products that are similar to (but not generic copies of) innovative biologics on the basis of less extensive data than is required by a full BLA. After an innovator has marketed its product for four years, any manufacturer may file an application for approval of a "biosimilar" version of the innovator product. However, although an application for approval of a biosimilar version may be filed four years after approval of the innovator product, qualified innovative biological products will receive 12 years of regulatory exclusivity, meaning that the FDA may not approve a biosimilar version until 12 years after the innovative biological product was first approved by the FDA. The law also provides a mechanism for innovators to enforce the patents that protect innovative biological products and for biosimilar applicants to challenge the patents. Such patent litigation may begin as early as four years after the innovative biological product is first approved by the FDA.

In the U.S., the increased likelihood of generic and biosimilar challenges to innovators' intellectual property has increased the risk of loss of innovators' market exclusivity. First, generic companies have increasingly sought to challenge innovators' basic patents covering major pharmaceutical products. Second, statutory and regulatory provisions in the U.S. limit the ability of an innovator company to prevent generic and biosimilar drugs from being approved and launched while patent litigation is ongoing. As a result of all of these developments, it is not possible to predict the length of market exclusivity for a particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity.

# 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. 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.

# European Union

A typical route used by innovator companies to obtain marketing authorization of pharmaceutical products in the EU is through the "centralized procedure." A company seeking to market an innovative pharmaceutical product through the centralized procedure must file a complete set of safety data and efficacy data as part of a Marketing Authorization Application ("MAA") with the EMA. After the EMA evaluates the MAA, it provides a recommendation to the European Commission ("EC") and the EC then approves or denies the MAA. Regulatory approval via the centralized procedure results in a marketing authorization for the innovative pharmaceutical product in each EU member state. It is also possible for new chemical products to obtain marketing authorization in the EU through a "mutual recognition procedure," in which an application is made to a single member state, and if the member state approves the pharmaceutical product under a national procedure, then the applicant may submit that approval to the mutual recognition procedure of some or all other member states. After obtaining marketing authorization approval, a company must obtain pricing and reimbursement for the pharmaceutical product, which is typically subject to

member state law. In certain EU countries, this process can take place simultaneously while the product is marketed but in other EU countries, this process must be completed before the company can market the new product. The pricing and reimbursement procedure can take months and sometimes years to complete. Throughout the EU, all products for which marketing authorizations have been filed after October/November 2005 are subject to an "8+2+1" regime. Eight years after the innovator has received its first community authorization for a medicinal product, a generic company may file a MAA for that product with the health authorities. If the MAA is approved, the generic company may not commercialize the product until after either 10 or 11 years have elapsed from the initial marketing authorization granted to the innovator. The possible extension to 11 years is available if the innovator, during the first eight years of the marketing authorization, obtains an additional indication that is of significant clinical benefit in comparison with existing treatments. For products that were filed prior to October/November 2005, there is a 10-year period of data protection under the centralized procedures and a period of either six or 10 years under the mutual recognition procedure (depending on the member state). In contrast to the U.S., patents in the EU are not listed with regulatory authorities. Generic versions of pharmaceutical products can be approved after data protection expires, regardless of whether the innovator holds patents covering its drug. Thus, it is possible that an innovator may be seeking to enforce its patents against a generic competitor that is already marketing its product. Also, the European patent system has an opposition procedure in which generic manufacturers may challenge the validity of patents covering innovator products within nine months of grant. In general, EU law treats chemically-synthesized drugs and biologicallyderived drugs the same with respect to intellectual property and data protection. In addition to the relevant legislation and annexes related to biologic medicinal products, the EMA has issued guidelines that outline the additional information to be provided for biosimilar products, also known as generic biologics, in order to review an application for marketing approval.

#### Japan

In Japan, medicines of new chemical entities are generally afforded eight years of data exclusivity for approved indications and dosage. Patents on pharmaceutical products are enforceable. Generic copies can receive regulatory approval after data exclusivity and patent expirations. As in the U.S., patents in Japan may be extended to compensate for the patent term lost during the regulatory review process. In general, Japanese law treats chemically-synthesized and biologically-derived drugs the same with respect to intellectual property and market exclusivity.

# China

To obtain marketing authorization of pharmaceutical products in China, an NDA must be submitted to the National Medical Product Administration ("NMPA") once safety and efficacy has been established in Chinese patients. For imported

drugs, this means issuance of an import license. The applicant must submit evidence of foreign approval (certificate of pharmaceutical product), unless it is an innovative drug that has never been approved anywhere in the world.

In China, medicines of new chemical entities are generally afforded 6 years of data exclusivity for approved indications and dosage. Generic copies can receive regulatory approval after data exclusivity and patent expirations.

# South Korea

To obtain marketing authorization of pharmaceutical products in South Korea, a marketing application must be submitted to the Ministry of Food and Drug Safety ("MFDS"). The application must contain data in South Korean patients, information regarding safety and efficacy, quality, a good manufacturing practice certificate, and a certificate of pharmaceutical product in an approved country to show that the drug being imported is being sold in the approved country in accordance with the with the relevant rules and regulations in that country.

In South Korea, medicines of new chemical entities are generally afforded 6 years of data exclusivity for first approved indications and dosage. Generic copies can receive regulatory approval after data exclusivity and patent expirations.

# Rest of the World

In countries outside of the U.S., the EU, Japan, China and South Korea, there is a wide variety of legal systems with respect to intellectual property and market exclusivity of pharmaceuticals. Most other developed countries utilize systems similar to either the U.S. or the EU. Among developing countries, some have adopted patent laws and/or regulatory exclusivity laws, while others have not. Some developing countries have formally adopted laws in order to comply with World Trade Organization ("WTO") commitments, but have not taken steps to implement these laws in a meaningful way. Enforcement of WTO actions is a long process between governments, and there is no assurance of the outcome.

# 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 41% of Medicare fee-for-service payments to alternative payment models ("APMs") tied to the quality or value of services by the end of 2018. HHS had set a goal of moving 50% of such Medicare payments into these alternative payment models by the end of 2018, but in 2019, it discontinued this performance goal and replaced it with a new developmental goal to increase the percentage of Medicare health care dollars tied to APMs incorporating downside risk, with a target of 40% for fiscal year 2021. 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 now agree to offer 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;
- 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. In January of 2021, an Executive Order entitled "Executive Order on Strengthening Medicaid and the Affordable Care Act" repealed two previous Executive Orders delaying the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that amend all or part of the ACA.

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 previous U.S. presidential administration's budget for fiscal year 2020 contained further drug price control measures that could be enacted in other future legislation. Additionally, the previous administration released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs. HHS solicited feedback on some of these measures and, concurrently, implemented others under its existing authority. While a number of these and other proposed measures would require authorization through additional legislation to become effective, Congress has 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.

# **Environmental, Social, Governance, and Human Capital**

#### Governance and Leadership

Our commitment to integrating sustainability across our organization begins with our Board of Directors. The Nominating and Governance Committee of the Board has oversight of strategy and risk management related to Environmental, Social and Governance (ESG). Applying NYSE's listing standards for independence, five of our seven directors are independent.

At the management level, we have implemented a cross-functional Sustainability Working Group, which is set to meet on a regular basis and report to the Board of Directors periodically. We also maintain a Chief Talent & Sustainability Officer position to work closely with the working group and coordinate efforts related to the advancement of ESG capabilities across the organization.

#### **Business Ethics**

We are committed to creating an environment where we are able to excel in our business while maintaining the highest standards of conduct and ethics. Our Code of Business Conduct and Ethics (the "Code of Conduct") reflects the business practices and principles of behavior that support this commitment, including our policies on bribery, corruption, conflicts of interest and our whistleblower program. We expect every director, officer, and employee to read, understand, and comply with the Code of Conduct and its application to the performance of his or her business responsibilities.

We encourage employees to come to us with observations and complaints, ensuring we understand the severity and frequency of an event in order to escalate and assess accordingly. Our Chief Compliance Officer strives to ensure accountability, objectivity, and compliance with our Code of Conduct. If a complaint is financial in nature, the Audit Committee Chair is notified concurrently, which triggers an investigation, action, and report. All incidents are reported up to the Board of Directors on a quarterly basis.

# **Environmental Commitment**

We are committed to protecting the environment and attempt to mitigate any negative impact of our operations. We monitor resource use, improve efficiency, and at the same time reduce our emissions and waste.

In order to reduce the overall impact of our product on the environment, we have taken steps to enhance the sustainability of our manufacturing processes for our drug substances.

In collaboration with our contract research organization partners, we apply various green chemistry methodologies to our commercial and development pipeline. We have especially focused on using

biocatalysis, a technology that makes use of enzymes instead of chemicals to accomplish specific chemical reactions used to construct organic small molecules such as Active Pharmaceutical Ingredients.

We have also initiated work in removing hazardous organic solvents from certain reactions and replacing them with water. This green technology relies on the use of micelles to enable such reactions to occur in water where they would normally not occur due in part to the very poor solubility of most organic compounds in water. These greener processes not only create less waste, but the waste that is produced is much less hazardous, therefore reducing the environmental impact of the manufacturing process.

We are systematically addressing the environmental impacts of the buildings we own as we make improvements, including adding energy control systems and other energy efficiency measures. Waste in our own operation is minimized by our commitment to reduce both single-use plastics and operating paper-free, primarily in a digital environment. We have safety protocols in place for handling biohazardous waste in our labs, and we use third-party vendors for biohazardous waste and chemical disposal.

# Social Responsibility

Our access to medicine strategy is simple: maximize access for all patients everywhere. In 2020, we not only met, but exceeded, our aggressive launch year target of 80% commercial lives access to medicine. We were able to reach 89% access across the board for commercial patients, which is a target we maintained throughout 2021. Our access within federally funded programs like Medicare, Medicaid, and VA/TRICARE also remains comprehensive. We have established drug donation programs for individuals who meet certain federal poverty standards.

For third-party vendor selection and oversight, we have standard operating procedures that apply to employees and subcontractors who on our behalf, oversee and conduct research regulated by the FDA. We retain ultimate authority and responsibility for the conduct of regulated research, manufacturing, and testing and we must ensure that contracted services are conducted in accordance with Good Practice Guidelines and all applicable regulations.

# **Human Capital Management**

At Biohaven, we foster and encourage a workplace environment that holds possibilities for everyone, with a commitment to respect and acceptance without biases.

Development and continuous feedback are priorities for our organization, which comprises 928 employees as of December 31, 2021. We believe each individual person is critical to our success and we invest in our people by supporting continuous training programs and courses. We encourage each employee to engage with their manager in developmental

discussions designed to focus on feedback rather than a rating.

An important part of our talent recruitment is our robust paid internship program for high school, college and graduate-level students. This program had over 50 participants in 2021 and offers opportunities to students in the community and develops a roadmap for 'entry-level' candidates. We evaluate the success of our recruitment program through metrics such as time to hire, offer acceptance rate, turnover rate and business results. Our voluntary turnover rate in 2021 was 4.7%, significantly under the industry average. Our low turnover rate demonstrates our commitment to our teams, the culture we are creating and our ability to retain our talent.

We strive to provide an inclusive workplace to foster growth and innovation. Our Diversity, Equity and Inclusion (DEI) Plan "Roadmap to Belonging" includes training to build DEI capabilities for all commercial employees, cultural competence capability building for leaders, as well as traditional anti-harassment and anti-discrimination training for all. Pulse surveys and individual interviews for commercial employees are conducted to assess program effectiveness. Combined with an agile mindset, this feedback enables our leadership team to further enhance program offerings to address the diverse needs of our team. We have expanded our team with an inclusive mindset from the beginning. We are actively focused on increasing the gender, racial/ethnic, and age diversity of our board composition and, over the past two years, we have made strides to diversify our senior leadership, with the number of females in scientific leadership positions becoming a strength of our organization.

When the COVID-19 pandemic hit in early 2020, we quickly established both an office-based and field-based response to protect our employees. We first and foremost encouraged all office-based employees to work from home and provided support for fully remote work. In our offices, we follow health and safety protocols by providing mandatory masks for anyone entering the building, foot-dispensing hand sanitizer stations, and disinfecting wipes at each workstation. We purchased high efficiency air filters to ensure air is not recirculated in the facilities. For our field-based teams we implemented virtual capabilities for meeting with healthcare providers, including the ability for physicians to verify, sign off, and receive Biohaven samples without putting our representatives at risk. We offer antibody testing and encourage employees to be tested for COVID-19 frequently.

# 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 website (www.sec.gov).

# Item 1A. Risk Factors

In connection with any investment decision with respect to our securities, 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 and in our other filings with the SEC. 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.

#### SUMMARY

# Risks Related to Our Financial Position and Need for Additional Capital

- We have a limited operating history, 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.
- An inability to raise capital when needed or on terms favorable to us could force us to curtail our planned operations and growth strategy.
- We are subject to significant obligations, including those related to payments under our license agreements.
- Redemptions of our Series A Preferred Shares and Series B Preferred Shares will require significant amounts of cash.
- The interests of the holders of our Series A Preferred Shares and Series B Preferred Shares could differ from those of our common shareholders.
- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

# Risks Related to the Development of Our Product Candidates

- We depend entirely on the success of NURTEC ODT and a limited number of product candidates.
- Clinical trials are very expensive, time-consuming and difficult to design and implement and involve uncertain outcomes, the results of clinical trials may not be predictive of results of future trials, and any delays, suspensions or terminations of clinical trials could increase our expenses.
- Regulatory approval processes in the U.S. and foreign jurisdictions are lengthy, time-consuming and unpredictable.

- Our product candidates may fail to demonstrate safety and efficacy in clinical trials, or may cause serious adverse or unacceptable side effects. If any of our approved product candidates 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.
- We may become exposed to costly and damaging liability claims, which may not be covered by insurance.

# Risks Related to Commercialization of Our Product Candidates

- We may lack the necessary expertise, personnel and resources to successfully commercialize any of our product candidates that may receive regulatory approval.
- · We operate in a highly competitive and rapidly changing industry.
- Failure to obtain or maintain adequate coverage and reimbursement for our approved product candidates could limit our ability to market those products and decrease our ability to generate revenue.
- Even after we obtain regulatory approval for our product candidates, they remain subject to ongoing regulatory oversight.
- Our approved product candidates 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.
- We may not be successful in commercializing our products candidates, including NURTEC ODT.
- Approval of generic versions of any of our approved products could adversely affect our sales.

# 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 rely on third parties to conduct our preclinical studies and clinical trials and to supply, manufacture and distribute clinical drug supplies for our product candidates and for NURTEC ODT.
- We may not be able to establish or maintain collaborations with third parties to develop or commercialize product candidates.
- If our collaboration with Pfizer is not successful, we may not be able to capitalize on the market potential of our proprietary compounds rimegepant and

zavegepant in all countries worldwide outside of the United States.

#### 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.
- Our business operations and relationships with investigators, health care professionals, consultants, third-party payors and customers are 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.
- We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

# **Risks Related to Our Intellectual Property**

- · We could lose market exclusivity earlier than expected.
- Litigation claiming infringement of intellectual property may adversely affect our business and future revenues.
- We are dependent on licensed intellectual property.
- Failure to obtain licenses from third parties on commercially reasonable terms could impact our business.
- Changes in intellectual property laws could impair our ability to protect our product candidates.
- We may not be able to obtain intellectual property rights in key markets in the world, which could negatively impact our business.
- Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

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

- The COVID-19 pandemic could impact our business, results of operations and financial performance.
- Our future growth and ability to compete depend on, among other things, retaining key personnel and recruiting additional qualified personnel and on our ability to penetrate foreign markets.
- 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.

- We may encounter difficulties in managing our growth, which could disrupt our operations.
- Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- Computer system failures or security breaches could materially impact our business and operations.

# Risks Related to Ownership of Our Common Shares

- The trading price of our common shares has been, and may continue to be, volatile, and purchasers of our common shares could incur substantial losses.
- Provisions in our memorandum and articles of association could make an acquisition of us more difficult, prevent attempts by our shareholders to replace or remove our current management and limit the market price of our common shares.
- 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 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.
- Holders of our common shares are subject to risks related to our organization under the laws of the BVI.
- Changes in tax law and effective tax rates and determinations by tax authorities may adversely affect our business and financial results. If we are a passive foreign investment company, there could be adverse U.S. federal income tax consequences to U.S. holders.
- If a significant portion of our total outstanding shares are sold into the market, the market price of our common shares could drop significantly, even if our business is doing well.

# Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history as a commercial company, 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. Prior to our commercialization of NURTEC ODT in 2020, we had not obtained marketing approvals for any product candidates, manufactured products on a commercial scale, or arranged for a third party to do so on our behalf, or conducted 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 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 have transitioned from a company with solely a research and development focus to a company also 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 \$848.4 million and \$768.6 million for the years ended December 31, 2021 and December 31, 2020, respectively. As of December 31, 2021, we had an accumulated deficit of \$2,585.8 million. We expect to continue to incur significant expenses and operating losses for the foreseeable future. It could be several years, if ever, before NURTEC ODT or other product candidates, if approved, generate significant revenues to offset these expenses and operating losses. 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:

- enter new sales territories, including international markets, related to sales of NURTEC ODT or future commercial products;
- initiate, continue, or complete planned or ongoing clinical trials of our current product candidates, including related support activities;
- 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 product purchase and 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 ("2018 Funding Agreement") and to RPI 2019 Intermediate Finance Trust ("RPI 2019 IFT") under the funding agreement entered into August 2020 between us and 2019 RPI IFT ("2020 Funding Agreement");
- make required payments and perform obligations under the Financing Agreement between the Company, our affiliate Biohaven Pharmaceuticals, Inc. and Sixth Street Specialty Lending, Inc. entered into in August 2020, as amended to date ("Sixth Street Financing 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;
- hire additional clinical, medical, commercial, and development personnel; and
- incur additional legal, accounting and other expenses in connection with operating as a public company.

To become and remain profitable, we must successfully 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 of our product candidates, manufacturing, marketing and selling NURTEC ODT and 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 these activities and, even if we do, we may never generate sufficient revenue to achieve profitability. In addition, our obligation to pay RPI royalties on future sales of NURTEC ODT, zavegepant and certain derivative compounds thereof pursuant to our funding agreements would impact the profitability of these products.

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 could 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 for our product candidates and achieve product sales for our approved products, including NURTEC ODT. 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. If the FDA requires us to conduct additional clinical trials of troriluzole, or any of our other product candidates, we would incur substantial additional, unanticipated expenses in order to obtain regulatory approval of those product candidates.

As of December 31, 2021, we had cash, cash equivalents and marketable securities of \$364.6 million, excluding restricted cash of \$2.4 million. We expect that our cash, cash equivalents and marketable securities as of December 31, 2021, and the funds available from the Sixth Street Financing Agreement, Series B Preferred Shares, the \$500 million received in January 2022 and potential future milestone payments in connection with the Pfizer Collaboration Agreement and sales of common shares under the Equity Distribution Agreement in 2022 will be sufficient to fund our current forecast for operating expenses, including commercialization of NURTEC ODT in the US, financial commitments and other cash requirements for more than one year. 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 commercial activities, including drug manufacturing, marketing, sales and distribution, for NURTEC ODT in the US and any of our other product candidates 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, product purchase agreements, the 2018 Funding Agreement, 2020 Funding Agreement, the Sixth Street Financing Agreement and any required redemption payments for the Series A Preferred Shares or the Series B 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. We have incurred and expect to continue to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution of NURTEC ODT and any other product candidates that may be approved in the future. 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.

We are subject to significant obligations, including potentially making significant payments under our funding agreements and financing agreement related to NURTEC ODT and zavegepant.

In June 2018, we entered into the 2018 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 zavegepant and certain derivative compounds thereof. The participation rate commences at 2.1 percent on global annual net sales of products up to and including \$1.5 billion, declining to 1.5 percent on global annual net sales of products exceeding \$1.5 billion.

In addition, under the 2018 RPI Funding Agreement, we are obligated to take certain steps to complete clinical trials and commercialize products containing the compounds rimegepant or zavegepant and certain derivative compounds thereof. These obligations could adversely impact or delay our ability to develop our other product candidates.

In August 2020, we entered into the 2020 Funding Agreement with RPI 2019 IFT which requires us to make participation payments based on global net sales of products containing zavegepant and rimegepant and certain payments based on success-based milestones relating to zavegepant. Under the 2020 RPI Funding Agreement, RPI 2019 IFT will be entitled to receive tiered, sales-based participation rights up to 3.0% of global net sales of products containing zavegepant, 0.4% of global net sales of products containing rimegepant, and success-based milestones payments ranging from 0.6x to 2.95x of the funded amount depending on the number of regulatory approvals achieved for zavegepant (including 1.9x for the first zavegepant migraine regulatory approval). If these payments become due under the terms of the 2020 RPI Funding Agreement, they will have a negative impact on our cash flows and on the future profitability of NURTEC ODT and zavegepant.

In February 2022, we entered into a definitive agreement with Channel Biosciences to acquire a Kv7 channel activator platform to target indications including epilepsy, pain disorders and effective disorders. The agreement contemplates an upfront payment of \$100.0 million, including \$65.0 million of common shares, additional success-based milestone payments totaling up to \$1.2 billion, and scaled royalty payments. Under the agreement, we are also required to make a true-up payment in late 2022 if the upfront payment in common shares has declined in value equal to the amount of such value decline. The Sixth Street Financing Agreement does not currently permit the full potential amount of that true-up payment; therefore an amendment or wavier under the Sixth Street Financing Agreement may be required for us to make a true-up payment without violating the terms of the Sixth Street Financing Agreement.

We are required to redeem our outstanding Series A Preferred Shares over the next few years and will be required to redeem our Series B Preferred Shares in the future.

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. The holders of our outstanding Series A Preferred Shares will have the right to require us to redeem their shares in certain circumstances. Following the FDA approval of NURTEC ODT in February 2020, we are required to redeem the Series A Preferred Shares for two times (2x) the original purchase price, payable in equal quarterly installments which began March 31, 2021 and will continue through December 31, 2024.

In the event that we default on our obligation to redeem Series A Preferred Shares when required, the redemption amount will 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 addition, in August 2020, we entered into the Series B preferred share agreement, pursuant to which RPI agreed to purchase up to 3,992 Series B Preferred Shares at a price of \$50,100 per share for a total purchase price of \$200.0 million payable in quarterly installments of approximately \$17.6 million in 2021, \$14.6 million in 2022, and \$8.9 million in each of 2023 and 2024. In return, we will be required to redeem the Series B Preferred Shares in 24 quarterly installments of \$14.8 million from 2025 to 2030.

The holders of outstanding Series B Preferred Shares will have the right to require redemption of the shares in certain circumstances. If a Change of Control occurs, as defined in our memorandum and article of association, and the Series B Preferred Shares have not previously been redeemed, holders of a majority of Series B Preferred Shares will have an option to redeem outstanding shares in a single payment at a price equal to 1.77 times the Series B original issuance price. We may redeem the Series B Preferred Shares at our option at any time in a single payment at a price equal to 1.77 times the Series B original issuance price.

Our obligation to redeem the Series A Preferred Shares and Series B Preferred Shares will require a substantial amount of cash, the expenditure of which will have a material adverse effect on our liquidity, capital resources and business prospects. The terms of our Series A Preferred Shares, Series B 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 and Series B 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 and Series B 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, and holders of our Series B Preferred Shares will have a right to receive a liquidation preference equal to 1.77x the original purchase price of such shares, in each case 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 and Series B Preferred Shares is entitled to vote with the common shares on the basis of 1,000 votes per share. Our amended and restated memorandum and articles of association grant the Series A Preferred Shares and Series B Preferred Shares customary protective provisions which provide that, without the approval of holders of a majority of the Series A Preferred Shares or Series B Preferred Shares, as applicable, we may not adversely affect the rights of the Series A Preferred Shares or Series B 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 or Series B Preferred Shares.

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

Our level of indebtedness and the terms of the Sixth Street Financing Agreement could adversely affect our operations and limit our ability to plan for or respond to changes in our business. If we are unable to comply with restrictions in the Sixth Street Financing Agreement, the repayment of our existing indebtedness could be accelerated.

Under the Sixth Street Financing Agreement, we have incurred a substantial amount of debt, which could adversely affect our business. In August 2020, we drew down the first tranche of \$275.0 million. In August 2021, we drew the second tranche of \$125.0 million. In September 2021, we drew down the third and fourth tranches of \$125.0 million and \$100.0 million, respectively. The facility includes additional delayed draw term loans in an aggregate principal amount not exceeding \$125.0 million available until June 30, 2022, currently available at our option.

Our high level of indebtedness could affect our business in the following ways, among other things: make it more difficult for us to satisfy our contractual and commercial commitments; require us to use a substantial portion of our cash flow from operations to pay interest and principal, which would reduce funds available for working capital, capital expenditures and other general corporate purposes; limit our ability to complete acquillimit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other investments or general corporate purposes; heighten our vulnerability to downturns in our business, our industry or in the general economy; place us at a disadvantage compared to those of our competitors that may have proportionately less debt; limit management's discretion in operating our business; and limit our flexibility in planning for, or reacting to, changes in our business, the industry in which we operate or the general economy.

The Sixth Street Financing Agreement requires us to make certain payments of principal and interest over time and contains several other restrictive covenants. Among other requirements of the Sixth Street Financing Agreement, we and our subsidiaries party to the Sixth Street Financing Agreement must maintain a minimum unrestricted cash balance of \$80.0 million, which requirement can be waived at our request for any fiscal quarter in which we achieve at least \$400.0 million in net sales for the prior four consecutive quarters. These and other terms in the Sixth Street Financing Agreement could restrict our ability to grow our business or enter into transactions that we believe would be beneficial to our business

Our business may not generate cash flows from operations in the future that are sufficient to service our debt and support our growth strategies. If we are unable to generate such cash flows, we may be required to adopt one or more alternatives, such as obtaining additional equity capital on terms that may be onerous or highly dilutive, selling assets, or restructuring debt. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, which could adversely our business and operations.

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

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.

On November 9, 2021, in connection with the Collaboration Agreement, pursuant to which we granted Pfizer exclusive rights to commercialize the Licensed Products in all countries worldwide outside of the United States, we agreed to sell to Pfizer \$350.0 million worth of our common shares at approximately \$173.05 per share, equal to 125% of the volume weighted average price per share for the 20 consecutive trading days prior to the signing of the subscription agreement with Pfizer. The sale of common shares to Pfizer occurred on January 4, 2022, upon the satisfaction of applicable closing conditions.

In February 2022, we entered into a definitive agreement with Channel Biosciences to acquire a Kv7 channel activator platform to target indications including epilepsy, pain disorders and effective disorders. The agreement contemplates an upfront payment of \$35.0 million in cash and \$65.0 million of common shares, and additional success-based milestone payments totaling up to approximately \$1.1 billion, which we may make by issuing common shares.

To the extent that we raise additional capital or acquire businesses or products 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.

# Risks Related to the Development of Our Product Candidates

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

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 3 clinical trials of troriluzole in OCD and patient tolerability studies, and completion of our Phase 3 trial for zavegepant. As a result, our business currently depends heavily on the successful development, regulatory approval and, if approved, commercialization of these product candidates. 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 preclinical 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 September 2021, we reported negative topline results from our Phase 3 clinical trial evaluating verdiperstat compared to placebo for the treatment of participants with MSA. While these efficacy results do not support continued development of verdiperstat as a treatment for MSA, we have ongoing studies evaluating verdiperstat in other disease indications. 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.

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.

If we fail to produce positive results in our planned preclinical 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.

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 preclinical 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.

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.

Additionally, we regularly assess our portfolio based on emerging data from preclinical 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 regulators in foreign jurisdictions is lengthy, time-consuming and unpredictable.

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;
- 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 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.

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.

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.

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 September 2021 we reported negative topline results from a Phase 3 clinical trial to evaluate the efficacy and safety of verdiperstat in participants with MSA. Results of the trial showed that Verdiperstat did not statistically differentiate from placebo on the prespecified primary efficacy measure, nor on the key secondary efficacy measures

Moreover, undesirable side effects caused by our product candidates have in the past caused, and may in the future 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 have in the past revealed and could in the future reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Accordingly, we have needed to, and may in the future 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. From time to time our studies have identified safety issues, in which case we have needed to complete additional studies, or abandon development of the applicable product candidate, and this may recur with other studies in the future. 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.

For example, in June 2021 a phase 1 trial began for BHV-3100, the most advanced candidate in a portfolio of novel, small-molecule CGRP receptor antagonists being developed with Sosei Heptares. During the fourth quarter of 2021, we decided to stop development of BHV-3100 based upon its emerging preclinical profile and will instead advance one of the portfolio's backup compounds in its place. Additionally, 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 and one patient dosed with rimegepant experienced an asymptomatic and mild increase in certain hepatic enzymes. In our 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.

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, such as NURTEC ODT, 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, including NURTEC ODT, 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.

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. The current and future use of product candidates by us in clinical trials, and the sale of NURTEC ODT and any other 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 products and 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 the commercialization of our products and, if approved, product candidates.

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.

# Risks Related to Commercialization of Our Product Candidates

We may lack the necessary expertise, personnel and resources to successfully commercialize any of our product candidates that may receive regulatory approval on our own or together with collaborators

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. Starting in 2019, we hired a sales force and started developing marketing and distribution capabilities in advance of the planned commercialization of NURTEC ODT in early 2020. The success of the commercialization of NURTEC ODT in the US and any of our product candidates that may be approved by the FDA in the future will depend on such capabilities.

Factors that may affect our ability to successfully commercialize our product candidates on our own include obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with adapting our sales and marketing organization to those product candidates. Maintaining a sales and marketing organization has required, and 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 for those product candidates in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities for our product candidates 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 zavegepant, we face competition from other companies that market or are developing migraine treatments. These include compounds in the class of products known as triptans, the 5-HT1F receptor antagonist lasmiditan developed by Eli Lilly and Company, as well as other small molecule CGRP receptor antagonists such as ubrogepant and atogepant, developed by AbbVie. Lasmiditan, ubrogepant and atogepant were approved by the FDA in October 2019, December 2019 and October 2021 and sold under the names Reyvow, Ubrelvy and Qulipta, respectively. Our other CGRP product candidate, zavegepant, is in Phase 3 clinical trials. In addition, four biologic CGRP receptor

binding mAbs entered the market, including Aimovig (Amgen/Novartis), Ajovy (Teva), Emgality (Lilly) and Vyepti (Lundbeck) for the preventive treatment of migraine in adults. As three of the four listed brands received marketing approval before our migraine product candidates, it could be more difficult for our products to achieve commercially successful market acceptance. In addition, the competitors identified above have substantial sales and marketing capabilities and continue to devote significant resources to the marketing of their products, which may also make it 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, Alovy and/or Vvepti 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 one or more less expensive drugs first, for patients to receive these newer and more expensive medications, thereby potentially slowing new product uptake and adoption.

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 OCD and if we continue to pursue this indication, we would face substantial competition from companies that develop or sell products that treat 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 is currently being developed for the potential treatment of ALS, if that development is successful, 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.

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 NURTEC ODT and our other product candidates, 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 NURTEC ODT and our other 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 develop, and any reimbursement that becomes 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. Our competitors may offer their products and services on a less expensive basis to gain coverage and reimbursement from third-party payors. 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.

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 NURTEC ODT 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 on 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, as we did with NURTEC ODT, 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.

From time to time the FDA's and other regulatory authorities' policies 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. In March of 2021, we received an untitled letter from the FDA regarding statements made by one of our promotional partners related to NURTEC ODT. In November of 2021, we received correspondence from FDA's Office of Prescription Drug Promotion that FDA's evaluation of our response was complete and the issues raised in the letter were addressed.

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.

NURTEC ODT and any of our other product candidates 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.

Physicians, patients, third-party payors or the medical community may not accept or use NURTEC ODT or any of our product candidates that may be approved in the future. 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. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. 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, including NURTEC ODT, 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.

Because we expect sales of NURTEC ODT and any of our other product candidates, 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 NURTEC ODT 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 NURTEC ODT.

We have expanded our marketing, sales and distribution capabilities in advance of the NURTEC ODT launch. This expansion greatly increased our expenses and was very time-consuming for management. We currently market, sell and distribute NURTEC ODT 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 additional collaboration agreements with respect to marketing, sales or distribution for NURTEC ODT and our other product candidates our product revenue may be lower than if we directly marketed or sold any approved products. In November 2021 we announced the Collaboration Agreement with Pfizer for sales of NURTEC ODT outside of the U.S. 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.

# We could lose market exclusivity of a product earlier than expected.

In the biopharmaceutical industries, a significant amount of an innovative product's commercial value is realized during its market exclusivity period. In the U.S. and in some other countries, when market exclusivity expires and generic versions are approved and marketed or when biosimilars are introduced (even if only for a competing product), there are usually very substantial and rapid declines in a product's revenues. Market exclusivity for our products is based upon patent rights and certain regulatory forms of exclusivity. The scope of our patent rights, if any, varies from country to country and may also be dependent on the availability of meaningful legal remedies in a country. The failure to obtain or maintain patent and other intellectual property rights, or limitations on the use or loss of such rights, could be material to us. In some countries, basic patent protections for our products may not exist because certain countries did not historically offer the right to obtain specific types of patents and/or we (or our

licensors) did not file in those countries. In addition, the patent environment can be unpredictable and the validity and enforceability of patents cannot be predicted with certainty. In addition, manufacturers of innovative drugs as well as generic drug manufacturers may be able to design their products around our owned or licensed patents and compete with us using the resulting alternative technology. Absent relevant patent protection for a product, once the data exclusivity period expires, generic or alternative versions can be approved and marketed.

The FDA may not approve an Abbreviated New Drug Application ("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 in the U.S. for a new drug containing a new chemical element ("NCE"). Although NURTEC ODT has been granted NCE status in the U.S., generic and biosimilar product manufacturers as well as other groups seeking financial gain are also increasingly seeking to challenge patents before they expire, and we could face earlier-than-expected competition for NURTEC ODT. Patents covering our key products, including NURTEC ODT are likely to be subject to validity and enforceability challenges in patent litigations and post-grant review patent office proceedings. In some cases, manufacturers may seek regulatory approval by submitting their own clinical study data to obtain marketing approval or choose to launch a generic product "at risk" before the expiration of the applicable patent(s) and/or before the final resolution of related patent litigation. There is no assurance that a particular product will enjoy market exclusivity for the full time period that appears in the estimates disclosed in this 2021 Form 10-K or that we assume when we provide our financial guidance.

# Litigation claiming infringement of intellectual property may adversely affect our business and future revenues.

We may become involved in patent litigation, including with NURTEC ODT, such as claims that our patents are invalid, unenforceable and/or do not cover the product of the generic drug manufacturer or where third parties seeks damages and/or injunctive relief to compensate for alleged infringement of their patents by our commercial or other activities. Resolving an intellectual property infringement claim can be costly and time consuming and may require us to enter into license agreements, which may not be available on commercially reasonable terms. A successful claim of patent or other intellectual property infringement could subject us to significant damages or an injunction preventing the manufacture, sale, or use of the affected product or products. Any of these events could have a material adverse effect on our profitability and financial condition.

#### 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 inlicense 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 zavegepant, 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.

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 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. 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. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process.

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 commercial supply related to NURTEC ODT and clinical supply of our product candidates and we intend to continue to rely on third parties for our commercial and clinical supply.

We currently rely on and expect to continue to rely on third parties for the manufacturing and supply of chemical compounds for our commercial supply and for the clinical trials of our product candidates. 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,

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 impacted.

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, and expect in the future to continue to rely on, third-party contractors, including certain sole-source suppliers and manufacturers, to supply, manufacture and distribute clinical drug supplies for our product candidates and NURTEC ODT and any product candidates that may be approved in the future.

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 drug products for Zydis formulation of BHV-0223, and NURTEC ODT. We may also have sole-source suppliers for one or more of our other product candidates. 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. 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.

We may in the future enter into collaborations with third parties to develop or commercialize 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. Collaboration arrangements are unique in nature and both parties are active participants in the operating activities and are exposed to significant risks and rewards depending on the commercial success of the activities. Performance obligations inherent in these arrangements may include the transfer of certain development or commercialization rights, ongoing development and commercialization services and product supply obligations.

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, for example, that the

collaborators may not: adequately perform their obligations under the collaboration agreement; devote sufficient resources to the collaboration to ensure success; or agree with us on the strategy or tactical aspects of the collaboration.

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 our collaboration with Pfizer Inc. ("Pfizer") is not successful, we may not be able to capitalize on the market potential of our proprietary compounds rimegepant (BHV-3000) and zavegepant (BHV-3500) (the "Licensed Products") in all countries worldwide outside of the United States.

In November 2021, we and certain of our affiliates entered into the Collaboration Agreement with a subsidiary of Pfizer pursuant to which Pfizer would commercialize the Licensed Products in all countries worldwide outside of the United States. Our control over the amount and timing of resources that Pfizer dedicates to the commercialization of the Licensed Products is very limited. Our ability to generate revenues from the Collaboration Agreement will depend, in part, on Pfizer's ability to successfully perform the functions assigned to it in such agreement. We cannot predict the success of this collaboration with Pfizer, and we cannot guarantee that this collaboration will lead to commercialization of the Licensed Products in the most efficient manner or at all.

If this collaboration with Pfizer does not result in the successful commercialization of the Licensed Products, or if Pfizer terminates the Collaboration Agreement, which it may do for convenience subject to certain notice periods, we may not receive any of the \$740.0 million in contingent payments based on specified commercial and sales-based milestones for the Licensed Products under the Collaboration Agreement.

In addition, many of the risks relating to collaborations with third parties described in our Annual Report on Form 10-K under the caption, "We may in the future enter into collaborations with third parties to develop or commercialize our product candidates. If these collaborations are not successful, our business

could be harmed." also apply to this collaboration with Pfizer.

#### 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 healthcare systems 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 2010, the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was enacted, which substantially changed 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 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.

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 41% of Medicare fee-for-service payments to alternative payment models ("APMs") tied to the quality or value of services by the end of 2018. Additionally, HHS had set a goal of moving 50% of Medicare payments into these alternative payment models by the end of 2018, but in 2019, it discontinued this performance goal and replaced it with a new developmental goal to increase the percentage of Medicare health care dollars tied to APMs incorporating downside risk, with a target of 40% for fiscal year 2021. 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. 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 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.

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 relationships with investigators, health care professionals, consultants, third-party payors and customers are 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.

Our operations relating to our approved products, such as NURTEC ODT, 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, such as state antikickback 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 its business.

Ensuring that our internal operations and current and future business arrangements with third parties comply with applicable healthcare laws and regulations involved and involves 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.

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 our 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.

#### **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.

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. 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 inhibit 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 and involves complex legal and factual questions.

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. 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 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. In addition, the laws of foreign countries may not protect

our rights to the same extent as the laws of the United States. 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.

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. 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. 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. Certain 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, Japan and other countries. However, we may ineligible or fail to obtain such extensions. As a result, our revenue from applicable products could be reduced.

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 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.

In addition, the degree of future protection afforded by our intellectual property rights may be limited. The following examples are illustrative of what others may achieve:

- 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;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; or
- 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

We may not identify relevant third-party patents which might adversely affect our ability to develop, manufacture or commercialize our product candidates.

We cannot guarantee that we or our licensors have identified all patents and patent applications, that are 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 relevant to 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.

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.

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"). Our U.S. Patent Nos. 10,485,791 and 10,905,681, which relate to troriluzole, are subject to the provisions of the Bayh-Dole Act. 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.

Litigation involving intellectual property may adversely affect our future revenues.

We may become involved in patent litigation, including with NURTEC ODT, such as claims that our patents are invalid, unenforceable and/or do not cover the product of the generic drug manufacturer or where third parties seek damages and/or injunctive relief to compensate for alleged infringement of their patents by our commercial or other activities. Resolving an intellectual property infringement claim can be costly

and time consuming and may require us to enter into license agreements, which may not be available on commercially reasonable terms. A successful claim of patent or other intellectual property infringement could subject us to significant damages or an injunction preventing the manufacture, sale, or use of the affected product or products. Any of these events could have a material adverse effect on our profitability and financial condition.

In the U.S., the increased likelihood of generic and biosimilar challenges to innovators' intellectual property has increased the risk of loss of innovators' market exclusivity. First, generic companies have increasingly sought to challenge innovators' basic patents covering major pharmaceutical products. Second, statutory and regulatory provisions in the U.S. limit the ability of an innovator company to prevent generic and biosimilar drugs from being approved and launched while patent litigation is ongoing.

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.

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.

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.

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

The COVID-19 pandemic could have a material adverse effect on our business, results of operations and financial performance, including our commercial launch of NURTEC ODT, and operations and sales in general.

In December 2019, an outbreak of COVID-19 began in Wuhan. China. In March 2020, the World Health Organization declared COVID-19 a pandemic. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The COVID-19 pandemic and responses to its spread have negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. This significant disruption of the global financial markets could reduce our ability to access equity or debt capital on attractive terms if at all, which in turn could negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common shares. The extent of the impact of the COVID-19 pandemic on our operational and financial performance, including our ability to execute our business strategies and initiatives, will depend on future developments, including the duration and spread of the pandemic and related restrictions on travel and transports. all of which are uncertain and cannot be predicted.

The COVID-19 pandemic may impair our commercialization of NURTEC ODT. The spread of COVID-19 may reduce access to NURTEC ODT. In response to regional quarantines, health professionals may reduce staffing and reduce or postpone appointments with patients, or patients may cancel or miss appointments, resulting in fewer prescriptions of NURTEC ODT than projected, thereby adversely affecting our revenues. In addition, in connection with the recent FDA approval of NURTEC ODT, we have been making presentations to physicians regarding the efficacy of NURTEC ODT but as a result of the COVID-19 pandemic, we may need to conduct some or all of these key meetings with medical professionals solely by virtual means instead of inperson, which could reduce the number of medical professionals we are able to present to, and we cannot guarantee that any such virtual meetings will be as successful as in-person meetings. Moreover, restrictions on travel and transport may

result in disruptions in NURTEC ODT distribution. Such events may result in a period of business disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations.

The continued spread of COVID-19 could also adversely impact our clinical trial operations. For example, we may be unable to enroll or retain an adequate number of patients to commence or complete our clinical trials, data may be missing, the FDA may delay or terminate clinical trials for any of our product candidates, or primary outcome measures may be impacted. As a result, our ability to generate product revenue from sales of any of those product candidates will be delayed or not realized at all.

Business interruptions from the current or future pandemics may also adversely impact the third parties we rely on to sufficiently manufacture NURTEC ODT and to produce our product candidates in quantities we require, which may impair the commercialization of NURTEC ODT and our research and development activities.

Some factors from the COVID-19 outbreak that may delay or otherwise adversely affect our business generally, and the third parties which we rely upon, including business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak impacts our business, including our commercial results and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, the development and severity of variants to the virus, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, the widespread distribution, acceptance and effectiveness of vaccines against COVID-19, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

In addition, to the extent the COVID-19 pandemic may adversely affect our business, financial condition or

results of operations, it may also heighten other risks described in this section.

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 are dedicating 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 few years and we expect to continue to expand our sales, marketing, distribution, development and regulatory capabilities as our portfolio evolves, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2021, most of our employees were employed directly by our U.S. subsidiary, Biohaven Pharmaceuticals, Inc. Our number of employees increased substantially in 2019 and early 2020 to prepare for the commercialization of NURTEC ODT. 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.

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 progress or 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 any of our product candidates;

- failure to successfully commercialize NURTEC ODT or any of our other product candidates that may be approved in the future;
- 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, RPI, or Pfizer;
- 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 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;
- failure to attract or retain 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.

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.

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.

The holders of our common shares may have fewer protections as shareholders 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.

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

As a company with international operations, we are subject to income taxes, as well as non-income based taxes, in both the U.S. and various foreign jurisdictions. Significant judgment is required in determining our worldwide tax liabilities. Although we believe our estimates are reasonable at the time made, the final taxes we owe may differ from the amounts recorded in our financial statements (and such differences may be material). If the IRS, or other taxing authority, disagrees with the positions we take, we could have additional tax liability, and this could have a material impact on our results of operations and financial position. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and regulations, changes in interpretations of tax laws, including pending tax law, changes in our tax filings due to examinations and audits, changes in the value of our uncertain tax positions and changes in our future levels of research and development spending.

We have designed, and from time to time we modify, our corporate structure, the manner in which we develop and use our intellectual property, and our intercompany transactions between our affiliates in a way that is intended to enhance our operational and financial efficiency and increase our overall profitability. The application of the tax laws and regulations of various countries in which we operate and to our global operations is subject to interpretation. We also must operate our business in a manner consistent with our corporate structure to realize such efficiencies. The tax authorities of the countries in which we operate may challenge our methodologies for valuing developed technology or for transfer pricing or other operations. If tax authorities determine that the manner in which we operate results in our business not achieving the intended tax consequences, our effective tax rate could increase (and such increase may be material) and harm our financial position and results of operations. In addition, certain governments are considering and may adopt tax reform measures that significantly increase our worldwide tax liabilities. The Organization for Economic Co-operation and Development and other government bodies have focused on issues related to the taxation of multinational corporations, including, in the area of "base erosion and profit shifting," where payments are made from affiliates in jurisdictions with high tax rates to affiliates in jurisdictions with lower tax rates. It is possible that these reform measures could

increase our effective tax rate (and such increase may be material) and harm our financial position and results of operations over the next several years.

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, 2021 and do not currently expect to be a PFIC for our taxable year ending December 31, 2022 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.

If a significant portion of our total outstanding shares are sold into the market, the market price of our common shares could 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 in the market that the holders of a large number of common shares intend to sell shares, could reduce the market price of our common shares.

On November 9, 2021, in connection with the Collaboration Agreement, we agreed to sell to Pfizer \$350.0 million worth of our common shares at approximately \$173.05 per share, equal to 125% of the volume weighted average price per share for the 20 consecutive trading days prior to the signing of the subscription agreement with Pfizer. The sale of common shares to Pfizer was completed on January 4, 2022, upon the satisfaction of applicable closing conditions. In addition, on November 9, 2021, we entered into an agreement and plan of merger with BioShin, the closing of which was conditioned on the effectiveness of the Collaboration Agreement and consummation of the sale of common shares to Pfizer described above. At the closing of the BioShin merger on January 6, 2022, each outstanding BioShin Series A Preferred Share was converted into the right to receive 0.080121 of a common share of the Company.

We have registered all common shares that we may currently issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume, notice and manner of sale limitations applicable to affiliates.

We currently have on file with the SEC universal shelf registration statements on Form S-3 which allow us to offer and sell registered common shares, preferred stock, debt securities, depositary shares, units and/or warrants from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. In December 2020, we entered into an Equity Distribution Agreement with Goldman Sachs & Co. LLC and certain other managers, pursuant to which, from time to time, we may offer and sell through the managers up to \$400.0 million of our common shares registered under the universal shelf registration statement pursuant to one or more "at-the-market" offerings.

Sales of substantial amounts of our common shares or other securities by our stockholders, by the managers pursuant to the Equity Distribution Agreement, under our universal shelf registration statement or otherwise could also dilute our shareholders.

### Item 1B. Unresolved Staff Comments

None

# Item 2. Properties

Our U.S. headquarters is located in New Haven, Connecticut, where, as of December 31, 2021, we occupied approximately 10,000 square feet of office space, used for executive and corporate office functions. We purchased the property in December 2018. In December 2021, we purchased an office building in New Haven, Connecticut to expand its office space for executive and corporate office functions to support our continued growth. The building is directly next to our U.S. headquarters and is approximately 42,000 square feet.

In August 2019, we entered into a lease agreement in Yardley, Pennsylvania for approximately 21,000 square feet of office space to support expansion of our commercial operations in anticipation of the rimegepant commercial launch. The lease commenced on March 1, 2020, and has a term of 88 months, with the ability to extend to 148 months. The lessor provided us a temporary space to occupy while leasehold improvements were completed prior to commencement in the first quarter of 2020.

In November 2020, our Irish subsidiary entered into a license agreement in Dublin, Ireland for approximately 1,000 square feet of office space to support its operations. Upon execution of the agreement, the licensor agreed to provide us a temporary space to occupy at no additional cost until building improvements were complete. The license commenced in January 2021, and has a term of 36 months, with an automatic renewal option equal to the current term of the license but no less than 3 months until the license is terminated by Biohaven or the licensor.

In January 2021, in connection with our acquisition of the remaining interest in Kleo Pharmaceuticals, Inc. ("Kleo") that we did not previously own, we acquired the lease on approximately 10,000 square feet of the recently established Kleo chemistry and discovery facilities at Science Park in New Haven, Connecticut. The lease has a remaining term of 24 months, with an option to extend.

In April 2021, BioShin entered into a lease agreement in Shanghai, China for approximately 4,600 square feet of office space to support its operations. The lease commenced on April 1, 2021, and has a term of 36 months. In November 2021, BioShin entered into a lease agreement in Beijing, China for approximately 1,700

square feet of office space to support its operations. The lease commenced on November 1, 2021, and has a term of 12 months.

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 expand our international commercial footprint, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion.

# 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.

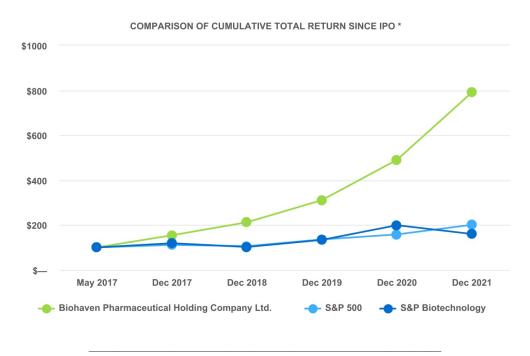
#### **PART II**

# 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**



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

#### **Shareholders**

As of February 21, 2022, there were 70 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**

In October 2021, we entered into a Purchase and Sale Agreement with 221 Church Street LLC, to purchase the building located at 221 Church Street in New Haven Connecticut (the "Purchase and Sale Agreement"). As consideration under the Purchase and Sale Agreement, in December 2021, we issued 39,004 of our common shares, valued at \$4.9 million, that were not registered under the Securities Act to 221 Church Street LLC in December 2021. 221 Church Street LLC represented that, among other things, it is an institutional accredited investor as defined in Rule 501(a) of Regulation D of the Securities Act, and the foregoing shares were issued in reliance on the private offering exemption provided by Section 4(a)(2) of the Securities Act.

In January 2022, we and Katholieke Universiteit Leuven ("KU Leuven") entered into an Exclusive License and Research Collaboration Agreement (the "KU Leuven Agreement") to develop and commercialize first-in-class TRPM3 antagonists. As consideration under the KU Leuven Agreement, we issued 15,340 of our common shares, valued at \$2.0 million, that were not registered under the Securities Act to KU Leuven in January 2022. KU Leuven represented that, among other things, it is an institutional accredited investor as defined in Rule 501(a) of Regulation D of the Securities Act, and the foregoing shares were issued in reliance on the private offering exemption provided by Section 4(a)(2) of the Securities Act. See Note 14 to our consolidated financial statements appearing elsewhere in this report for additional details on this transaction.

# **Issuer Purchases of Equity Securities**

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

# **Use of Proceeds from Registered Securities**

Not applicable.

Item 6. Reserved

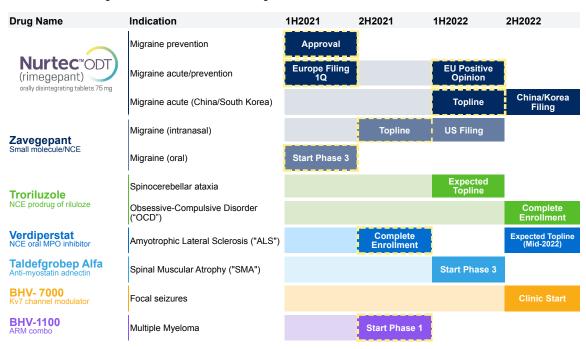
#### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

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 commercial-stage biopharmaceutical company with a portfolio of innovative, best-in-class therapies to improve the lives of patients with debilitating neurological and neuropsychiatric diseases, including rare disorders. Our Neuroinnovation portfolio includes FDA-approved NURTEC ODT (rimegepant) for the acute and preventive treatment of migraine and a broad pipeline of product candidates across five distinct mechanistic platforms: calcitonin gene related peptide ("CGRP") receptor antagonism, glutamate modulation, myeloperoxidase ("MPO") inhibition, Kv7 Ion Channel Activators ("Kv7"), and Myostatin.

Our clinical-stage milestones include the following:



#### **CGRP Platform**

Milestone Achieved

In July 2016, we acquired exclusive, worldwide rights to our CGRP receptor antagonist platform, including rimegepant and zavegepant (previously known as BHV-3500 and vazegepant), through a license agreement, as amended, with Bristol-Myers Squibb Company ("BMS"). In December 2020, Sosei Heptares and Biohaven entered a global collaboration and license agreement (the "Heptares Agreement") under which Biohaven received exclusive global rights to develop, manufacture and commercialize a portfolio of novel, small-molecule CGRP receptor antagonists discovered

by Sosei Heptares for the treatment of CGRP-mediated disorders.

# 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 have developed 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 for the Zydis ODT formulation of rimegepant was submitted using an FDA priority review voucher, purchased in March 2019, providing for an expedited 6-month review. The Zydis ODT formulation of rimegepant (NURTEC ODT) was approved by the FDA for the acute treatment of migraine on February 27, 2020 and was available by prescription in U.S. pharmacies on March 12, 2020. During the fourth quarter of 2020, we submitted an sNDA for the preventive treatment of migraine to the FDA for NURTEC ODT. The FDA approved NURTEC ODT for the preventive treatment of episodic migraine on May 27, 2021.

We remain focused on investing in long-term success by driving new-to-brand prescriptions, and ultimately market share, in this rapidly growing oral CGRP market and are continuing to observe a positive return on investment with increasing physician advocacy and attracting a greater pool of patients. We believe that the rapid adoption of NURTEC ODT is evidence of significant unmet need among people with migraine and an associated large acute and preventive therapy market opportunity. We continue to expand commercial payer coverage, with NURTEC ODT now covered by insurance providers reflecting 89% of commercial lives.

A summary of key rimegepant studies is described below.

#### 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 most bothersome symptom ("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 were consistent with regulatory guidance from the FDA and provided the basis for the submission of an 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 co-primary endpoints achieved in the Phase 3 trials were consistent with regulatory guidance from the FDA and formed the basis of efficacy data required by the FDA for approval.

#### 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"). In March 2020 we announced positive topline results from this study. Rimegepant 75 mg, dosed every other day, demonstrated statistically significant superiority, compared to placebo, on the primary endpoint of reduction in the mean number of migraine days per month in both episodic and chronic migraine patients. The safety profile seen in the 370 patients who received rimegepant 75 mg every other day was consistent with prior clinical trial experience. With this trial, rimegepant has become the only CGRP targeted therapy to demonstrate efficacy in both the acute and preventive treatment of migraine. An sNDA for rimegepant for prevention of migraine was filed with the FDA and accepted for review in the fourth quarter of 2020. The FDA approved NURTEC ODT for the preventive treatment of migraine on May 27, 2021.

#### Pediatric Study Plan

In June 2019, the FDA agreed to our Pediatric Study Plan for the acute treatment of migraine. The pediatric program for the acute treatment of migraine was initiated in the fourth quarter of 2020.

# 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.

#### Plaque Psoriasis

In the fourth quarter of 2020, we announced a collaboration with Weill Cornell Medicine's Dr. Richard Granstein, Chairman of Dermatology, to initiate an investigator-led clinical trial, which will explore whether treatment with one of our CGRP-receptor antagonists will reduce the severity of disease and percentage of area affected as measured by patients' Psoriasis Activity Severity Index (PASI) score after 16 weeks of treatment as compared to placebo. In addition, the study will assess the potential impact on itch and patient quality-of-life measures. Psoriasis is a chronic and painful autoimmune disease characterized by red patches of dry, cracked skin that may bleed, itch, and burn that affects approximately 7-8 million people in the U.S.

#### Rhinosinusitis

In February 2022, we announced that we have begun enrollment in a Phase 2/3 clinical trial assessing the safety and efficacy of NURTEC ODT 75mg in patients with chronic rhinosinusitis ("CRS") with or without nasal polyps. CRS is a symptomatic inflammation of the paranasal sinuses and nasal cavity lasting more than 12 weeks. CRS typically manifests as facial pain/pressure/fullness, nasal obstruction (congestion), nasal discharge, and/or a decreased sense of smell. Both preclinical and human studies have indicated that increased CGRP levels are associated with CRS, and suggest that blocking CGRP receptors with NURTEC ODT may have beneficial effects for those suffering from CRS. We expect to enroll approximately 200 patients in a randomized, doubleblind, placebo-controlled trial across approximately 25 sites in the U.S. Researchers will evaluate acute symptomatic treatment with rimegepant in patients with chronic rhinosinusitis with and without nasal polyps. The primary outcome measure is the change in a patient's facial pain/pressure/fullness score on a Numerical Rating Scale (0-10). The trial will also assess the safety and tolerability of rimegepant.

# Temporomandibular Disorder

In the first quarter of 2022, we received "Study May Proceed" communications from the FDA regarding our proposed clinical trial for the use of NURTEC ODT in temporomandibular disorder ("TMD"). TMD is a disorder of the jaw muscles, temporomandibular joints, and the nerves associated with chronic facial pain. We expect to commence a clinical trial during the first quarter of 2022.

#### International Health Authority Interactions

Scientific advice for rimegepant for acute and preventive migraine treatment was received from the CHMP, a committee of the European Medicines Agency, in June and December 2018, respectively. In the first quarter of 2021, we submitted the MAA for rimegepant dual activity, inclusive of acute and prevention of migraine. In February 2022, we were notified that CHMP adopted a positive opinion, recommending the granting of a marketing authorization in the EU for rimegepant 75 mg (available as an orally dissolving tablet), intended for the prophylaxis and acute treatment of migraine. If approved, VYDURA (rimegepant) will be the commercial name for rimegepant in the EU. The full indication for VYDURA is the acute treatment of migraine with or without aura in adults and preventive treatment of episodic migraine in adults who have at least four migraine attacks per month. We expect to receive determination regarding our Marketing Authorization Application in the EU for rimegepant in the first half of 2022.

Filings in Israel and the Middle East began in 2020. In March 2021, we received approval for rimegepant in Israel and the UAE for the acute treatment of migraine. In the fourth quarter of 2021, we received approval for rimegepant in Israel for the preventive treatment of episodic migraine in adults and in Kuwait for the acute treatment of episodic migraine in adults. We expect further approvals in 2022.

With respect to Japan, we have engaged the Pharmaceuticals and Medical Devices Agency ("PMDA") on a path forward, and initiation of Phase 2/3 bridging studies are anticipated to begin mid-2022.

In January 2019, we and our subsidiary, BioShin (Shanghai) Consulting Services Company Ltd. ("BioShin Shanghai"), a Shanghai based limited liability company, jointly announced that the National Medical Products Administration ("NMPA," formerly, the China FDA) had accepted the IND application for rimegepant for the treatment of migraine. As previously announced, BioShin Shanghai 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. In September 2020, BioShin Limited ("BioShin"), our subsidiary and the parent organization of BioShin Shanghai, raised \$60.0 million in series A funding (the "Bioshin Funding") which is being used to build out BioShin in China and advance our clinical portfolio in the Asia-Pacific region.

In November 2020, BioShin initiated a double-blind, randomized Phase 3 clinical trial evaluating the safety and efficacy of NURTEC ODT (rimegepant) for the acute treatment of migraine in China and South Korea.

In February 2022, we announced positive topline results from the study. The study met its co-primary endpoints of freedom from pain (p<0.0001) and freedom from MBS including either nausea, phonophobia or photophobia (p<0.0001) at 2-hours following a single oral dose of rimegepant. The early onset and durable 48 hour efficacy observed in China and South Korea is consistent with previous clinical trial results. In addition to the positive results on the co-primary endpoints, NURTEC ODT demonstrated rapid onset efficacy that was superior to placebo on multiple clinically important outcomes, including: pain relief at 2 hours (p < 0.0001); normal functioning at 2 hours post-dose (p<0.0001); no need for rescue medication within 24 hrs of dosing (p < 0.0001), and showed lasting efficacy with sustained pain freedom from 2 through 24 hours (p < 0.0001) and sustained pain freedom from 2 through 48 hours (p < 0.0001). Initial analysis of topline data indicates NURTEC ODT was numerically advantaged compared to placebo on multiple early-onset measures, including: pain relief within 45 minutes and freedom from MBS within 45 minutes; return to normal function within 60 min; and pain freedom within 90 min. Rimegepant also showed a favorable safety and tolerability profile among study participants that was consistent with prior clinical trial results in the United States. Detailed data from the study will be presented at future medical meetings to help inform ongoing and future research. We expect to submit an NDA during the second half of 2022

Pursuant to the terms of our Collaboration Agreement with Pfizer, we will continue to perform development activities required for the regulatory approval of rimegepant and zavegepant in all countries outside of the U.S. ("the Territory"). The development activities are to be performed under a mutually agreed-upon development plan. In addition, Pfizer has the right to conduct certain development activities in the Territory and will be the marketing authorization holder in all countries in the Territory where permitted under applicable law.

### Zavegepant

BHV-3500, formerly "vazegepant", is now referred to as "zavegepant" (za ve' je pant). The World Health Organization (WHO) International Nonproprietary Names (INN) Expert Committee revised the name to "zavegepant" which was accepted by the United States Adopted Names Council for use in the U.S. and is pending formal adoption by the INN for international use.

### Acute Treatment of Migraine

Administration of intranasal zavegepant in a Phase 1 clinical trial was initiated in October 2018 and achieved targeted therapeutic exposures. We advanced zavegepant into a Phase 2/3 trial to evaluate its efficacy for the acute treatment of migraine in the first quarter of 2019. We believed that intranasal zavegepant could provide an ultra-rapid onset of action that could be used in a complementary fashion with other migraine

treatments when the speed of onset is critical to a patient and/or for patients experiencing severe nausea and/or vomiting symptoms. In December 2019, we announced positive topline results from the Phase 2/3 trial. Zavegepant 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.

In January 2021, we announced the initiation of the Phase 3 clinical trial for the use of intranasal zavegepant for the acute treatment of migraine and in December 2021, we announced top-line results. The results of the study showed that zavegepant was statistically superior to placebo on the co-primary endpoints of pain freedom (24% vs 15%, p <.0001) and freedom from most bothersome symptom (40% vs 31%, p = 0.0012) at 2 hours. Zavegepant was superior to placebo demonstrating pain relief as early as 15 minutes, with patients achieving return to normal function as early as 30 minutes after dosing (p < 0.006). The efficacy benefits of zavegepant were durable, including superiority versus placebo (p < 0.05) on: sustained pain freedom 2 to 24 hours; sustained pain freedom 2 to 48 hours: sustained pain relief 2 to 24 hours: and sustained pain relief 2 to 48 hours. Based upon these results, combined with our prior positive Phase 2/3 trial, we plan to proceed with regulatory submissions in the United States and other countries and expect to submit an NDA for zavegepant with the FDA in the first half of 2022.

#### Preventative Treatment of Migraine

In September 2020, we announced that the FDA authorized the initiation of clinical trials for oral zavegepant and that we had achieved first in human dosing in a Phase 1 trial designed to assess the safety and pharmacokinetics of oral formulations of zavegepant. In March 2021, we announced that our Phase 2/3 clinical program to assess the efficacy of oral zavegepant in the preventive treatment of migraine began enrollment. The Phase 2/3 trial is ongoing with results expected in the second half of 2022.

#### COVID-19

In April 2020, we announced our plan to study intranasal zavegepant in pulmonary complications of COVID-19 disease. The IND was approved by the Division of Pulmonary, Allergy, and Critical Care at FDA in April 2020, and a Phase 2 trial began in April 2020 in collaboration with Thomas Jefferson University and other academic medical institutions. The clinical trial will assess the potential benefits of CGRP receptor-blockade in mitigating an excessive immune response which in some cases can be fatal in COVID-19 patients.

#### Asthma

In October 2021, we began enrollment in a Phase 1b, double-blind, placebo-controlled, parallel-group study to evaluate the safety and efficacy of oral zavegepant for the treatment of subjects with mild allergic asthma. Enrollment in the trial is ongoing.

#### **Next Generation CGRP Receptor Antagonists**

Several clinical candidates are being developed through a global collaboration and license agreement between Biohaven and Sosei Heptares. Under the agreement, Biohaven received exclusive global rights to develop, manufacture and commercialize a portfolio of novel, small-molecule CGRP receptor antagonists discovered by Sosei Heptares for the treatment of CGRP-mediated disorders.

BHV-3100, previously known as HTL0022562, was developed successfully through preclinical trials by Sosei Heptares and demonstrated promising and differentiated properties in target CGRP-mediated disorders. During the fourth quarter of 2021, we decided to stop development of BHV-3100 based upon its emerging preclinical profile and will instead advance one of the portfolio's backup compounds in its place.

#### **Glutamate Platform**

The most advanced product candidate from our glutamate receptor antagonist platform is troriluzole (previously referred to as trigriluzole and BHV-4157), which is in multiple Phase 3 trials. Other product candidates include BHV-5500 which 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 spinocerebellar ataxia ("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 completed enrollment in the Phase 3 trial of troriluzole in SCA in the first quarter of 2021. Results are expected in the first half of 2022.

#### Other Indications

A Phase 2/3 double-blind, randomized, controlled trial to assess the efficacy of troriluzole in OCD commenced in December 2017. The Phase 2/3 study results were announced in June 2020. Troriluzole 200 mg administered once daily as adjunctive therapy in OCD patients with inadequate response to standard of care treatment showed consistent numerical improvement over placebo on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) at all study timepoints (weeks 4 to 12) but did not meet the primary outcome measure at week 12 (p = 0.22 at week 12), including significant improvement at week 8 (p < 0.05). Troriluzole was well tolerated with a safety profile consistent with past

clinical trial experience. Given the strong signal in the Phase 2/3 proof of concept study and after receiving feedback from the FDA in an End of Phase 2 meeting, in December 2020 we initiated enrollment in the Phase 3 program. Two Phase 3 studies are currently ongoing with results expected in the second half of 2022.

In addition, a Phase 2/3 double-blind, randomized, controlled trial of troriluzole in the treatment of mild-to-moderate Alzheimer's disease was advanced with the Alzheimer's Disease Cooperative Study, a consortium of sites funded by the National Institutes of Health. In January 2021, topline data from the trial revealed that troriluzole did not statistically differentiate from placebo at 48 weeks on the study's prespecified coprimary endpoints on the Alzheimer's Disease Assessment Scale-Cognitive Subscale and the Clinical Dementia Rating Scale Sumo of Boxes in study participants with mild-to-moderate AD. Troriluzole also did not differentiate from placebo on the key secondary measure of hippocampal volume assessed by magnetic resonance imaging (MRI) in the overall population. A subgroup analysis consisting only of mild AD patients did, however, reveal that troriluzole exhibited a nonsignificant numerical difference of a potential benefit at week 48 on both the ADAScog and hippocampal volumetric MRI. Although the numerical effects on the ADAS-cog and hippocampal MRI measured in mild AD patients suggests a potential biologic effect of troriluzole in patients with early stage disease, additional analyses and biomarker data will be informative and help determine whether any further study in early AD is warranted. With regard to safety and tolerability, treatment with troriluzole at a dose of 280 mg once daily was relatively well tolerated and demonstrated a safety profile consistent with previous studies of troriluzole. In December 2021, we completed an ongoing long-term extension study of troriluzole in AD for mild AD patients.

In December 2021, the Global Coalition for Adaptive Research ("GCAR") selected troriluzole for evaluation in Glioblastoma Adaptive Global Innovative Learning Environment - NCT03970447 ("GBM AGILE"). GBM AGILE is a revolutionary patient-centered, adaptive platform trial for registration that tests multiple therapies for patients with newly-diagnosed and recurrent glioblastoma ("GBM"), the most fatal form of brain cancer. Troriluzole will be evaluated in all patient subgroups of the trial which include newly-diagnosed methylated MGMT, newly-diagnosed unmethylated MGMT, and recurrent GBM. Troriluzole was selected for inclusion in GBM AGILE based on compelling evidence showing deregulation of glutamate in GBM. The therapeutic potential of troriluzole in GBM and other oncology indications is supported by several recent clinical and translational research studies conducted with troriluzole and its active moiety.

#### International Development

In the third quarter of 2020, BioShin raised \$60.0 million in series A funding (the "Bioshin Funding") which

will be used to build out BioShin Limited in China and advance our clinical portfolio in the Asia-Pacific region, including initiating sites in China to participate in the global registrational trial of troriluzole in SCA.In December 2021, in connection with entering into the Collaboration Agreement with Pfizer,we merged Bioshin into a Biohaven subsidiary. BioShin completed enrollment for the SCA trial in China in the first quarter of 2021 with results expected in the first half of 2022.

#### BHV-5000 and BHV-5500

We are developing BHV-5500, a low-trapping NMDA receptor antagonist. 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 post-herpetic neuralgia and diabetic peripheral neuralgia. We acquired worldwide rights to BHV-5000 and BHV-5500 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. Results from nonclinical studies limiting clinical dose of BHV-5000 have led us to focus on BHV-5500 (lanicemine). Current work is focused on formulation development.

#### **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. In addition, Fast Track status was granted by the FDA in March 2020 for verdiperstat for the treatment for MSA. A Phase 3 trial began enrollment in July 2019 to evaluate the efficacy of verdiperstat in MSA. In September 2021, we announced results from a focused analysis of a clinical trial of verdiperstat in MSA. Verdiperstat did not statistically differentiate from placebo on the prespecified primary efficacy measure, nor on the key secondary efficacy measures. Initial analysis of safety data was consistent with the overall profile of verdiperstat from prior clinical trial experience. Additional analyses are still pending, and full study results will be presented at an upcoming scientific meeting.

Another potential target indication is ALS. In September 2019, we announced that verdiperstat was selected to be studied in the Phase 3 HEALEY ALS Platform Trial, which is being conducted by the Sean M. Healey & AMG Center for ALS at Massachusetts General Hospital 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. The Phase 3 HEALEY ALS Platform Trial of verdiperstat began enrollment in July 2020. Enrollment in the trial was completed in November of 2021, with results expected in mid-2022.

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. We have entered into an exclusive license agreement with AstraZeneca for the product candidate.

#### Kv7 Platform

#### BHV-7000

In February 2022, we announced that we entered into a definitive agreement with Channel Biosciences, LLC, a subsidiary of Knopp Biosciences, LLC, to acquire a Kv7 channel targeting platform, adding the latest advances in ion-channel modulation to our growing neuroscience portfolio. BHV-7000 (formerly known as KB-3061) is the lead asset from the Kv7 platform and is a potentially best-in-class potassium channel activator with a profile suggestive of a wide therapeutic index, high selectivity, and significantly reduced GABA-ergic activity. We intend to bring BHV-7000 to the clinic in in 2022 in preparation for a development program in focal epilepsy.

#### **Myostatin Platform**

#### Taldefgrobep Alfa License Agreement

In February 2022, following the transfer of intellectual property we announced that we entered into a worldwide license agreement with BMS for the development and commercialization rights to taldefgrobep alfa (also known as BMS-986089), a novel, Phase 3-ready anti-myostatin adnectin. Myostatin is a natural protein that limits skeletal muscle growth, an important process in healthy muscular development. However, in patients with neuromuscular diseases, active myostatin can critically limit the growth needed to achieve developmental and functional milestones. Myostatin inhibition is a promising therapeutic strategy for enhancing muscle mass and strength in a range of pediatric and adult neuromuscular conditions. Taldefgrobep is a muscle-targeted treatment for neuromuscular disease and offers the opportunity for combination therapy. We plan to initiate a Phase 3 clinical trial of taldefgrobep in SMA in 2022. SMA is a rare, progressively debilitating motor neuron disease in which development and growth of muscle mass are compromised, resulting in progressive weakness and muscle atrophy, reduced motor function, impaired quality of life and often death. The in-licensing of taldefgrobep expands our portfolio of innovative, late-stage product candidates for the treatment of

neurologic, neuroinflammatory, and psychiatric indications.

#### **Biohaven Labs**

#### Kleo Pharmaceuticals, Inc. and Biohaven Labs

In January 2021, we acquired the remaining approximately 58% of Kleo that we did not previously own. We have assumed Kleo's laboratory facilities located in Science Park in New Haven, Connecticut and formed Biohaven Labs to serve as the integrated chemistry and discovery research arm of Biohaven. Biohaven Labs will continue several existing Kleo discovery partnerships, including one with the Bill and Melinda Gates Foundation for the development of a of a SARS-CoV-2 neutralizing therapy for COVID-19 and one with PeptiDream for the development of immuno-oncology therapeutics (See Note 6).

Biohaven's proprietary Multimodal Antibody Therapy Enhancer ("MATE") conjugation technology uses a new class of synthetic peptide binders to target the spike protein of SARS-CoV-2 that are then selectively conjugated to commercially available intravenous immunoglobulin. The Biohaven synthetic binders for SARS-CoV2 were designed to establish a much wider area and number of contacts with the spike protein that other agents like monoclonal antibodies. In February 2021, we announced that BHV-1200, developed with Biohaven's proprietary MATE platform, has demonstrated functional binding and neutralization of the SARS-CoV-2 virus, including the strains known as the "English" and "South African" variants (also known as B.1.1.7 and B.1.351, respectively). The preliminary experiments conducted by Biohaven Labs and an academic collaborator demonstrated that BHV-1200 substantially reduced viral entry into cells. We intend to advance BHV-1200 into a full clinical development program. Accelerated development of the COVID-19 MATE program has been supported by the Bill and Melinda Gates Foundation. In addition, the in vitro data indicated that BHV-1200 may activate important immune system components including antibody-dependent cellular phagocytosis and antibody dependent cellular cytotoxicity. We believe our proprietary MATEconjugation technology could also be used against other infectious diseases by changing the targeting moiety of its antibody binders.

# Option and 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.

# Fox Chase Chemical Diversity Center, Inc.

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 us 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 14).

#### Sosei Heptares

In November 2020, we entered into a global collaboration and license agreement with Sosei Heptares, an international biopharmaceutical group focused on the discovery and early development of new medicines originating from their proprietary GPCR-targeted StaR technology and structure-based drug design platform capabilities. Under the agreement, Sosei Heptares will be eligible to receive development, regulatory and commercialization milestone payments, as well as tiered royalties on net sales of products resulting from the collaboration. In return, we will receive exclusive global rights to develop, manufacture and commercialize a portfolio of novel, small-molecule CGRP receptor antagonists discovered by Sosei Heptares for the treatment of CGRP-mediated disorders (See Note 14).

#### Artizan Biosciences, Inc.

In December 2020, we entered into an Option and License Agreement with Artizan Biosciences Inc ("Artizan"), a biotechnology company focused on addressing inflammatory diseases involving the human intestinal microbiota. Pursuant to the agreement, we acquired an option to obtain a royalty-based license from Artizan to manufacture, use and commercialize certain products. Artizan will use the proceeds to continue advancing the preclinical research and development of its lead program for inflammatory bowel disease, which is anticipated to enter the clinic in 2022, as well as to explore additional disease targets (See Note 14). In November 2021, we announced a collaborative therapeutic discovery and development program in Parkinson's disease (PD), to exploit recent scientific advances in the understanding of pathogenic roles played by the gut microbiome in PD

#### BHV-1100

In the fourth quarter of 2021, Biohaven initiated a Phase 1a/1b trial in multiple myeloma patients using its antibody recruiting molecule (ARM) BHV-1100 in combination with autologous cytokine induced memory-

like (CIML) natural killer (NK) cells and immune globulin (IG) to target and kill multiple myeloma cells expressing the cell surface protein CD38. BHV-1100 is the lead clinical asset from Biohaven's Antibody Recruiting Molecule (ARM™) Platform developed from a strategic alliance with PeptiDream Inc. (TYO: 4587). This clinical trial will assess the safety and tolerability as well as exploratory efficacy endpoints in newly diagnosed multiple myeloma patients who have tested positive for minimal residual disease (MRD+) in first remission prior to autologous stem cell transplant (ASCT).

# Reliant Glycosciences, LLC

In July 2021, Biohaven entered into a development and license agreement with Reliant Glycosciences, LLC ("Reliant") for collaboration on a program with Biohaven Labs' multifunctional molecules to develop and commercialize conjugated antibodies for therapeutic uses relating to IgA nephropathy and treatment of other diseases and conditions. Under the Agreement, Reliant was entitled to an upfront share payment and will be eligible to receive development milestone payments and royalties of net sales of licensed products (See Note 14).

#### **KU** Leuven

In January 2022, we entered into the KU Leuven Agreement to develop and commercialize first-in-class TRPM3 antagonists to address the growing proportion of people worldwide living with chronic pain disorders. The TRPM3 antagonist platform was discovered at the Centre for Drug Design and Discovery and the Laboratory of Ion Channel Research at KU Leuven. Under the KU Leuven Agreement, we receive exclusive global rights to develop, manufacture and commercialize KU Leuven's portfolio of small-molecule TRPM3 antagonists. The portfolio includes the lead candidate, henceforth known as BHV-2100, which has demonstrated promising efficacy in preclinical pain models and will be the first to advance towards Phase 1 studies. We will support further basic and translational research at KU Leuven on the role of TRPM3 in pain and other disorders (See Note 14).

# **Recent Developments**

The following is a summary of key developments affecting our business in 2021.

# **Pfizer Collaboration Agreement**

In November 2021, we entered into the Collaboration Agreement with Pfizer, pursuant to which Pfizer would commercialize the Licensed Products in all countries worldwide outside of the United States. In consideration thereof, in January 2022 Pfizer made an upfront payment of \$150.0 million to Biohaven upon receipt of the requisite regulatory approvals needed for the effectiveness of the Collaboration Agreement. In addition, in January 2022 Pfizer purchased \$350.0 million worth of Biohaven common shares at approximately \$173.05 per share, equal to 125% of the volume weighted average price per share for the 20

consecutive trading days prior to the signing. We will be eligible to receive an aggregate additional \$740.0 million in contingent payments based on specified commercial and sales-based milestones for the Licensed Products.

We are also entitled to tiered, escalating royalties from the upper teens to twenty percent of net sales of Licensed Products in the Territory. In general, Pfizer's obligation to pay royalties continues on a product-by-product and country-by-country basis until the latest of ten years after the first commercial sale of such product in such country, the expiration of the patent rights covering such product in such country or the expiration of the period of exclusivity applicable to such product in such country. In addition to the upfront payments, contingent payments and royalties described above, Pfizer will also compensate us for a pro-rata share of certain of its sales-based milestone obligations owed to BMS under the BMS License, and related net sales royalties owed to BMS and RPI that result from Pfizer's commercialization and sale, respectively, of the Licensed Products in the Territory.

# Merger Agreement with BioShin

On November 9, 2021, we entered into an agreement and plan of merger (the "Merger Agreement") with BioShin. The Merger Agreement provides for the merger of a wholly owned indirect subsidiary of the Company with and into BioShin, with BioShin surviving the merger as a wholly owned indirect subsidiary of the Company (the "BioShin Merger"). As a result of the satisfaction of the closing conditions described in the Merger Agreement, on January 6, 2022, each Series A convertible preferred share of BioShin, no par value, other than Excluded Shares (as defined in the Merger Agreement), was converted into the right to receive 0.080121 of a Company common share.

#### Amendments to the Sixth Street Financing Agreement

In August 2020, the Company and Biohaven Pharmaceuticals, Inc., our wholly-owned subsidiary (together with the Company, the "Borrowers"), entered into a financing agreement, as amended, with Sixth Street Specialty Lending, Inc., as administrative agent, and the lenders party thereto (the "Lenders") pursuant to which the Lenders agreed to extend a senior secured credit facility to us providing for term loans in an aggregate principal amount up to \$500.0 million, plus any capitalized interest paid in kind. In September 2021, the Borrowers, and certain other of our subsidiaries entered into Amendment No. 2 (the "Second Amendment") to the financing agreement (as previously amended and as amended by the Second Amendment, the "Sixth Street Financing Agreement"). Pursuant to the Second Amendment, the parties agreed to, among other things, increase the size of the credit facility by providing for additional term loans in an aggregate principal amount of \$250.0 million for a total facility size of \$750.0 million plus any capitalized interest paid in kind. The facility consists of drawn amounts for an initial

term loan of \$275.0 million that the Borrowers drew at closing in August 2020 (the "Initial Term Loan"), \$125.0 million drawn in August 2021 (the "DDTL-2"), and \$125.0 million (the "2021 Term Loan") and \$100.0 million (the "DDTL-1") both drawn in September 2021. The remaining \$125.0 million delayed draw term loan commitments (the "2021 DDTL Commitment") was available to be drawn by the Borrowers until December 31, 2021 (the "Delayed Draw Term Loan Commitment Termination Date"). In November 2021, the Company entered into Amendment No. 3 and Limited Consent to Financing Agreement ("the Third Amendment and Limited Consent") to our Sixth Street Financing Agreement. Pursuant to the Third Amendment and Limited Consent, the lenders consented to the Company's entry into the Collaboration Agreement with Pfizer. In December 2021, we entered into Amendment No. 4 (the "Fourth Amendment") to the Sixth Street Financing Agreement, which extended the Delayed Draw Term Loan Commitment Termination Date to June 30, 2022. For additional details please refer to "Liquidity and Capital Resources" and Note 14, "Debt."

#### Artizan Biosciences Inc.

In December 2020, we entered into a Series A-2 Preferred Stock Purchase Agreement with Artizan Biosciences Inc. ("Artizan") (Note 14). Under the agreement, we paid Artizan 61,494 shares valued at \$6.0 million, which were issued in January 2021. In exchange, we acquired 34,472,031 shares of series A-2 preferred stock of Artizan.

#### Yale MoDE Agreement

On January 1, 2021, we entered into a worldwide, exclusive license agreement for the development and commercialization of a novel Molecular Degrader of Extracellular Protein (MoDEs) platform based on ground-breaking research conducted in the laboratory of Professor David Spiegel at Yale University (Note 14). Under the agreement, we paid Yale University an upfront cash payment of \$1.0 million and 11,668 shares valued at \$1.0 million, both of which were included in research and development expense in the consolidated statements of operations.

# Consulting Agreement with Moda Pharmaceuticals LLC

On January 1, 2021, we entered into a consulting services agreement with Moda Pharmaceuticals LLC to further the scientific and commercial advancement of technology, drug discovery platforms, product candidates and related intellectual property owned or controlled by us (Note 14). Under the agreement, we paid Moda an upfront cash payment of \$2.7 million and 37,836 shares valued at \$3.2 million, both of which were included in research and development expense in the consolidated statements of operations and comprehensive loss.

# KU Leuven Agreement

In January 2022, Biohaven and Katholieke Universiteit Leuven ("KU Leuven") entered into an Exclusive License and Research Collaboration Agreement (the "KU Leuven Agreement") to develop and commercialize first-in-class TRPM3 antagonists to address the growing proportion of people worldwide living with chronic pain disorders. The TRPM3 antagonist platform was discovered at the Centre for Drug Design and Discovery ("CD3") and the Laboratory of Ion Channel Research ("LICR") at KU Leuven. Under the KU Leuven Agreement, Biohaven receives exclusive global rights to develop, manufacture and commercialize KU Leuven's portfolio of small-molecule TRPM3 antagonists. The portfolio includes the lead candidate, henceforth known as BHV-2100, which has demonstrated promising efficacy in preclinical pain models and will be the first to advance towards Phase 1 studies. Biohaven will support further basic and translational research at KU Leuven on the role of TRPM3 in pain and other disorders. As consideration, KU Leuven received an an upfront cash payment of \$3.0 million and 15,340 shares valued at \$1.8 million, and is eligible to receive additional development, regulatory, and commercialization milestones payments of up to \$327.8 million. In addition, KU Leuven will be eligible to receive mid-single digit royalties on net sales of products resulting from the collaboration.

#### Kv7 Platform Acquisition

In February 2022, we announced that we entered into a definitive agreement with Channel Biosciences, LLC, a subsidiary of Knopp Biosciences, LLC, to acquire a Kv7 channel targeting platform, adding the latest advances in ion-channel modulation to our growing neuroscience portfolio. BHV-7000 (formerly known as KB-3061) is the lead asset from the Kv7 platform and is a potentially best-in-class potassium channel activator with a profile suggestive of a wide therapeutic index, high selectivity, and significantly reduced GABA-ergic activity. We intend to bring BHV-7000 to the clinic in in 2022 in preparation for a development program in focal epilepsy. In consideration for the transaction, we will make an upfront payment comprised of \$65 million in Biohaven common shares and \$35 million in cash to Knopp Biosciences. We have also agreed to make additional success-based earnout payments (i) up to \$325 million based on BHV-7000 developmental and regulatory epilepsy milestones through approvals in the US, EU and Japan, (ii) up to an additional \$250 million based on developmental and regulatory milestones for the Kv7 pipeline development in other indications and additional country approvals, and (iii) up to \$562.5 million for commercial sales-based milestones of BHV-7000. Biohaven has also agreed to make scaled royalty payments for BHV-7000 and the pipeline programs, starting at high single digits and peaking at low teens for BHV-7000 and starting at mid-single digits and peaking at low double-digits for the pipeline programs.

#### Taldefgrobep Alfa Platform License

In February 2022, following the transfer of intellectual property we announced that we entered into a worldwide license agreement with BMS for the development and commercialization rights to taldefgrobep alfa, a novel, Phase 3-ready anti-myostatin adnectin. The in-licensing of taldefgrobep expands our portfolio of innovative, late-stage product candidates for the treatment of neurologic, neuroinflammatory, and psychiatric indications. Under the terms of the agreement, we will receive worldwide rights to taldefgrobep alfa and BMS will be eligible for regulatory approval milestone payments, as well as tiered, sales-based royalty percentages from the high teens to the low twenties (Note 14). We plan to initiate a Phase 3 clinical trial of taldefgrobep alfa in SMA in 2022.

### **COVID-19 Update**

A novel strain of coronavirus (COVID-19) was first identified in Wuhan, China in December 2019, and subsequently declared a pandemic by the World Health Organization. To date, COVID-19 has surfaced in nearly all regions around the world and resulted in travel restrictions and business slowdowns or shutdowns in affected areas.

Although, as of the date of this Annual Report on Form 10-K, we do not expect any material impact on our long-term activity, the extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others, including government-imposed quarantines, travel restrictions and other public health safety measures.

The COVID-19 pandemic may impair our commercialization of NURTEC ODT. The spread of COVID-19 may reduce demand for NURTEC ODT. In response to regional quarantines, health professionals may reduce staffing and reduce or postpone appointments with patients, or patients may cancel or miss appointments, resulting in less prescriptions of NURTEC ODT than projected, thereby adversely affecting our revenues. In addition, in connection with the recent FDA approval of NURTEC ODT, we have been making presentations to physicians regarding the efficacy of NURTEC ODT but as a result of the COVID-19 pandemic, we have needed to and may continue to need to conduct some or all of these key meetings with medical professionals solely by virtual means instead of in-person, which could reduce the number of medical professionals we are able to present to, and we cannot guarantee that any such virtual meetings will be as successful as in-person meetings. Moreover, restrictions on travel and transport may result in disruptions in NURTEC ODT distribution. Such events may result in a period of business disruption, and in reduced operations, any of which could materially affect

our business, financial condition and results of operations.

The continued spread of COVID-19 could also adversely impact our clinical trial operations. For example, we may be unable to enroll or retain an adequate number of patients to commence or complete our clinical trials, data may be missing, the FDA may delay or terminate clinical trials for any of our product candidates, or primary outcome measures may be impacted. As a result, our ability to generate product revenue from sales of any of those product candidates may be delayed or not realized at all.

Business interruptions from the current or future pandemics may also adversely impact the third parties we rely on to sufficiently manufacture NURTEC ODT and to produce our product candidates in quantities we require, which may impair the commercialization of NURTEC ODT and our research and development activities.

The COVID-19 pandemic and responses to its spread have negatively impacted the global economy, disrupted global supply chains, and created significant volatility and disruption of financial markets. This significant disruption of the global financial markets could reduce our ability to access equity or debt capital on attractive terms if at all, which in turn could negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common shares.

We have taken numerous steps, and will continue to take further actions, in our approach to addressing the COVID-19 pandemic. We have implemented internal controls to contemplate a remote work environment and our incident management teams are in place to respond to changes in our work environment quickly and effectively. As a result of the COVID-19 pandemic, we have instructed most of our employees to work from home. In April 2020, we announced a collaboration with Cove in order to facilitate telemedicine evaluation for migraine sufferers while patients are increasingly looking to remote evaluations during this time of unprecedented decreased access to routine office visits.

We continue to monitor the rapidly evolving situation and guidance from international and domestic authorities, including federal, state and local public health authorities and may take additional actions based on their recommendations. In these circumstances, there may be developments outside our control requiring us to adjust our operating plan. As such, given the dynamic nature of this situation, we cannot reasonably estimate the impacts of COVID-19 on our business, financial condition or results of operations.

#### Components of Our Results of Operations

#### Product Revenues, Net

We began to recognize revenue from product sales, net of rebates, chargebacks, discounts and other adjustments, in March 2020 in conjunction with the launch of our first product, NURTEC ODT. We will continue to evaluate trends related to revenue momentum for NURTEC ODT, including any discernible impacts of the COVID-19 pandemic. If our development efforts for our other product candidates are successful and result in regulatory approval, or additional license agreements with third parties, we may generate additional revenue in the future from product sales.

#### Cost of Goods Sold

Cost of goods sold includes direct and indirect costs related to the manufacturing and distribution of NURTEC, including third-party manufacturing costs, packaging services, freight-in, third-party royalties payable on our net product revenues and amortization of intangible assets associated with NURTEC ODT.

#### **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;
- development milestone payments incurred prior to regulatory approval of the product candidate;
- payments made in cash, equity securities or other forms of consideration under third-party licensing agreements prior to

regulatory approval of the product candidate; and

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 and certain development milestones 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 INDenabling 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.

## Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of personnel costs, including salaries, benefits and travel expenses for our executive, commercial, finance, business, commercial, corporate development and other administrative functions; and non-cash share-based compensation expense. Selling, general and administrative expenses also include facilities and other related expenses, including rent, depreciation, maintenance of facilities, insurance and supplies; professional fees for expenses incurred under agreements with third parties relating to the commercialization of NURTEC ODT; and for public relations, audit, tax and legal services, including legal expenses to pursue patent protection of our intellectual property.

We anticipate that our selling, general and administrative expenses, including payroll and related expenses, will remain significant in the future as we continue to expand our operations and organizational capabilities, continue to support our commercial activities associated with NURTEC ODT, and prepare for potential commercialization of our product candidates, if successfully developed and approved. We also anticipate increased expenses associated with general operations, including costs related to accounting and legal services, director and officer insurance premiums, facilities and other corporate infrastructure and office-related costs, such as information technology costs.

#### Other Income (Expense)

#### Interest Expense

Interest expense primarily consists of interest on our outstanding term loan with Sixth Street Specialty Lending, Inc., which includes interest expense on the outstanding loan balance, accretion of the debt discount and amortization of issuance costs. Our interest expense also includes implied interest on our finance leases associated with our commercial car fleet. We utilize the effective interest method to determine our interest expense on the term loan and finance leases and the straight-line method for the amortization of the debt issuance costs.

#### Interest Expense on Mandatorily Redeemable Preferred Shares

Interest expense on mandatorily redeemable preferred shares is being recognized in connection with the issuance of series A preferred shares and series B preferred shares pursuant to the Series A preferred share purchase agreement and Series B preferred shares forward contracts we entered into with RPI. Since we are required to redeem the series A preferred shares for 2x the original purchase price in equal quarterly installments by December 31, 2024 and the series B preferred shares for 1.77x the original purchase price in equal installments beginning on March 31, 2025 and ending December 31, 2030, we concluded that the Series A preferred shares and Series B preferred shares are mandatorily redeemable instruments and initially classified the preferred shares at their fair value as a liability. Interest expense on the mandatorily redeemable preferred shares represents the accretion of the carrying value of the preferred shares liability to its redemption value using the effective interest rate method.

## Change in Fair Value of Derivatives

The fair value of the derivative liability recognized in connection with contingent payments under the Series A 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 consolidated balance sheet as a Series A preferred derivative liability with changes in fair value recorded in other income (expense) in the consolidated statements of operations.

The fair value of the derivative liability recognized in connection with the Series B Preferred Shares Forward Contracts is determined using discounted cash flow and Monte Carlo valuation methods. As inputs into the valuation, we considered the probability of occurrence of certain change of control 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 consolidated balance sheet as a Series B preferred shares forward contact with changes in fair value recorded in other income (expense) in the consolidated statements of operations and comprehensive loss.

#### Interest Expense on Liability Related to Sale of Future Royalties

We have accounted for the 2018 RPI Funding Agreement and a unit of accounting of the 2020 RPI Funding Agreement with RPI Trust both as liability financings, primarily because they have significant continuing involvement in generating the future revenue on which the royalties are based. The liabilities related to sale of future royalties and the related non-cash interest expense are measured based on our current estimate of the timing and amount of future royalties expected to be paid over the estimated terms of the 2018 RPI Funding Agreement and 2020 RPI Funding Agreement. The liabilities are 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, we assess the estimated timing and amount of future expected royalty payments over the estimated terms. If there is a change to one of the estimates, we recognize the impact to the liability's amortization schedule and the related non-cash interest expense prospectively. Our estimate of the amount of expected future royalties to be paid considers the probability of success of compounds not yet approved for sale, and market penetration rates, compliance rate, and net pricing of both NURTEC ODT and compounds not yet approved for sale. Additionally, the transaction costs associated with the liabilities will be amortized to non-cash interest expense over the estimated term of the 2018 RPI Funding Agreement and 2020 RPI Funding Agreement, respectively.

#### Gain (Loss) from Equity Method Investment

Prior to our acquisition of Kleo in January 2021, we owned approximately 42% of the outstanding shares as of December 31, 2020, and accounted 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 was included in other income (expense), net, in our consolidated statement of operations and results in a corresponding adjustment to the carrying value of the equity method investment on our consolidated balance sheet.

On January 4, 2021, we acquired the rest of the shares of Kleo, and post-transaction we own 100% of the outstanding shares of Kleo.

# Provision for Income Taxes

As a company incorporated in the British Virgin Islands ("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. As a result, we have not recorded any income tax

benefits from losses incurred in the BVI during each reporting period, and no net operating loss carryforwards will be available to us for those losses. We have historically outsourced all of the research and clinical development for our programs under a master services agreement with our wholly owned subsidiary, Biohaven Pharmaceuticals, Inc., a Delaware corporation ("BPI"). As a result of providing services under this agreement and profit from US commercial sales of NURTEC ODT, BPI was profitable during the year ended December 31, 2021, and BPI is subject to taxation in the United States.

In August 2020, we completed an intra-entity asset transfer of certain of our intellectual property to our Irish subsidiary. As a result of the transfer, we recorded a deferred tax asset of \$875.0 million for the step up in tax basis received pursuant to Irish tax law. Based on our analysis of all available objective evidence, we concluded that it was more likely than not that the deferred tax asset from the intra-entity transfer will not be realized due to the lack of net operating income history of our subsidiary. Therefore, we established a full valuation allowance against our net deferred tax asset in Ireland.

We continue to maintain a valuation allowance against our US deferred tax assets. We periodically review our position and have determined that a full valuation allowance on these assets was appropriate due to excess research and development ("R&D") credit carryforwards as of December 31, 2021. We will continue to evaluate the need for a valuation allowance on our deferred tax assets until there is sufficient positive evidence to support the reversal of all or some portion of these allowances. We anticipate the commercialization of NURTEC ODT will result in future earnings and believe sufficient positive evidence may become available to allow us to reach a conclusion that a significant portion, or all, of the valuation allowance will no longer be needed. Release of the valuation allowance would result in the recognition of certain deferred tax assets and a decrease to income tax expense for the period the release is recorded. However, the exact timing and amount of the valuation allowance release is subject to change on the basis of the level of profitability that we are able to actually achieve.

In January 2021, we completed the acquisition of Kleo. The acquisition and inclusion of Kleo did not result in a material impact on the provision for income taxes or the effective tax rate for the year ended December 31, 2021. We recorded a full valuation allowance against our Kleo US deferred tax assets and will periodically review our position and have determined that a full valuation allowance on these assets was appropriate due to Kleo's cumulative loss history. We will continue to evaluate the need for a valuation allowance on our deferred tax assets until there is sufficient positive evidence to support the reversal of all or some portion of these allowances.

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We recorded an income tax provision during the year ended December 31, 2021 of \$5.1 million which primarily represents certain state taxes for the period and US federal taxes due to general business credit limitations.

## **Results of Operations**

### Comparison of the Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,						
<u>In thousands</u>		2021	2020		Change		
Product revenue, net	\$	462,509	\$ 63,62	27 \$	398,882		
Cost of goods sold		91,664	17,69	)4	73,970		
Gross profit	<del></del>	370,845	45,93	33	324,912		
Operating expenses:							
Research and development		361,340	228,99	8	132,342		
Selling, general and administrative		713,549	462,32	23	251,226		
Total operating expenses		1,074,889	691,32	21	383,568		
Loss from operations		(704,044)	(645,38	8)	(58,656)		
Other income (expense):							
Interest expense		(41,551)	(12,63	6)	(28,915)		
Interest expense on mandatorily redeemable preferred shares		(32,293)	(27,62	(3)	(4,670)		
Interest expense on liability related to sale of future royalties		(60,605)	(45,23	(8)	(15,367)		
Change in fair value of derivatives		(2,833)	(19,32	(1)	16,488		
Gain (loss) from equity method investment		5,261	(4,16	(2)	9,423		
Other expense, net		(7,258)	(4,02	(0)	(3,238)		
Total other expense	_	(139,279)	(113,00	0)	(26,279)		
Loss before provision for income taxes		(843,323)	(758,38	88)	(84,935)		
Provision for income taxes		5,073	10,22	27	(5,154)		
Net loss	\$	(848,396)	\$ (768,61	5) \$	(79,781)		
Less: Net loss attributable to non-controlling interests		(1,810)	(1,81	9)	9		
Net loss attributable to Biohaven Pharmaceutical Holding Company Ltd.	\$	(846,586)	\$ (766,79	(6) \$	(79,790)		

#### Product Revenue, Net

We began recording product revenues in the first quarter of 2020 following the approval of NURTEC ODT by the FDA on February 27, 2020 and its subsequent commercial launch in the U.S. in March 2020. Net product revenue was \$462.5 million for the year ended December 31, 2021, compared to \$63.6 million for the year ended December 31, 2020. The increase of \$398.9 million in net product revenues was due to both increased NURTEC ODT sales volume and improvements in net price realization due to decreases in sales allowances in 2021, compared to 2020, and a full year of NURTEC ODT sales during 2021 compared to a partial period of NURTEC ODT sales in 2020. Sales allowances and accruals mostly consisted of patient affordability programs, distribution fees and rebates.

#### Cost of Goods Sold

Cost of goods sold of \$91.7 million for the year ended December 31, 2021 is primarily related to

royalties on net sales payable to BMS under a license agreement, manufacturing costs for NURTEC ODT, certain distribution costs and amortization of intangible assets related to milestone payments to BMS and Catalent. The increase of \$74.0 million in cost of goods sold was primarily due to increased NURTEC ODT sales during the year ended December 31, 2021, compared to the year ended December 31, 2020, which had no material manufacturing costs included as the majority of the costs were incurred prior to FDA approval and as such recorded as research and development expense.

#### Research and Development Expenses

	Year Ended December 31,					
<u>In thousands</u>		2021		2020		Change
		•				
Direct research and development expenses by program:						
Rimegepant	\$	65,394	\$	53,838	\$	11,556
Troriluzole		50,637		42,127		8,510
Zavegepant		54,717		36,836		17,881
Verdiperstat		34,518		24,987		9,531
Other programs		4,329		383		3,946
Unallocated research and development costs:						
Personnel related (including non-cash share-based compensation)		105,182		52,248		52,934
Preclinical research programs		29,031		12,092		16,939
Other		17,532		6,487		11,045
Total research and development expenses	\$	361,340	\$	228,998	\$	132,342

R&D expenses, including non-cash share-based compensation costs, were \$361.3 million for the year ended December 31, 2021, compared to \$229.0 million for the year ended December 31, 2020. The increase of \$132.3 million was primarily due to:

- a \$52.9 million increase in personnel costs, driven by a \$28.4 million increase in share-based compensation expense, as well as increases in headcount, merit increases and bonuses;
- increased expenses from later stage trials in our zavegepant programs of \$17.9 million, which included a partial offset related to a \$30.8 million reduction in our obligation to perform R&D services for zavegepant; and
- increases in preclinical research costs of \$16.9 million, which included upfront payments of \$2.0 million to Yale University in connection with a license agreement, \$5.9 million to Moda Pharmaceuticals LLC in connection with a consulting agreement, and \$3.7 million to Reliant Glycosciences, LLC in connection with a development and license agreement;
- increases in direct costs of \$11.6 million, \$9.5 million and \$8.5 million for our rimegepant, verdiperstat and troriluzole programs, respectively, in 2021; and
- increases of \$11.0 million in various other unallocated R&D costs.

#### Selling, General and Administrative Expenses

SG&A expenses, including non-cash share-based compensation costs, were \$713.5 million for the year ended December 31, 2021, compared to \$462.3 million for the year ended December 31, 2020. The increase of \$251.2 million was primarily due to increased spending to support the continued launch of NURTEC ODT, including the launch of NURTEC ODT for the

preventative treatment of migraine which was approved by the FDA in May of 2021. The increased spending included increases in marketing and advertising expenses, professional fees and non-cash share based compensation. Less than half of the SG&A expense was for commercial organization personnel costs, excluding non-cash share-based compensation expense. The increase of \$41.3 million in non-cash share based compensation expense was primarily due to our annual equity incentive awards that were granted in the first quarter of 2021.

#### Other Income (Expense), Net

Other income (expense), net was a net expense of \$139.3 million for the year ended December 31, 2021, compared to net expense of \$113.0 million for the year ended December 31, 2020. The increase of \$26.3 million in net expense was primarily due to increased interest expense on our term loans with Sixth Street, which were drawn in the third quarter of 2020 and the third quarter of 2021, an increase in the interest expense recognized on our liability related to the sale of future royalties, and increased 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. These increases were partially offset by a change in gain (loss) on equity investment of \$9.4 million, primarily due to the acquisition of Kleo Pharmaceuticals, Inc. in the first quarter of 2021, and a \$16.5 million decrease in expense related to changes in the fair value of our derivatives.

#### Provision for Income Taxes

We recorded a provision for income taxes of \$5.1 million for the year ended December 31, 2021, compared to a provision for income taxes of \$10.2 million for the year ended December 31, 2020. The tax provision recorded for the year ended December 31, 2021 was primarily attributable to our profitable operations in the United States during the year.

#### Comparison of the Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

	Year Ended December 31,							
In thousands		2020	2	019		Change		
Product revenue, net	\$	63,627	\$	_	\$	63,627		
Cost of goods sold		17,694		_	\$	(17,694)		
Gross profit		45,933			\$	(45,933)		
Operating expenses:								
Research and development		228,998		344,673		(115,675)		
Selling, general and administrative		462,323		134,449		327,874		
Total operating expenses		691,321		479,122		212,199		
Loss from operations		(645,388)		(479,122)		(166,266)		
Other income (expense):								
Interest expense		(12,636)		_		12,636		
Interest expense on mandatorily redeemable preferred shares		(27,623)		(12,711)		(14,912)		
Interest expense on liability related to sale of future royalties		(45,238)		(26,580)		(18,658)		
Change in fair value of derivatives		(19,321)		(3,875)		(15,446)		
Gain (loss) from equity method investment		(4,162)		(6,076)		1,914		
Other expense, net		(4,020)		(22)		(3,998)		
Total other expense		(113,000)		(49,264)		(63,736)		
Loss before provision for income taxes		(758,388)		(528,386)		(230,002)		
Provision for income taxes		10,227		419		9,808		
Net loss	\$	(768,615)	\$	(528,805)	\$	(239,810)		
Less: Net loss attributable to non-controlling interests		(1,819)		_		(1,819)		
Net loss attributable to Biohaven Pharmaceutical Holding Company Ltd.	\$	(766,796)	\$	(528,805)	\$	(237,991)		

#### Product Revenue, net

We began recording product revenues in the first quarter of 2020 following the approval of NURTEC ODT by the FDA on February 27, 2020 and its subsequent commercial launch in the U.S. in March 2020. During the year ended December 31, 2020, we recognized \$63.6 million of net product revenues related to sales of NURTEC ODT. Sales allowances and accruals mostly consisted of co-pay card discounts, distribution fees and rebates.

#### Cost of Goods Sold

Cost of goods sold of \$17.7 million for the year ended December 31, 2020 is related to royalties on net sales payable to BMS under a license agreement (see Note 17 "Commitments and Contingencies" to our consolidated financial statements), product costs

incurred after FDA approval, certain distribution costs and amortization of intangible assets related to milestone payments to BMS and Catalent, Inc. ("Catalent"). See Note 14 "License and Other Agreements" to our consolidated financial statements. Prior to receiving initial FDA approval for NURTEC ODT on February 27, 2020, we manufactured NURTEC ODT inventory to be sold upon commercialization and recorded all costs incurred as research and development expense. As a result, the manufacturing costs related to the NURTEC inventory build-up incurred before FDA approval were already expensed in a prior period and are therefore excluded from the cost of goods sold for the year ended December 31, 2020. These previously expensed costs were not material for the year ended December 31, 2020. The inventory build-up incurred before FDA approval was sold prior to the start of the fourth quarter of 2020.

#### Research and Development Expenses

	Year Ended December 31,					
In thousands		2020		2019		Change
Direct research and development expenses by program:						
BHV-0223	\$	172	\$	849	\$	(677)
Troriluzole		42,127		37,812		4,315
Rimegepant						
Priority review voucher		_		105,000		(105,000)
Program expenses'		53,838		88,948		(35,110)
Zavegepant		36,836		44,821		(7,985)
BHV-5000		211		850		(639)
Verdiperstat		24,987		10,922		14,065
Unallocated research and development costs:						
Personnel related (including share-based compensation)		52,248		45,683		6,565
Preclinical research programs		12,092		6,193		5,899
Other		6,487		3,595		2,892
Total research and development expenses	\$	228,998	\$	344,673	\$	(115,675)

Research and development expenses including one-time regulatory and license fees were \$229.0 million for the year ended December 31, 2020, compared to \$344.7 million for the year ended December 31, 2019. The decrease of \$115.7 million was primarily due to:

- one-time \$105.0 million purchase of a priority review voucher to expedite the regulatory review of rimegepant ODT formulation in the second guarter of 2019;
- filing fees of \$7.6 million related to our rimegepant NDA submissions to the FDA in the second quarter of 2019;
- development milestones payable to BMS of \$11.5 million for rimegepant NDA submissions in 2019;
- non-cash research and development expense of \$5.6 million due to issuance of common shares in the second quarter of 2019 relating to the collaborative discovery program with Fox Chase;
- decreases in direct costs of \$8.0 million for our zavegepant program, mainly due to expenses for development milestones payable to BMS of \$10.0 million in 2019;
- increases in direct costs of \$4.3 million for our troriluzole program in 2020, which include increases for our OCD, and Alzheimer's Disease trials;
- increases in direct costs of \$14.1 million for our verdiperstat program in 2020; and
- increases in personnel costs of \$6.6 million mainly due to an increase of \$8.4 million in non-

cash share-based compensation in 2020 as a result of additional share-based compensation awards, hiring additional research and development personnel, and the implementation of the Employee Share Purchase Plan.

 increases due to the global collaboration and license agreement with Sosei Heptares, which included an upfront cash payment of \$5.0 million and the issuance 54,617 shares valued at \$4.9 million to Sosei Heptares.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$462.3 million for the year ended December 31, 2020, compared to \$134.4 million for the year ended December 31, 2019. The increase of \$327.9 million was primarily due to an increase in spending to support the commercial launch of NURTEC ODT. Less than half of the SG&A expense was for commercial organization personnel costs, excluding non-cash share-based compensation expense. Non-cash share-based compensation expense, included in personnel related costs, was \$33.7 million for the year ended December 31, 2020, an increase of \$5.0 million as compared to the same period in 2019.

#### Other Income (Expense), Net

Other income (expense), net was a net expense of \$113.0 million for the year ended December 31, 2020, compared to net expense of \$49.3 million for the year ended December 31, 2019. The increase of \$63.7 million in net expense was primarily due to interest expense on our outstanding term loan with Sixth Street Specialty Lending, Inc, the non-cash interest expense on our liability related to the mandatorily redeemable preferred shares resulting from the sale of Series A Preferred

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Shares to RPI in April 2019, an increase in the non-cash interest expense recognized on our liability related to the sale of future royalties, and an increase in the change in fair value of derivative liability related to the Series B Preferred Shares Forward Contracts.

#### Provision for Income Taxes

We recorded a provision for income taxes of \$10.2 million for the year ended December 31, 2020, compared to a provision for income taxes of \$0.4 million for the year ended December 31, 2019. The provision for income taxes is comprised of \$5.0 million relating to US federal and state income taxes for BPI's profitable operations in the United States and \$5.2 million of uncertain tax benefits recognized in the period December 31, 2020.

#### **Liquidity and Capital Resources**

Since our inception, we have incurred significant operating losses and negative cash flows from our operations. We have funded our operations primarily with proceeds from sales of our common and preferred equity, sales of revenue participation rights related to future royalties, a senior secured credit facility and the Collaboration Agreement with Pfizer. In addition, we began to generate net product revenue in the first

quarter of 2020 in conjunction with the launch of our first product, NURTEC ODT.

We continuously assess our working capital needs, capital expenditure requirements and future investments or acquisitions. As of February 25, 2022, we expect that our cash, cash equivalents and marketable securities as of December 31, 2021, our future operating cash flows from sales of NURTEC ODT, \$125.0 million in potential future borrowings under our credit facility, proceeds related to the settlement of our Series B preferred shares forward contracts, potential sales of common shares under the Equity Distribution Agreement in 2022, and the \$500.0 million in proceeds received on January 4, 2022 and potential milestone payments from the strategic collaboration with Pfizer will be sufficient sources of cash to meet our cash needs for more than one year.

As of December 31, 2021, we had cash and cash equivalents of \$171.9 million, excluding restricted cash of \$2.4 million. Cash in excess of immediate requirements is invested in marketable securities with a view to liquidity and capital preservation. As of December 31, 2021, we had marketable securities of \$192.6 million.

#### Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Year Ended December 31,						
<u>In thousands</u>	2021	2020	2019				
Net cash used in operating activities	\$ (831,100)	\$ (702,879)	\$ (377,331)				
Net cash provided by (used in) investing activities	26,552	(269,880)	(3,784)				
Net cash provided by financing activities	844,849	788,824	434,593				
Effect of exchange rate changes on cash and cash equivalents and restricted cash	(189)	439	\$				
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 40,112	\$ (183,496)	\$ 53,478				

## **Operating Activities**

During the year ended December 31, 2021, we used \$831.1 million of cash in operating activities, an increase of \$128.2 million as compared to the year ended December 31, 2020. The increase in cash usage was primarily due to an increase in SG&A expenses due to increased costs, including advertising, to support the commercial growth of NURTEC ODT and an increase in R&D expenses to support our portfolio of late stage product candidates and preclinical assets, partially offset by an increase in cash receipts from an increase in net product revenue from sales of NURTEC ODT. The increase in cash usage was also due to \$62.5 million in payments to RPI for the mandatory redemption of 624 Series A preferred shares, which were accounted for as payments of accrued interest on the mandatorily redeemable preferred shares liability.

## **Investing Activities**

During the year ended December 31, 2021, net cash provided by investing activities was \$26.6 million, an increase of \$296.4 million as compared to the year ended December 31, 2020. The increase was primarily due to an increase of \$126.6 million of sales and maturities of marketable securities, a decrease of \$126.1 million of purchases of marketable securities, and a decrease of \$41.5 million of payments for intangible assets during the year ended December 31, 2021. The \$41.5 million of payments for intangible assets during the year ended December 31, 2020 are milestone payments related to the FDA approval and launch of NURTEC ODT.

# Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was \$844.8 million, an increase of \$56.0 million compared to the year ended

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December 31, 2020. The increase was primarily due to an increase of \$97.9 million of R&D funding, \$75.0 million of long-term debt and \$70.4 million for the issuance of Series B preferred shares all in the year ended December 31, 2021 partially offset by \$147.5 million from the sale of future royalties and \$60.0 million from the sale of contingently redeemable non-controlling interests during the year ended December 31, 2020.

#### Pfizer Collaboration Agreement

In November 2021, we entered into the Collaboration Agreement with Pfizer, pursuant to which Pfizer would commercialize the Licensed Products in all countries worldwide outside of the United States. In consideration thereof, in January 2022 Pfizer made an upfront payment of \$150.0 million to Biohaven upon receipt of the requisite regulatory approvals needed for the effectiveness of the Collaboration Agreement. In addition, in January 2022 Pfizer purchased \$350.0 million worth of Biohaven common shares at approximately \$173.05 per share. We will be eligible to receive an aggregate additional \$740.0 million in contingent payments based on specified commercial and sales-based milestones for the Licensed Products.

We are also entitled to tiered, escalating royalties from the upper teens to twenty percent of net sales of Licensed Products in the Territory. In general, Pfizer's obligation to pay royalties continues on a product-by-product and country-by-country basis until the latest of ten years after the first commercial sale of such product in such country, the expiration of the patent rights covering such product in such country or the expiration of the period of exclusivity applicable to such product in such country. In addition to the upfront payments, contingent payments and royalties described above, Pfizer will also compensate us for a pro-rata share of certain of our sales-based milestone obligations owed to BMS under the BMS License, and related net sales royalties owed to BMS and RPI that result from Pfizer's commercialization and sale, respectively, of the Licensed Products in the Territory.

# Credit Facility

In August 2020, we entered into a financing agreement, as amended, with the Lenders pursuant to which the Lenders agreed to extend a senior secured credit facility to the Company providing for term loans in an aggregate principal amount up to \$500.0 million, plus any capitalized interest paid in kind. We drew an initial term loan of \$275.0 million at closing in August 2020 (the "Initial Term Loan"), and had \$100.0 million of immediately available delayed draw term loan commitments and \$125.0 million of delayed draw term loan commitments available upon achievement of the Delay Draw Sales Milestone (as defined in the Sixth Street Financing Agreement).

In March 2021, we entered into Amendment No. 1 (the "First Amendment") to the financing agreement

pursuant to which the parties agreed to, among other things, remove the Delayed Draw Sales Milestone tied to the availability of the \$125.0 million tranche of delayed draw term loans. In August 2021, we drew the \$125.0 million tranche of delayed draw term loans (the "DDTL-2).

In September 2021, we entered into Amendment No. 2 (the "Second Amendment") to the financing agreement. Pursuant to the Second Amendment, the parties agreed to, among other things, increase the size of the credit facility by providing for additional term loans in an aggregate principal amount of \$250.0 million for a total facility size of \$750.0 million plus any capitalized interest paid in kind. At closing of the Second Amendment, we drew an initial term loan of \$125.0 million (the "2021 Term Loan") and \$100.0 million of delayed draw term loan commitments (the "DDTL-1"). The remaining \$125.0 million in delayed draw term loan commitments (the "2021 DDTL Commitment") was available to be drawn by the Borrowers until December 31, 2021 (the "Delayed Draw Term Loan Commitment Termination Date").

In November 2021, we entered into Amendment No. 3 and Limited Consent to Financing Agreement ("the Third Amendment and Limited Consent") to our Sixth Street Financing Agreement. Pursuant to the Third Amendment and Limited Consent, the Lenders consented to our entry into the Collaboration Agreement with Pfizer.

In December 2021, we entered into Amendment No. 4 (the "Fourth Amendment") to the financing agreement (as previously amended and as amended by the Fourth Amendment, the "Sixth Street Financing Agreement"), pursuant to which the parties agreed to, among other things, extend the Delayed Draw Term Loan Commitment Termination Date to June 30, 2022.

#### 2020 Loans

In August 2020, we borrowed the Initial Term Loan for total proceeds of \$262.2 million, net of discounts and issuance costs. In August 2021, we borrowed the DDTL-2 for total proceeds of \$123.8 million, net of discounts and issuance costs. The DDTL-2 was borrowed under the same financing terms as the Initial Term Loan. The Initial Term Loan and the DDTL-2 (collectively, the "August 2020 Loans") become due and payable in August 2025. The August 2020 Loans accrue interest at a variable rate, with interest paid on a quarterly basis. The interest rate on the August 2020 Loans as of December 31, 2021 was 10.0%. We have the option to pay-in-kind up to 4.0% interest per annum for the first two years and have elected to pay-in-kind the maximum amount for all interest payments as of December 31, 2021. The proceeds from the August 2020 Loans are being used for general corporate purposes.

#### 2021 Loans

In September 2021, we borrowed the 2021 Term Loan for total proceeds of \$119.7 million and the DDTL-1

for total proceeds of \$97.8 million, both net of discounts and issuance costs. The 2021 Term Loan and the DDTL-1 (collectively, the "September 2021 Loans") become due and payable in September 2026. The September 2021 Loans accrue interest at a variable rate, with interest paid on a quarterly basis. The interest rate on the September 2021 Loans as of December 31, 2021 was 9.25%. We have the option to pay-in-kind up to 4.0% interest per annum for the first two years that the loans are outstanding. The proceeds from the September 2021 Loans are being used for general corporate purposes.

As of December 31, 2021, we have \$125.0 million in delayed draw term loan commitments still available to borrow under the Sixth Street Financing Agreement until June 30, 2022. If drawn, the loans will be borrowed under the same financing terms as the September 2021 Loans.

# **Equity Distribution Agreement**

In December 2020, we entered into an equity distribution agreement in which we may offer and sell common shares having an aggregate offering price of up to \$400.0 million from time to time through or to the sales agents, acting as our agents or principals (the "Equity Distribution Agreement"). Sales of our common shares, if any, will be made in sales deemed to be "at the market offerings". The sales agents are not required to sell any specific amount of securities but will act as our sales agents using commercially reasonable efforts consistent with their normal trading and sales practices, on mutually agreed terms between the sales agents and us. We currently plan to use the net proceeds from the offering for general corporate purposes.

As of December 31, 2021, we have issued and sold 939,328 common shares for net proceeds of approximately \$78.7 million all in the first quarter of 2021 under the Equity Distribution Agreement.

#### Series B Preferred Shares Forward Contracts

In August 2020, we entered into the Series B preferred share agreement, whereby RPI will invest in the Company through the purchase of up to 3,992 Series B preferred shares at a price of \$50,100 per share for aggregate proceeds of approximately \$200.0 million (the "RPI Series B Preferred Share Agreement"). The shares will be issued in quarterly increments from March 31, 2021 to December 31, 2024. We are required to redeem the Series B Preferred Shares for 1.77 times the original purchase price, payable beginning March 31, 2025 in equal quarterly installments through December 31, 2030. The gross proceeds from the transaction with RPI will be used for the clinical development of zavegepant and other general corporate purposes.

As of December 31, 2021, we have issued 1,406 Series B preferred shares to RPI for proceeds of \$70.4 million.

#### **Funding Requirements**

We expect our expenses to increase in connection with our ongoing activities, particularly as we advance and expand preclinical activities, clinical trials and commercialization of our product candidates. Our costs will also increase as we:

- continue and expand our commercial activities related to NURTEC ODT for the acute treatment of migraine;
- advance and expand the development of our CGRP and glutamate modulation platform product candidates and continue development of our MPO platform;
- conduct 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 3 trials of troriluzole in OCD, 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 clinical trial of oral zavegepant and related support activities, and continue other clinical trials of oral zavegepant;
- 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;
- 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;

- support our sales, marketing and distribution infrastructure to commercialize any future product candidates 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.

As of February 25, 2022, the issuance date of our consolidated financial statements, we expect that our cash, cash equivalents, and marketable securities as of December 31, 2021, our furture operating cash flows from sales of NURTEC ODT, the funds available from the Sixth Street Financing Agreement, proceeds from the issuance of Series B Preferred Shares, potential sales under the Equity Distribution Agreement in 2022, and proceeds from our Collaboration Agreement with Pfizer will be sufficient to fund our current forecast for operating expenses, including commercialization of NURTEC ODT, financial commitments and other cash requirements for more than one year. We may need to raise additional capital until we are 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, we may delay, limit or reduce discretionary spending in areas related to research and development activities and other general and administrative expenses in order to fund our operating costs and working capital needs.

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 troriluzole, or our other product candidates, we expect to incur additional commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on 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 effect of COVID-19 pandemic on our business operations and funding needs;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for NURTEC ODT, in addition to any of our product candidates for which we receive marketing approval;
- the revenue from NURTEC ODT, and 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 inlicensing 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 certain estimated future obligations by period under our various contractual obligations as of December 31, 2021 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period									
<u>In thousands</u>		Total	2022		2023 - 2024		023 - 2024 2025		25 - 2026 T	
Long-term debt obligations										
Principal payments <sup>(1)</sup>	\$	675,333	\$	_	\$	47,811	\$	627,522	\$	_
Interest payment <sup>(2)</sup>		225,062		43,967		120,984		60,111		_
Finance leases		9,518		5,714		3,804		_		_
Operating leases		4,155		689		1,420		1,477		569
Purchase obligations										
Commercial commitments <sup>(3)</sup>		107,882		90,809		17,073		_		_
Research commitments <sup>(4)</sup>		33,485		33,485		_		_		_
Other long-term liabilities										
Mandatorily redeemable preferred shares <sup>(5)</sup>		187,500		62,500		125,000		_		_
Series B preferred shares forward contracts <sup>(6)</sup>		354,552						118,184		236,368
Total	\$	1,597,487	\$	237,164	\$	316,092	\$	807,294	\$	236,937

- (1) Principal payments on long-term debt relate to the \$625.0 million in term loans drawn under our senior secured credit facility with Sixth Street Specialty Lending, Inc., and includes the capitalization and payment as principal of \$50.3 million of interest paid-in-kind.
- (2) Interest payments on long-term debt are calculated using the 10.00% interest rate on the August 2020 Loans and 9.25% on the September 2021 Loans, our outstanding term loans in effect on December 31, 2021. It excludes 4% of interest paid-in-kind for the first eight quarters that the loans are outstanding and includes the effect of the inclusion of the interest paid-in-kind as part of the outstanding loan principal.
- (3) Commercial commitments primarily related to advertising, data license agreements and manufacturing preparation services 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.
- (4) Research commitments are primarily CRO and CMO 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.
- (5) Pursuant to the Series A Preferred Shares Agreement with RPI, the mandatorily redeemable preferred shares are redeemed in cash in equal quarterly installments beginning on March 31, 2021 and ending December 31, 2024.
- (6) The Series B preferred shares forward contracts require RPI to purchase \$200.0 million of Series B preferred shares from us on a quarterly basis beginning on March 31, 2021 and ending on December 31, 2024. After December 31, 2024, we are required to redeem the Series B preferred shares at 1.77x the purchase price in quarterly installments ending December 31, 2030.

In addition to the contractual obligations in the table above, 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 license 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 annual license maintenance payments related to our license agreements in the next 12 months.

# 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 Note 2 "Summary of Significant Accounting Policies" 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.

#### Revenue Recognition

Revenues from product sales are recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from (a) invoice discounts for prompt payment and distribution service fees, (b) government and private payor rebates, chargebacks, discounts and fees, (c) product returns and (d) costs of co-pay assistance programs for patients, as well as other incentives for certain indirect customers. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales. The reserves are classified as reductions to trade receivable, net if payable to a Customer or accrued expenses if payable to a third-party. Where appropriate, we utilize the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results vary from our estimates, we adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

We make significant estimates and judgments that materially affect our recognition of net product revenue. Claims by third-party payors for rebates, chargebacks and discounts frequently are submitted to us significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. We will adjust our estimates based on new information, including information regarding actual rebates, chargebacks and discounts for our products, as it becomes available.

# Interest Expense and Liability Related to Sale of Future Royalties

We have accounted for the 2018 Funding Agreement with RPI Finance Trust ("RPI") and a portion of the 2020 Funding Agreement with RPI 2019 Intermediate Finance Trust ("RPI 2019 IFT") as liability financings. See Note 7 "Liability Related to Sale of Future Royalties, net" for additional details. The liability related to sale of future royalties and the related interest expense are measured based on our current estimate of the timing and amount of expected future royalties expected to be paid over the estimated term of the related funding agreement with RPI Trust. The liability is amortized using the effective interest rate method, resulting in recognition of interest expense over the estimated term of the agreement. Each reporting period, we assess the estimated timing and amount of future expected royalty payments over the estimated term. If there are changes to the estimate, we recognize the impact to the liability's amortization schedule and the related interest expense prospectively. Our 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.

#### Valuation of Series B Forward Contract Derivative

The fair value of the derivative recognized in connection with the RPI Series B Preferred Share Agreement was determined based on significant inputs not observable in the market. The fair value of the derivative primarily relates to the difference between the fair value of the Series B Preferred Shares and the contractual future purchase price. The fair value of the Series B Preferred Shares is calculated based on the cash flows to RPI (1.77 times the original purchase price as scheduled or accelerated upon certain events) and our estimated cost of capital for those cash flows. The cash flows to RPI are based on probability adjusted cash flows from certain scenarios outlined in the agreement that would result in accelerated payments modeled using a Monte Carlo simulation. As inputs into the valuation, we considered the type and probability of occurrence of certain change of control events, the amount of the payments, the expected timing of certain acceleration of payments, and a risk-adjusted discount rate. Assessing the probability of certain change of control events over a 10-year time period requires significant judgment and the successful completion of a

change of control is largely dependent on the outcome of potential negotiations with a third party. Due to this uncertainty, our expectation of the probability of the timing of a change of control event at the reporting date could reasonably be different than the timing of an actual change of control event, and if so, would mean the estimated fair value could differ from the fair value determined.

#### Income Taxes

In August 2020, we completed an intra-entity asset transfer of intellectual property ("IP"). See Note 15 "Income Taxes" for additional details. The fair value of the transferred IP required significant and complex management judgments to establish assumptions about the intellectual property's fair value, including revenue growth rates, projected profit margins, and discount rate. The fair value determination was based upon a discounted cash flow model that was subject to significant judgement given the IP asset transferred had been recently launched and there was limited historical sales activity. As a result of the transfer, we recognized a deferred tax asset for the step up in tax basis based on the fair value of the transferred IP.

We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. We continue to maintain a full valuation allowance against our deferred tax assets recognized in connection with our intra-entity transfer of IP as realization is not certain due to a lack of net operating income history by taxing jurisdictions. We consider many factors when assessing the likelihood of future realization of deferred tax assets, including our current operating results, expectations of future taxable income, carryforward periods available to us for tax reporting purposes, various income tax strategies, and other relevant factors. Significant judgment is required in making this assessment and, to the extent future expectations change, we would assess the recoverability of our deferred tax assets at that time.

# **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

## **Foreign Currency Translation**

Our operations include activities in countries outside the U.S. As a result, our financial results are impacted by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets where we operate. Our monetary

exposures on our balance sheet are currently immaterial to our financial position.

We do not engage in any hedging activities against changes in foreign currency exchange rates.

#### Interest Rate Risk

As of December 31, 2021, we invest our excess cash balances in marketable securities of highly rated financial institutions and investment-grade debt instruments. We seek to diversify our investments and limit the amount of investment concentrations for individual institutions, maturities and investment types. Most of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Based on the type of securities we hold, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1.00%, the fair value of our investment portfolio would (decrease) increase by approximately \$(1.3) million and \$0.8 million, respectively.

In August 2020, we became subject to market risk in connection with borrowings under the Sixth Street Financing Agreement. The August 2020 Term Loans borrowed under the agreement accrue interest at the LIBOR Rate, subject to a floor of 1.00%, plus 9.00%. The September 2021 Term Loans borrowed under the agreement accrue interest at the LIBOR Rate, subject to a floor of 1.00%, plus 8.25%. Considering the total outstanding principal balance for all the loans drawn under the Sixth Street Financing Agreement of approximately \$645.0 million at December 31, 2021, a 1.00% change in the LIBOR Rate would result in an impact to loss before income taxes of less than \$1.5 million per year.

We do not engage in any hedging activities against changes in interest rates.

#### **Credit Risk**

Financial instruments that potentially subject us to concentrations of credit risk consist of cash, cash equivalents, and marketable securities. Our cash management policy permits investments in U.S. federal government and federal agency securities, corporate bonds or commercial paper, supranational and sovereign obligations, certain qualifying money market mutual funds, certain repurchase agreements, and places restrictions on credit ratings, maturities, and concentration by type and issuer. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents and marketable securities to the extent recorded on the balance sheet.

We are also subject to credit risk from our accounts receivable related to our product sales. Our trade accounts receivable primarily consists of amounts due from pharmacy wholesalers in the U.S. (collectively, our "Customers") related to sales of NURTEC ODT and have

standard payment terms. For certain Customers, the trade accounts receivable for the Customer is net of distribution service fees, prompt pay discounts and other adjustments. We monitor the financial performance and creditworthiness of our Customers so that we can properly assess and respond to changes in their credit profile. Our reserves against trade accounts receivable for estimated losses that may arise from a Customer's inability to pay and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The reserve amount for estimated losses was not significant as of December 31, 2021, and we do not expect any such delays in collections to have a material impact on our financial condition or results of operations.

#### 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, 2021, 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, 2021 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, 2021.

#### Report of Independent Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by Ernst & Young LLP., an independent registered public accounting firm, as stated in their report, which is included below.

#### Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of

Biohaven Pharmaceutical Holding Company Ltd.

#### **Opinion on Internal Control Over Financial Reporting**

We have audited Biohaven Pharmaceutical Holding Company Ltd. internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Biohaven Pharmaceutical Holding Company Ltd. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, stockholders' deficit and cash flows for the years then ended, and the related notes of the Company and our report dated February 25, 2022 expressed an unqualified opinion thereon.

#### **Basis for Opinion**

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

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

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

#### **Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ Ernst & Young LLP Hartford, Connecticut February 25, 2022

#### 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, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### ITEM 9B. OTHER INFORMATION

On February 24, 2022, Biohaven and certain of its affiliates (collectively, for purposes of this Item 9B, the "Company") entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with Knopp Biosciences LLC ( "Knopp") and Channel Biosciences, LLC, a newly formed wholly owned subsidiary of Knopp ("Channel"), pursuant to which (a) Knopp will contribute its assets related to its Kv7 channel targeting platform, and (b) the Company will subsequently acquire all of the equity interests in Channel (the "Transaction").

In consideration for the Transaction, the Company will make an upfront payment comprised of \$35 million in cash and \$65 million in common shares of Biohaven Holdco ("Biohaven Shares") issued through a private placement. The Company has also agreed to pay additional success-based payments comprised of (i) up to \$325 million based on developmental and regulatory milestones through approvals in the United States, EMEA and Japan for the lead asset, BHV-7000 (formerly known as KB-3061), (ii) up to an additional \$250 million based on developmental and regulatory milestones for the Kv7 pipeline development in other indications and additional country approvals, and (iii) up to \$562.5 million for commercial sales based milestones of BHV-7000. These contingent milestone payments may be paid in cash or Biohaven Shares at the election of the Company, but if the Company elects to pay in Biohaven Shares, such amounts are subject to increases of a mid-single-digit percentage increase (or in one case, a ten-percent increase). Additionally, the Company has agreed to make scaled royalty payments in cash for BHV-7000 and the pipeline programs, starting at high single digits and peaking at low teens for BHV-7000 and starting at mid-single digits and peaking at low double digits for the pipeline programs.

The Company has also given Knopp the option to request a onetime cash true-up payment from the Company in December 2022 in the event that Knopp continues to hold Biohaven Shares issued as a component of the upfront payment and the value of such shares has declined, subject to certain conditions.

The requisite approvals of Knopp equityholders have been obtained. The Transaction is subject to the satisfaction of certain customary closing conditions, including the receipt of select third-party consents.

At the closing of the Transaction, 493,254 common shares of Biohaven Holdco will be issued as part of the initial consideration. The contemplated issuances and sales of that initial consideration payable in common shares and those contingent payments payable in Biohaven Shares have not been registered under the Securities Act or any state securities laws. Biohaven has relied on the exemption from the registration requirements of the Securities Act under Section 4(a)(2) thereof, for a transaction by an issuer not involving any public offering.

# ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

#### **PART III**

We will file a definitive Proxy Statement for our 2022 Annual Meeting of Shareholders (the "2022 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 2021 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 2022 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 2022 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 2022 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 2022 Proxy Statement under the captions "Transactions with Related Persons" and "Independence of the Board of Directors."

# Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated herein by reference to the information that will be contained in the 2022 Proxy Statement under the caption "Ratification of Selection of Independent Auditors."

## **PART IV**

# Item 15. Exhibit and 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	Agreement and Plan of Merger, dated as of January 1, 2021, by and among Biohaven Pharmaceutical Holding Company, Ltd., Biohaven Therapeutics Ltd., Kleo Acquisition, Inc., Kleo Pharmaceuticals, Inc. and Shareholder Representative Services LLC, as the stockholders' representative (incorporated by reference to Exhibit 1.1 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on January 8, 2020).
2.5	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).
2.6	Agreement and Plan of Merger, dated November 9, 2021, by and among Biohaven Pharmaceutical Holding Company Ltd., Biohaven Therapeutics Ltd., Atlas Merger Sub and BioShin Ltd. (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 November 12, 2021).
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 August 17, 2020).
4.1	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).
4.2	Description of Biohaven's Securities Registered under Section 12 of the Exchange Act (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K (File No. 001-38080) filed with the Securities and Exchange Commission on March 1, 2021).
10.1 #	Amendment No. 1 to Financing Agreement, dated as of August 7, 2020, by and between Biohaven Pharmaceuticals Holding Company Ltd., Biohaven Pharmaceuticals, Inc., the guarantors party thereto from time to time, the lenders party thereto from time to time and Sixth Street Specialty Lending, Inc., as administrative agent (incorporated by reference to Exhibit 10.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38080) filed with the Securities and Exchange Commission on March 1, 2021).
10.2 #	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).
10.3 #	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).
10.4 #	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).
10.5	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).

- 10.6 # <u>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).</u>
- 10.7 # 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).
- 10.8 # 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).
- 10.9 # 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).
- 10.10 # 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).
- 10.11 # 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).
- 10.12 # 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).
- 10.13 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).
- 10.14 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).
- 10.15 + 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).
- 10.16 + 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).
- 10.17 + 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).
- 10.18 + 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).
- 10.19 + 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).
- 10.20 + 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).
- 10.21 + 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).
- 10.22 + 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)).)
- 10.23 + 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).
- 10.24 + 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)).)
- 10.25 + 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).

- 10.26 + Employment Agreement dated March 30, 2019 by and between Biohaven Pharmaceuticals, Inc. and William Jones, Jr. (incorporated by reference to Exhibit 10.25 to the Registrant's Annual Report on Form 10-K (File No. 001-38080) filed with the Securities and Exchange Commission on February 26, 2020).
- 10.27 + Employment Agreement dated February 1, 2014 by and between Biohaven Pharmaceuticals, Inc. and Kimberly A. Gentile. (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K (File No. 001-38080) filed with the Securities and Exchange Commission on February 26, 2020).
- 10.28 + Offer Letter dated April 5, 2017 by and between Biohaven Pharmaceuticals, Inc. and Elyse Stock. (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K (File No. 001-38080) filed with the Securities and Exchange Commission on February 26, 2020).
- 10.29 # Zydis Commercial Supply Agreement, dated as of June 29, 2018, by and between Biohaven Pharmaceuticals, Inc. and Catalent U.K. Swindon Zydis Limited. (incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K (File No. 001-38080) filed with the Securities and Exchange Commission on February 26, 2020).
- 10.30 Funding Agreement, dated as of August 7, 2020, by and between Biohaven Pharmaceuticals Holding Company Ltd. and RPI 2019 Intermediate Finance Trust (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 9, 2020).
- 10.31 Amendment No. 1 to Funding Agreement, dated as of August 7, 2020, by and between Biohaven Pharmaceuticals Holding Company Ltd.,
  Biohaven Pharmaceuticals Ireland DAC and RPI 2019 Intermediate Finance Trust (incorporated by reference to Exhibit 10.2 to the Registrant's
  Quarterly Report on Form 10-Q (File No. 001-38080) filed with the Securities and Exchange Commission on November 9, 2020).
- Biohaven Pharmaceutical Holding Company Ltd. Series B Preferred Share Purchase Agreement, dated as of August 7, 2020, by and between Biohaven Pharmaceuticals Holding Company Ltd. and RPI 2019 Intermediate Finance Trust (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38080) filed with the Securities and Exchange Commission on November 9, 2020).
- Financing Agreement, dated as of August 7, 2020, by and between Biohaven Pharmaceuticals Holding Company Ltd., Biohaven Pharmaceuticals, Inc., the guarantors party thereto from time to time, the lenders party thereto from time to time and Sixth Street Specialty, Lending, Inc., as administrative agent (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 9, 2020),
- 10.34 Collaboration Agreement, dated November 9, 2021, by and among Pfizer Ireland Pharmaceuticals, Biohaven Pharmaceutical Holding Company
  Ltd., Biohaven Pharmaceutical Ireland DAC and BioShin, Ltd. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on
  Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on November 12, 2021).
- Sublicense Agreement, dated November 9, 2021, by and among Pfizer Ireland Pharmaceuticals, Biohaven Pharmaceutical Holding Company, Ltd., Biohaven Pharmaceutical Ireland DAC and BioShin, Ltd. (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 November 12, 2021).
- Subscription Agreement, dated November 9, 2021, by and between Pfizer Inc. and Biohaven Pharmaceutical Holding Company Ltd.

  (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on November 12, 2021).
- Amendment No. 3 and Limited Consent to Financing Agreement, dated November 9, 2021, by and between Biohaven Pharmaceuticals Holding Company Ltd., Biohaven Pharmaceuticals, Inc., the guarantors party thereto from time to time, the lenders party thereto from time to time and Sixth Street Specialty Lending, Inc., as administrative agent (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on November 12, 2021).
- 10.38 + Consulting Agreement, dated December 5, 2021, between the Company and Declan Doogan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on December 9, 2021).
- 10.39 + Employment Agreement, dated December 8, 2021, between the Company and Matthew Buten (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 December 9, 2021).
- 10.40 + 2022 Deferral Election Agreement for Executives (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the Securities and Exchange Commission on December 30, 2021).
- 10.41 + Amendment No. 1 to Employment Agreement, dated December 14, 2021, by and between Biohaven Pharmaceuticals, Inc. and James Engelhart.
- 10.42 Amendment No. 4 to Financing Agreement, dated as of December 28, 2021, by and between Biohaven Pharmaceuticals Holding Company Ltd., Biohaven Pharmaceuticals, Inc., the guarantors party thereto from time to time, the lenders party thereto from time to time and Sixth Street Specialty Lending, Inc., as administrative agent.
- 21.1 <u>Subsidiaries of the Registrant.</u>
- 23.1 Consent of Ernst & Young LLP.
- 23.2 <u>Consent of PricewaterhouseCoopers LLP.</u>
- 24.1 Power of Attorney (contained on signature page hereto).
- 31.1 <u>Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.</u>

#### **Table of Contents**

- 31.2 <u>Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.</u>
- 32.1 Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.
- The following materials from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2021 formatted in Inline XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statements of Convertible Preferred Shares and Shareholders' Equity (Deficit), (v) the Consolidated Statements of Cash Flows, (vi) Notes to Consolidated Financial Statements, and (vi) Cover Page, tagged as holders of text
- The cover page from the Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, 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.

Dated: February 25, 2022	BIOHAVEN F	PHARMACEUTICAL HOLDING COMPANY LTD.
Dated. I coloury 23, 2022	Ву:	/s/ Vlad Coric, M.D.
	_	Vlad Coric, M.D.
		Chief Executive Officer
		(On behalf of the Registrant and as the Principal Executive Officer)
	Ву:	/s/ Matthew Buten
	_	Matthew Buten
		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-infact 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.

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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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ VLAD CORIC, M.D. Vlad Coric, M.D.	Chief Executive Officer and Director (Principal Executive Officer)	February 25, 2022
/s/ MATTHEW BUTEN  Matthew Buten	Chief Financial Officer (Principal Financial Officer)	February 25, 2022
/s/ GEORGE C. CLARK George C. Clark	Vice President, Chief Accounting Officer (Principal Accounting Officer)	February 25, 2022
/s/ GREGORY H. BAILEY, M.D. Gregory H. Bailey, M.D.	Director	February 25, 2022
/s/ JOHN W. CHILDS  John W. Childs	Director	February 25, 2022
/s/ JULIA P. GREGORY  Julia P. Gregory	Director	February 25, 2022
/s/ MICHAEL HEFFERNAN Michael Hefferenan	Director	February 25, 2022
/s/ ROBERT J. HUGIN Robert J. Hugin	Director	February 25, 2022
/s/ KISHEN MEHTA Kishen Mehta	Director	February 25, 2022
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# Biohaven Pharmaceutical Holding Company Ltd.

# **Financial Statements**

# For the Years Ended December 31, 2021, 2020 and 2019

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#### Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of

Biohaven Pharmaceutical Holding Company Ltd.

#### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Biohaven Pharmaceutical Holding Company Ltd. (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive loss, shareholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 25, 2022 expressed an unqualified opinion thereon.

#### **Basis for Opinion**

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

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

#### **Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter 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.

#### **Government Rebates**

Description of the Matter

As described in Note 2 to the consolidated financial statements, the Company's revenues from product sales are recorded at the net sales price which includes estimates of variable consideration for government rebates paid under the Medicaid Drug Rebate Program. The estimates of variable consideration are based on the amounts earned or to be claimed on the related sales. These estimates are established by management based on historical experience, current statutory requirements and forecasted customer buying patterns and will be adjusted to reflect known changes in the factors that impact such amounts.

Auditing the amount of consideration to be paid related to government rebates was complex because the calculation includes subjective management assumptions regarding the levels of expected future claims from governmental entities, the amount of forecasted shipments from wholesalers that will be dispensed to eligible benefit plan participants as well as the complexity of the governmental pricing calculations. Governmental pricing calculations are complex as a result of assumptions such as the average manufacturer price, best price and the unit rebate amount. The reductions to gross product revenues are sensitive to these significant estimates and calculations.

How We Addressed the Matter in Our Audit We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over management's review of government rebates. For example, we tested controls over management's review of the government pricing calculations, the significant assumptions and the data inputs used in the calculations of government rebates.

To test the revenue adjustments related to the government rebates, our audit procedures included, among others, evaluating the methodology used, testing the accuracy and completeness of the underlying data used in the calculations and evaluating the significant assumptions described above that are used by management in its analysis. We compared the assumptions used by management to historical experience, evaluated rebate adjustments recorded and assessed the historical accuracy of management's estimates against actual results. In addition, we involved a governmental pricing subject matter professional to assist with our evaluation of management's governmental pricing calculations.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2020.

Hartford, Connecticut

February 25, 2022

#### Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Biohaven Pharmaceutical Holding Company Ltd.

#### Opinion on the Financial Statements

We have audited the consolidated statements of operations, of comprehensive loss, of shareholders' equity (deficit) and of cash flows of Biohaven Pharmaceutical Holding Company Ltd. and its subsidiaries (the "Company") for the year ended December 31, 2019, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the results of operations and cash flows of the Company for the year ended December 31, 2019 in conformity with accounting principles generally accepted in the United States of America.

# **Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. 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 audit of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit 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 audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Hartford, Connecticut

February 25, 2020

We served as the Company's auditor from 2017 to 2020.

# BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

# **CONSOLIDATED BALANCE SHEETS**

(Amounts in thousands, except share amounts)

		Decem		
		2021		2020
Assets				
Current assets:				
Cash and cash equivalents	\$	171,945	\$	132,149
Marketable securities		192,648		223,185
Trade receivables, net		308,269		120,111
Inventories		80,608		39,563
Prepaid expenses		88,838		76,682
Other current assets		33,946		11,716
Total current assets	<u>-</u>	876,254		603,406
Property and equipment, net		14,690		9,340
Equity method investment		_		1,176
Intangible assets, net		56,438		39,087
Other assets		129,830		33,966
Total assets	\$	1,077,212	\$	686,975
Liabilities and Shareholders' Deficit				
Current liabilities:				
Accounts payable	\$	51,683	\$	48,476
Accrued expenses and other current liabilities		420,019		166,630
Current portion of mandatorily redeemable preferred shares		62,500		62,500
Total current liabilities		534,202		277,606
Long-term debt		626,720		267,458
Liability related to sale of future royalties, net		367,645		328,350
Mandatorily redeemable preferred shares, net		155,737		111,591
Derivative liability		13,110		14,190
Obligation to perform R&D services		50,571		932
Other long-term liabilities		12,236		19,037
Total liabilities		1,760,221		1,019,164
Commitments and contingencies (Note 17)				
Contingently redeemable non-controlling interests		60,000		60,000
Shareholders' Deficit:				
Common shares, no par value; 200,000,000 shares authorized as of December 31, 2021 and 2020; 66,933,531 and 60,436,876 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively		1,676,792		1,249,547
Additional paid-in capital		169,656		98,938
Accumulated other comprehensive (loss) income		(73)		314
Accumulated deficit		(2,585,755)		(1,739,169)
Total shareholders' deficit attributable to Biohaven Pharmaceutical Holding Company Ltd.		(739,380)		(390,370)
Non-controlling interests in consolidated subsidiaries		(3,629)		(1,819)
Total shareholders' deficit		(743,009)		(392,189)
Total liabilities and shareholders' deficit	\$	1,077,212	\$	686.975
Total habilities and Stratcholders deficit	Ψ	1,011,212	Ψ	000,010

# BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

# **CONSOLIDATED STATEMENTS OF OPERATIONS**

(Amounts in thousands, except share and per share amounts)

	Year Ended December 31,					
		2021		2020		2019
Product revenue, net	\$	462,509	\$	63,627	\$	_
Cost of goods sold		91,664		17,694		
Gross profit		370,845		45,933		_
Operating expenses:						
Research and development		361,340		228,998		344,673
Selling, general and administrative		713,549		462,323		134,449
Total operating expenses		1,074,889		691,321		479,122
Loss from operations		(704,044)		(645,388)		(479,122)
Other income (expense):	·					
Interest expense		(41,551)		(12,636)		_
Interest expense on mandatorily redeemable preferred shares		(32,293)		(27,623)		(12,711)
Interest expense on liability related to sale of future royalties		(60,605)		(45,238)		(26,580)
Change in fair value of derivatives		(2,833)		(19,321)		(3,875)
Gain (loss) from equity method investment		5,261		(4,162)		(6,076)
Other expense, net		(7,258)		(4,020)		(22)
Total other expense		(139,279)		(113,000)		(49,264)
Loss before provision for income taxes	'	(843,323)		(758,388)		(528,386)
Provision for income taxes		5,073		10,227		419
Net loss		(848,396)		(768,615)		(528,805)
Less: Net loss attributable to non-controlling interests		(1,810)		(1,819)		_
Net loss attributable to Biohaven Pharmaceutical Holding Company Ltd.	\$	(846,586)	\$	(766,796)	\$	(528,805)
Net loss per share attributable to Biohaven Pharmaceutical Holding Company Ltd.—basic and diluted	\$	(13.09)	\$	(13.06)	\$	(10.91)
Weighted average common shares outstanding—basic and diluted		64,677,823		58,732,415		48,489,890

# BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD. CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

# (Amounts in thousands)

		Year Ended December 31,						
		2021		2020		2019		
Net loss	\$	(848,396)	\$	(768,615)	\$	(528,805)		
Other comprehensive (loss) income, net of tax:		<u>.</u>		<u>.</u>				
Foreign currency translation adjustments		(189)		439		_		
Net unrealized losses related to available-for-sale debt securities		(198)		(125)		_		
Other comprehensive (loss) income		(387)		314		_		
Comprehensive loss		(848,783)		(768,301)		(528,805)		
Less: comprehensive loss attributable to non-controlling interests	· ·	(1,810)		(1,819)		_		
Comprehensive loss attributable to Biohaven Pharmaceutical Holding Company Ltd.	\$	(846,973)	\$	(766,482)	\$	(528,805)		

# BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD. CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT

(Amounts in thousands, except share amounts)

Common Shares								
	Shares	Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Biohaven Shareholders' Deficit	Non- controlling Interests	Total Shareholders' Deficit
Balances as of December 31, 2018	44,197,549	\$ 554,384	\$ 40,104	\$ (443,568)	\$ —	\$ 150,920	\$ —	\$ 150,920
Issuance of common shares, net of offering costs	7,501,745	302,321	_	_	_	302,321	_	302,321
Exercise of related party warrants	215,000	7,201	(5,203)	_	_	1,998	_	1,998
Issuance of common shares as payment for TDP-43 asset	100,000	5,646	_	_	_	5,646	_	5,646
Issuance of common stock under equity incentive plan	370,989	11,874	(6,350)	_	_	5,524	_	5,524
Non-cash share-based compensation expense	_	_	54,972	_	_	54,972	_	54,972
Net loss				(528,805)		(528,805)		(528,805)
Balances as of December 31, 2019	52,385,283	881,426	83,523	(972,373)	_	(7,424)	_	(7,424)
Issuance of common shares as payment for agreement	54,617	4,858	_	_	_	4,858	_	4,858
Issuance of common shares, net of offering costs	5,555,554	282,833	_	_	_	282,833	_	282,833
Issuance of common shares under equity incentive plan and employee share purchase plan	2,441,422	80,430	(41,999)	_	_	38,431	_	38,431
Non-cash share-based compensation expense	_	_	57,414	_	_	57,414	_	57,414
Net loss	_	_	_	(766,796)	_	(766,796)	(1,819)	(768,615)
Other comprehensive income					314	314		314
Balances as of December 31, 2020	60,436,876	1,249,547	98,938	(1,739,169)	314	(390,370)	(1,819)	(392,189)
Issuance of common shares, net of offering costs	4,037,204	308,243	_	_	_	308,243	_	308,243
Issuance of common shares as payments for agreements	295,135	29,473	_	_	_	29,473	_	29,473
Issuance of common shares under equity incentive plan and employee share purchase plan	2,158,695	89,437	(56,317)	_	_	33,120	_	33,120
Exercise of warrants, net settlement of shares	5,621	92	(92)	_	_	_	_	_
Non-cash share-based compensation expense	_	_	127,127	_	_	127,127	_	127,127
Net loss	_	_	_	(846,586)	_	(846,586)	(1,810)	(848,396)
Other comprehensive loss	_	_	_	_	(387)	(387)	_	(387)
Balances as of December 31, 2021	66,933,531	\$ 1,676,792	\$ 169,656	\$ (2,585,755)	\$ (73)	\$ (739,380)	\$ (3,629)	\$ (743,009)

# BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD. **CONSOLIDATED STATEMENTS OF CASH FLOWS**

(Amounts in thousands)

(Amounto in thousands)	iousunus)				Year ended December 31,					
		2021		2020	31,	2019				
Cash flows from operating activities:						2010				
Net loss	\$	(848,396)	\$	(768,615)	\$	(528,805)				
Adjustments to reconcile net loss to net cash used in operating activities:		, , ,								
Non-cash share-based compensation expense		127,127		57,414		54,972				
Deferred interest on mandatorily redeemable preferred shares		32,293		27,623		12,711				
Deferred interest on liability related to sale of future royalties		60,605		45,238		26,580				
Deferred interest paid-in-kind on long-term debt		15,506		4,478		_				
Issuance of common shares as payment for license and consulting agreements		7,929		4,858		5,646				
Change in fair value of derivatives		2,833		19,321		3,875				
Gain (loss) from equity method investment		(5,261)		4,162		6,076				
Depreciation and amortization		24,932		9,447		646				
Change in obligation to perform R&D services		(30,767)		(345)		_				
Other non-cash items		(1,130)		_		_				
Changes in operating assets and liabilities:										
Trade receivables, net		(188,158)		(120,111)		_				
Inventories		(24,102)		(37,965)						
Prepaid expenses and other current assets		(31,804)		(81,369)		(3,464)				
Other assets		(89,909)		(46)		(232)				
Accounts payable		2,215		32,807		3,319				
Accrued expenses and other current liabilities		113,459		92,424		43,320				
Other long-term liabilities		1,528	_	7,800		(1,975)				
Net cash used in operating activities	\$	(831,100)	\$	(702,879)	\$	(377,331)				
Cash flows from investing activities:										
Purchase of marketable securities		(193,295)		(319,395)						
Sales of marketable securities		113,441		85,167		_				
Maturities of marketable securities		108,124		9,818						
Purchases of property and equipment		(1,718)		(2,370)		(2,534)				
Payments for leasehold improvements				(1,600)		(1,250)				
Payments for intangible assets				(41,500)		_				
Net cash provided by (used in) investing activities	\$	26,552	\$	(269,880)	\$	(3,784)				
Cash flows from financing activities:										
Proceeds from issuance of long-term debt		350,000		275,000						
Proceeds from issuance of common shares		308,743		283,333		303,221				
Proceeds from sale of future royalties				147,476						
Proceeds from sale of contingently redeemable non-controlling interests		_		60,000		_				
Proceeds from obligation to perform R&D services		100,000		2,124		105.000				
Proceeds from issuance of mandatorily redeemable preferred shares		70,441		_		125,000				
Proceeds from exercise of warrants		36.883		38.431		1,998 5,524				
Proceeds from exercise of share options and employee share purchase plan		,		, -						
Payments for term loan, finance leases and other	\$	(21,218)	_	(17,540)	•	(1,150)				
Net cash provided by financing activities	\$	844,849	\$	788,824	\$	434,593				
Effect of exchange rates on cash, cash equivalents and restricted cash		(189) 40.112		439	_	53.478				
Net increase (decrease) in cash, cash equivalents and restricted cash		-,		(183,496)		, -				
Cash, cash equivalents and restricted cash at beginning of period	_	134,231	_	317,727	_	264,249				
Cash, cash equivalents and restricted cash at end of period	\$	174,343	\$	134,231	\$	317,727				
Supplemental disclosure of cash flow information:										
Cash paid for interest	\$	93,610	\$	6,983	\$	_				
Cash paid for income taxes	\$	16,710	\$	2,866	\$	823				

# 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", "our," "Biohaven" or the "Company") was incorporated in Tortola, British Virgin Islands in September 2013. We are a biopharmaceutical company with a portfolio of innovative product candidates targeting neurological diseases, including rare disorders. The Company's lead product, NURTEC™ ODT (rimegepant), was approved by the U.S. Food and Drug Administration ("FDA") on February 27, 2020, which became available by prescription in U.S. pharmacies on March 12, 2020, and was approved for the preventive treatment of migraine on May 27, 2021. NURTEC ODT is the first and only calcitonin gene-related peptide ("CGRP") receptor antagonist available in a quick-dissolve orally dissolving tablet ("ODT") formulation that is approved by the FDA for both the acute and preventive treatment of migraine in adults. Our other late-stage product candidates are based on multiple mechanisms — CGRP receptor antagonists, glutamate modulators and myeloperoxidase inhibition—which we believe have the potential to significantly alter existing treatment approaches across a diverse set of neurological indications with high unmet need in both large and orphan indications.

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry, including, but not limited to, the risks associated with developing product candidates at each stage of non-clinical and clinical development; the challenges associated with gaining regulatory approval of such product candidates; the risks associated with commercializing pharmaceutical products for marketing and sale; the potential for development by third parties of new technological innovations that may compete with the Company's products; the dependence on key personnel; the challenges of protecting proprietary technology; the need to comply with government regulations; the high costs of drug development; and the uncertainty of being able to secure additional capital when needed to fund operations.

Subsequent to its May 2017 initial public offering, the Company has primarily raised funds through sales of equity in private placements and public offerings, sales of revenue participation rights related to potential future royalties, and a debt financing. On November 9, 2021, the Company and certain of its affiliates (collectively, the "Company") entered into a licensing and collaboration arrangement (the "Collaboration Agreement") with a subsidiary of Pfizer Inc. ("Pfizer") pursuant to which Pfizer would commercialize product candidates containing the Company's proprietary compounds rimegepant (BHV-3000) and gain rights to zavegepant

(BHV-3500) (the "Licensed Products") in all countries worldwide outside of the United States (the "Territory"). The Collaboration Agreement became effective on January 4, 2022. Refer to Note 19, "Subsequent Events," for further details.

The Company has incurred recurring losses since its inception, had an accumulated deficit as of December 31, 2021, and expects to continue to generate operating losses during the continued 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.

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, issuance of debt and and proceeds from our Subscription Agreement and Collaboration Agreement with Pfizer (see Note 19). The Company has incurred recurring losses since its inception, including net losses attributable to the Company of \$846,586, \$766,796, and \$528,805 during the years ended December 31, 2021, 2020 and 2019, respectively, and had an accumulated deficit of \$2,585,755 as of December 31, 2021. As a result of the Company's commercial launch of NURTEC ODT, 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, 2022, the issuance date of these consolidated financial statements, the Company expects that its cash, cash equivalents and marketable securities as of December 31, 2021, and the funds available from the Sixth Street Financing Agreement, Series B Preferred Shares, and proceeds from our Subscription Agreement and Collaboration Agreement with Pfizer will be sufficient to fund its current forecast for operating expenses, including commercialization of NURTEC ODT, financial commitments and other cash requirements for more than one year. The Company may 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 may 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.

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United

#### 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 (Continued)

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. revenue recognition, non-cash interest expense on liability related to sale of future royalties, valuation of Series B preferred shares forward contracts and income taxes. 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.

#### Reclassifications

Certain items in the prior period's consolidated financial statements have been reclassified to conform to the current year presentation.

# Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less at the date of purchase to be cash equivalents. As of December 31, 2021 and December 31, 2020, cash equivalents was comprised of money market funds.

#### Restricted Cash

Restricted cash included in other current assets in the consolidated balance sheets primarily represents employee contributions to the Company's employee share purchase plan held for future purchases of the Company's outstanding shares. See Note 12 "Share-Based Compensation" for additional information on the Company's employee share purchase plan.

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 17 "Commitments and Contingencies" for additional information on the real estate lease. The following represents a reconciliation of cash and cash equivalents in the consolidated balance sheets to total cash, cash equivalents and restricted cash for the years ended December 31, 2021, 2020 and 2019, respectively, in the consolidated statements of cash flows:

	December 31,						
		2021		2020	2019		
Cash and cash equivalents	\$	171,945	\$	132,149	\$	316,727	
Restricted cash (included in other current assets)		1,648		1,082		_	
Restricted cash (included in other assets)		750		1,000		1,000	
Total cash, cash equivalents and restricted cash at the end of the period in the consolidated statement of cash flows	\$	174,343	\$	134,231	\$	317,727	

#### Marketable Securities

We invest our excess cash balances in marketable securities of highly rated financial institutions and investment-grade debt instruments. We seek to diversify our investments and limit the amount of investment concentrations for individual institutions, maturities and investment types. We classify marketable debt securities as available-for-sale and, accordingly, record such securities at fair value. We classify these securities as current assets as these investments are intended to be available to the Company for use in funding current operations.

Unrealized gains and losses on our marketable debt securities that are deemed temporary are included in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. If any adjustment to fair value reflects a significant decline in the value of the security, we evaluate the extent to which the decline is determined to be other-than-temporary and would mark the security to market through a charge to our consolidated statement of operations. Credit losses are identified when we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security. In the event of a credit loss, only the amount associated with the credit loss is recognized in operating results, with the amount of loss relating to other factors recorded in accumulated other comprehensive income (loss).

# BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 2. Summary of Significant Accounting Policies (Continued)

#### Trade Receivables, Net

The Company's trade accounts receivable consists of amounts due primarily from pharmacy wholesalers in the U.S. (collectively, its "Customers") related to sales of NURTEC ODT and have standard payment terms. For certain Customers, the trade accounts receivable for the Customer is net of distribution service fees, prompt pay discounts and other adjustments. The Company monitors the financial performance and creditworthiness of its Customers so that it can properly assess and respond to changes in their credit profile. The Company reserves against trade accounts receivable for estimated losses that may arise from a Customer's inability to pay and any amounts determined to be uncollectible are written off against the reserve when it is probable that the receivable will not be collected. The reserve amount for estimated losses was not significant as of December 31, 2021 and 2020.

# Inventory

The Company values its inventories at the lower-of-cost or net realizable value. The Company determines the cost of its inventories, which includes costs related to products held for sale in the ordinary course of business, products in process of production for such sale and items to be currently consumed in the production of goods to be available for sale, on a first-in, first-out (FIFO) basis. Due to the nature of the Company's supply chain process, inventory that is owned by the Company, is physically stored at third-party warehouses, logistics providers and contract manufacturers. The Company classifies inventory costs as noncurrent when we expect to utilize the inventory beyond our normal operating cycle and includes these costs in other assets in our consolidated balance sheets. The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified. If they occur, such impairment charges are recorded as a component of cost of goods sold in the consolidated statements of operations.

The Company capitalizes inventory costs associated with products following regulatory approval when future commercialization is considered probable and the future economic benefit is expected to be realized. Products which may be used in clinical development programs are excluded from inventory and charged to research and development expense in the consolidated statement of operations as incurred. Prior to the initial date regulatory approval is received, costs related to the production of inventory are recorded as research and development expense on the Company's

consolidated statements of operations in the period incurred.

#### **Acquisitions**

Our consolidated financial statements include the operations of acquired businesses after the completion of the acquisitions. We account for acquired businesses using the acquisition method of accounting, which requires, among other things, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date and that the fair value of acquired In-Process Research and Development ("IPR&D") be recorded on the balance sheet. Transaction costs are expensed as incurred. Any excess of the consideration transferred over the assigned values of the net assets acquired is recorded as goodwill. Contingent consideration in a business acquisition is included as part of the consideration transferred and is recognized at fair value as of the acquisition date. Fair value of IPR&D and contingent consideration is generally estimated by using a probability-weighted discounted cash flow approach.

# **Equity Method Investments**

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 results in a corresponding adjustment to the carrying value of the investment on the consolidated balance sheet. Dividends received reduce the carrying value of the investment.

As of December 31, 2020, the Company owned approximately 42% of the outstanding shares of Kleo Pharmaceuticals, Inc. ("Kleo"), which was accounted for as an equity method investment. In January 2021, the Company acquired the remaining 58% of Kleo's common shares that it did not previously own and ceased accounting for Kleo as an equity method investment. See Note 6 "Business Acquisition" for additional details.

# **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, 2021 and December 31, 2020, the Company's property and equipment consisted of office buildings, office equipment, computer software and computer equipment.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 2. Summary of Significant Accounting Policies (Continued)

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.

#### Intangible Assets

#### FDA Milestone Payments

The Company paid milestone payments of \$41,500 related to the FDA approval and launch of NURTEC ODT in 2020. These milestone payments were capitalized as an intangible asset, and will be amortized to cost of goods sold over the remaining expected life of the patents of 17 years. The gross carrying value and accumulated amortization of the finite-lived intangible asset was \$41,500 and \$4,921 as of December 31, 2021, respectively, and \$41,500 and \$2,413 as of December 31, 2020, respectively. For the years ended December 31, 2021 and December 31, 2020, the Company recognized \$2,508 and \$2,413, respectively, of amortization on the asset and recorded the expense to cost of goods sold.

Estimated future amortization expense for the intangible assets subsequent to December 31, 2021 is a follows:

2022	2,121
2023	2,121
2024	2,121
2025	2,121
2026	2,121
Thereafter	25,977
	36,579

# Acquired In-Process Research and Development

IPR&D that the Company acquires in conjunction with the acquisition of a business represents the fair value assigned to incomplete research projects which, at the time of acquisition, have not reached technological feasibility. The amounts are capitalized and accounted for as indefinite-lived intangible assets, subject to impairment testing until completion or

abandonment of the projects. Upon successful completion of each project, the Company will make a determination as to the then-useful life of the intangible asset, generally determined by the period in which the substantial majority of the cash flows are expected to be generated, and begin amortization. The Company evaluates IPR&D for impairment at least annually, or more frequently if impairment indicators exist, by performing a quantitative test that compares the fair value of the IPR&D intangible asset with its carrying value. If the fair value is less than the carrying amount, an impairment loss is recognized in operating results.

In January 2021, in connection with our acquisition of Kleo, we recorded intangible assets consisting of IPR&D assets of \$18,400, which included an oncology therapeutic candidate entering Phase I clinical trials and a COVID-19 therapeutic candidate in the planning stage for clinical development, and goodwill of \$1,390. See Note 6 "Business Acquisition" for additional details.

# Impairment of Long-lived Assets

The Company monitors its long-lived assets and finite-lived intangibles for indicators of impairment. If such indicators are present, the Company assesses the recoverability of affected assets by determining whether the carrying value of such assets is less than the sum of the undiscounted future cash flows of the assets. If such assets are found not to be recoverable, the Company measures the amount of such impairment by comparing the carrying value of the assets to the fair value of the assets, with the fair value generally determined based on the present value of the expected future cash flows associated with the assets. The Company believes no impairment of long-lived assets existed as of December 31, 2021 or December 31, 2020.

#### 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.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 2. Summary of Significant Accounting Policies (Continued)

- 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.

The Company's Series A preferred shares derivative liability and Series B preferred shares forward contracts are carried at fair value, with fair value based upon Level 3 inputs described above (see Note 4). The carrying values of other current assets, accounts payable, accrued expenses, and long-term debt approximate their fair values due to the short-term nature of these assets and liabilities.

#### **Derivative Instruments**

The Company recognizes all derivatives at fair value either as assets or liabilities in the consolidated balance sheets and changes in fair value of such instruments are recognized in current period earnings, unless specific hedge accounting criteria are met on its derivative instruments. As of December 31, 2021, the Company accounted for its Series B preferred forward contract as a derivative instrument (see Note 4 and 8). As of December 31, 2020, the Company accounted for certain scenarios as described in the Series A preferred shares agreement with RPI as a derivative liability (see Note 4 and 8).

# Leases

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. If 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. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Leases with an initial term of 12 months or less are not recorded on the balance sheet. Lease expense is recognized on a straight-line basis over the term of the short-term lease and variable lease costs are expensed as incurred.

For our real estate lease, the Company elected the practical expedient to include both the lease and non-lease components as a single component and account for it as an operating lease. 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 in the consolidated balance sheets prior to lease commencement and on commencement, reclassified to the right-of-use asset. The commencement date for the Company's leased office space in Yardley, Pennsylvania occurred during the second quarter of 2020. In connection with the commencement of the office lease, the Company reclassified \$2,850 for leasehold improvements related to assets of the lessor from prepaid rent to operating right-of-use asset. As of December 31, 2021, the Company had restricted cash of \$750 included in other assets in the consolidated financial statements, which represents collateral held by a bank for an LOC issued in connection with the leased office space in Yardley, Pennsylvania. The restricted cash is deposited in a non-interest bearing account. See Note 17 "Commitments and Contingencies" for additional information on the real estate lease.

For our vehicle leases, the Company elected the practical expedient to include both the lease and non-lease components as a single component and account for it as a finance lease. Each of the Company's vehicle leases are considered a single lease under a master service agreement, and each vehicle lease has a residual value guarantee equivalent to the wholesale value of the vehicle at termination of the lease. During 2020, the Company took delivery of the majority of its commercial car fleet. In connection with the vehicle leases, the Company recorded finance lease right-of-use assets in other assets and finance lease liabilities in other long-term liabilities on its consolidated balance sheet. See Note 17 "Commitments and Contingencies" for additional information on the vehicle leases.

# **Obligation to Perform Research and Development Services**

The Company accounts for obligations to perform Research and Development ("R&D") services by recording the consideration received as a liability, which then is recognized in the consolidated statement of

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 2. Summary of Significant Accounting Policies (Continued)

operations as an offset to R&D expense using the percentage completion method. The percentage complete is determined based on incurred R&D costs as a percent of the total forecasted costs of the contractual R&D commitment

# Foreign Currency Translation

The financial statements of our subsidiaries with functional currencies other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income, net of tax, in stockholders' equity. Foreign currency transaction gains and losses are included in other expense in the consolidated statement of operations. The Company's aggregate foreign currency transaction loss of \$8,951 was included in determining the consolidated results for the year ended December 31, 2021. The Company's aggregate foreign currency transaction losses were immaterial for the years ended December 31, 2020 and 2019.

# Revenue Recognition

Pursuant to Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("ASC 606"), the Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied.

Generally, the Company's performance obligations are transferred to customers at a point in time, typically upon delivery.

# Product Revenue, Net

The Company sells its product principally to its Customers in the United States. The Company's Customers subsequently resell the products to pharmacies and health care providers. In accordance with ASC 606, the Company recognizes net product revenues from sales when the Customers obtain control of the Company's products, which typically occurs upon delivery to the Customer. The Company's payment terms are generally between 30 - 65 days.

Revenues from product sales are recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from (a) invoice discounts for prompt payment and distribution service fees, (b) government and private payor rebates, chargebacks, discounts and fees, (c) product returns and (d) costs of co-pay assistance programs for patients, as well as other incentives for certain indirect customers. Reserves are established for the estimates of variable consideration based on the amounts earned or to be claimed on the related sales. The reserves are classified as reductions to trade receivable, net if payable to a Customer or accrued expenses if payable to a third-party. Where appropriate, the Company utilizes the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration that is included in the transaction price may be constrained and is included in net product revenues only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Distribution Service Fees: The Company engages with wholesalers to distribute its products to end customers. The Company pays the wholesalers a fee for services such as: Data Reporting, Inventory Management, Chargeback Administration and Service Level Commitment. The Company estimates the amount of distribution services fees to be paid to the Customers and adjusts the transaction price with the amount of such estimate at the time of sale to the Customer.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 2. Summary of Significant Accounting Policies (Continued)

Prompt Pay Discounts: The Company provides its Customers with a percentage discount on their invoice if the Customers pay within the agreed upon timeframe. The Company estimates the probability of Customers paying promptly and the percentage of discount outlined in the agreement, and deducts the full amount of these discounts from its gross product revenues and accounts receivable at the time such revenues are recognized.

Product Returns: The Company provides Customers a return credit in the amount of the purchase price paid by Customers for all products returned in accordance with the Company's returned goods policy. In the initial sales period, the Company estimates its provision for sales returns based on industry data and adjusts the transaction price with such estimate at the time of sale to the Customer. Once sufficient history has been collected for product returns, the Company will utilize that history to inform its estimate assumption. Once the product is returned, it is destroyed. The Company does not record a right-of-return asset.

Chargeback: A chargeback is the difference between the manufacturer's invoice price to the wholesaler and the wholesaler's customers contract price. The wholesaler tracks these sales and "charges back" the manufacturer for the difference between the negotiated prices paid between the wholesaler's customers and wholesaler's acquisition cost. Biohaven estimates the percentage of goods sold that are eligible for chargeback and adjusts the transaction price for such discount at the time of sale to the Customer.

Administration Fees: Biohaven engages with Pharmacy Benefit Managers ("PBMs") to administer prescription-drug plans for people with third-party insurance through a self-insured employer, health insurance plan, labor union or government plan. The Company pays PBMs "administrative fees" for their role in providing utilization data, administering rebates, and administering claims payments. Biohaven estimates the amount of administration fees to be paid to PBMs and adjusts the transaction price with the amount of such estimate at the time of sale to the Customer.

Rebates: Rebates apply to:

- Medicaid, managed care, expansion programs, the AIDS Drug Assistance Program, the State Pharmaceutical Assistance Program, and supplemental rebates to all applicable states as defined by the statutory government pricing calculation requirements under the Medicaid Drug Rebate Program;
- Tricare rebate to the TRICARE third party administrator based on the statutory calculation

defined in the Agreement with Defense Health Agency; and

 Part D and Commercial Managed Care rebates are paid based on the contracts with PBMs and Managed Care Organizations.
 Rebates are paid to these entities upon receipt of an invoice from the contracted entity which is based on the utilization of the product by the members of the contracted entity.

The Company estimates the percentage of goods sold that are eligible for rebates and adjusts the transaction price for such discounts at the time of sale to the Customers.

Coverage Gap: The Medicare Part D coverage gap (also called the "donut hole") is a period of consumer payment for prescription medication costs which lies between the initial coverage limit and the catastrophic-coverage threshold, when the patient is a member of a Medicare Part D prescription-drug program administered by the Centers for Medicare & Medicaid Services. The Company estimates the percentage of goods sold under Coverage Gap and adjusts the transaction price for such discount at the time of sale to the Customer.

The Company makes significant estimates and judgments that materially affect its recognition of net product revenue. Claims by third-party payors for rebates, chargebacks and discounts frequently are submitted to the Company significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. The Company will adjust its estimates based on new information, including information regarding actual rebates, chargebacks and discounts for its products, as it becomes available.

# **Cost of Goods Sold**

Cost of goods sold includes direct and indirect costs related to the manufacturing and distribution of NURTEC ODT, including third-party manufacturing costs, packaging services, freight-in, third-party royalties payable on the Company's net product revenues and amortization of intangible assets associated with NURTEC ODT. Cost of goods sold may also include period costs related to certain inventory manufacturing services and inventory adjustment charges. In connection with the FDA approval of NURTEC on February 27, 2020, the Company subsequently began capitalizing inventory manufactured or purchased after this date. As a result, certain manufacturing costs associated with product shipments of NURTEC ODT were expensed prior to FDA approval and, therefore, are not included in cost of goods sold

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 2. Summary of Significant Accounting Policies (Continued)

during 2020. These previously expensed costs were not material for the year ended December 31, 2020.

# 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 cancellable, 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.

# Interest Expense and Liability Related to Sale of Future Royalties

The Company accounted for the 2018 Funding Agreement with RPI Finance Trust ("RPI") and a portion of the 2020 Funding Agreement with RPI 2019 Intermediate Finance Trust ("RPI 2019 IFT") as liability financings. See Note 7 "Liability Related to Sale of Future Royalties, net" for additional details. 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 agreements. The liability is amortized using the effective interest rate method, resulting in recognition of non-cash interest expense over the estimated term of the agreements. 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 agreements.

#### Interest Expense on Mandatorily Redeemable Preferred Shares

The Company accounts for the sale of mandatorily redeemable preferred shares as liability financing. See Note 8 "Mandatorily Redeemable Preferred Shares, net" for additional details. Mandatorily redeemable preferred share liabilities are initially measured at fair value as of the transaction date, and are amortized under the effective interest method. The transaction costs associated with mandatorily redeemable preferred shares liabilities are amortized to interest expense on mandatorily redeemable preferred shares until termination of the liability.

# 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.

The Company classifies non-cash share-based compensation expense in its consolidated statement of operations 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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 2. Summary of Significant Accounting Policies (Continued)

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.

# **Advertising Costs**

Advertising costs include costs of endorsement and sponsorship contracts, television, digital and print advertising, media fees and brand events. The Company's endorsement contracts are generally expensed on a straight-line basis over the term of the contract. However, certain contract elements may be accounted for differently based upon the facts and circumstances of each individual contract. Prepayments made under the contract are included in prepaid expenses and other current assets in the consolidated statement of operations. For other advertising, the Company expenses the advertising costs as incurred. The Company incurred and expensed advertising costs in the amount of \$162,900 and \$106,961 for the years ended December 31, 2021 and 2020, respectively. The Company had no material advertising costs in 2019. These costs were included in selling, general and administrative expenses in the consolidated statements of operations.

# 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 Loss per Share

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net 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 loss per share attributable to common shareholders is calculated based on net loss attributable to Biohaven Pharmaceutical Holding Company Ltd. and excludes net loss attributable to non-controlling interests for relevant periods.

Basic net loss per share attributable to common shareholders is computed by dividing the net loss attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common shareholders is computed by adjusting net loss attributable to common shareholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common shareholders is computed by dividing the diluted net 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 is the same as basic net loss per share attributable to common shareholders, since potentially dilutive common shares are considered to be anti-dilutive.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 2. Summary of Significant Accounting Policies (Continued)

#### Concentrations of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash, cash equivalents, and marketable securities. Our cash management policy permits investments in U.S. federal government and federal agency securities, corporate bonds or commercial paper, supranational and sovereign obligations, certain qualifying money market mutual funds, certain repurchase agreements, and places restrictions on credit ratings, maturities, and concentration by type and issuer. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents and marketable securities to the extent recorded on the balance sheet.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit primarily to pharmaceutical wholesale distributors. Customer creditworthiness is monitored and collateral is not required. Historically, we have not experienced credit losses on our accounts receivable and as of December 31, 2021 and 2020, allowances on receivables were not material.

As of December 31, 2021, three customers accounted for 94% of the accounts receivable balance, with each these individual customers ranging from 30% to 33% of the accounts receivable balance. As of December 31, 2020, three customers accounted for 99% of the accounts receivable balance, with each these individual customers ranging from 29% to 37% of the accounts receivable balance.

For the year ended December 31, 2021, three customers accounted for 92% of our product sales, with these individual customers ranging from 29% to 32% of our product sales. For the year ended December 31, 2020, three customers accounted for 98% of our product sales, with these individual customers ranging from 32% to 34% of our product sales.

# Segment Information

The Company manages its operations as a single segment, focusing on serving patients affected by neurological diseases through development and commercialization of life changing therapies. Consistent with our operational structure, the Company's chief decision maker manages and allocates resources at a consolidated level. Therefore, results of our operations are reported on a consolidated basis for the purposes of assessing performance and making operating decisions. In 2021 and 2020, materially all the Company's net

product revenues were attributed to external customers in the United States and materially all the Company's long-lived assets are held in the United States

# Recently Adopted Accounting Pronouncements

Effective January 1, 2021, the Company adopted ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). This ASU 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 adoption of ASU 2019-12 did not have a material impact on the Company's consolidated financial statements.

# **Future Adoption of New Accounting Pronouncements**

In August 2020 the FASB issued ASU No. 2020-06, Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. The update addresses issues identified as a result of the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity. The amendments in ASU 2020-06 are effective for fiscal years beginning after December 15, 2021, with early adoption permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. Adoption of the standard requires changes to be made through either a modified retrospective method of transition or a fully retrospective method. In applying the modified retrospective method, the updated guidance is applied to transactions outstanding as of the beginning of the fiscal year in which the amendments are adopted. The Company does not expect the adoption of ASU 2020-06 to have a material effect on its consolidated financial statements.

In January 2021 the FASB issued ASU No. 2021-01, Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting, providing temporary guidance to ease the burden in accounting for reference rate reform primarily resulting from the discontinuation of LIBOR, which is currently expected to occur in mid-2023 for legacy contracts. The amendments in ASU 2021-01 are elective immediately and apply to all entities that have contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued. The Company does not expect that the adoption of ASU 2021-01 will have a material effect on its consolidated financial statements.

# BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 2. Summary of Significant Accounting Policies (Continued)

In May 2021 the FASB issued ASU No. 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force), which provides guidance on modifications or exchanges of a freestanding equity-classified written call option that is not within the scope of another topic. An entity should treat a modification of the terms or conditions or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as an exchange of the original instrument for a new instrument, and provides further guidance on measuring the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification

or exchange. ASU 2021-04 also provides guidance on the recognition of the effect of a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange on the basis of the substance of the transaction, in the same manner as if cash had been paid as consideration. The guidance is applied prospectively and is effective for all entities for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years. Early adoption is permitted. The Company has evaluated the impact that the adoption of ASU 2021-04 will have on the consolidated financial statements. The effect will largely depend on the terms of written call options or financings issued or modified in the future.

#### 3. Marketable Securities

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and fair value of debt securities available-for-sale by type of security at December 31, 2021 and 2020 was as follows:

	Am	ortized Cost	lowance for edit Losses	N	let Amortized Cost	Gr	oss Unrealized Gains	Gr	oss Unrealized Losses	Fair Value
December 31, 2021										
Corporate bonds										
U.S.	\$	130,388	\$ _	\$	130,388	\$	1	\$	(234)	\$ 130,155
Foreign		20,643	_		20,643		_		(82)	20,561
Government related obligations										
U.S.		41,939	_		41,939				(8)	41,931
Total	\$	192,971	\$ 	\$	192,971	\$	1	\$	(324)	\$ 192,648
December 31, 2020 Corporate bonds										
U.S.	\$	185,989	\$ _	\$	185,989	\$	1	\$	(106)	\$ 185,884
Foreign		37,321			37,321		1_		(21)	37,301
Total	\$	223,310	\$ 	\$	223,310	\$	2	\$	(127)	\$ 223,185

# BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 3. Marketable Securities (Continued)

The net amortized cost and fair value of debt securities available-for-sale at December 31, 2021 and 2020 are shown below by contractual maturity. Actual maturities may differ from contractual maturities because securities may be restructured, called or prepaid, or the Company intends to sell a security prior to maturity.

	December 31, 2021				December :			r 30, 2020	
	Net Amortized Cost			Fair Value		Net Amortized Cost		Fair Value	
Due to mature:									
Less than one year	\$	155,359	\$	155,226	\$	215,292	\$	215,177	
One year through two years		37,612		37,422		8,018		8,008	
Total	\$	192,971	\$	192,648	\$	223,310	\$	223,185	

Summarized below are the debt securities available-for-sale the Company held at December 31, 2021 and 2020 that were in an unrealized loss position, aggregated by the length of time the investments have been in that position:

		;		
	Number of Securities	Fair Value	Unrealize	ed Losses
December 31, 2021				
Corporate bonds				
U.S.	38	\$ 122,804	\$	(234)
Foreign	8	20,561		(82)
Government related obligations				
U.S.	7	41,931		(8)
Total	53	\$ 185,296	\$	(324)
December 31, 2020				
Corporate bonds				
U.S.	41	\$ 177,620	\$	(105)
Foreign	6	34,759		(21)
Total	47	\$ 212,378	\$	(126)

The Company did not have any investments in a continuous unrealized loss position for more than twelve months as of December 31, 2021 and 2020.

The Company reviewed the securities in the table above and concluded that they are performing assets generating investment income to support the needs of the Company's business. In performing this review, the Company considered factors such as the credit quality of the investment security based on research performed by external rating agencies and the prospects of realizing the carrying value of the security based on the investment's current prospects for recovery. As of December 31, 2021, the Company did not intend to sell these securities and did not believe it was more likely than not that it would be required to sell these securities prior to the anticipated recovery of their amortized cost basis.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 3. Marketable Securities (Continued)

#### Net Investment Income

Sources of net investment income included in other expense, net under other income (expense) in the consolidated statements of operations for the years ended December 31, 2021 and 2020 were as follows:

	2021		2020
Gross investment income from debt securities available-for-sale	\$ 304	\$	168
Investment expenses	(100)		(12)
Net investment income (excluding net realized capital gains or losses)	 204	-	156
Net realized capital gains	 19		11
Net investment income	\$ 223	\$	167

The Company had no net investment income during the year ended December 31, 2019.

We utilize the specific identification method in computing realized gains and losses. The proceeds from the sale of debt securities available-for-sale and the related gross realized capital gains and losses for the year ended December 31, 2021 and 2020 were the following:

	2021	2020
Proceeds from sales	\$ 113,441	\$ 85,167
Gross realized capital gains	19	12
Gross realized capital losses	\$ _	(1)

#### 4. Fair Value of Financial Assets and Liabilities

The preparation of the Company's consolidated financial statements in accordance with GAAP requires certain assets and liabilities to be reflected at their fair value and others to be reflected on another basis, such as an adjusted historical cost basis. In this note, the Company provides details on the fair value of financial assets and liabilities and how it determines those fair values.

#### Financial Instruments Measured at Fair Value on the Consolidated Balance Sheets

Certain of the Company's financial instruments are measured at fair value on the consolidated balance sheets on a recurring basis. The fair values of these instruments are based on valuations that include inputs that can be classified within one of three levels of a hierarchy established by GAAP. See Fair Value Measurements in Note 2 "Summary of Significant Accounting Policies" for a brief description of the type of valuation information ("valuation inputs") that qualifies a financial asset or liability for each level.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 4. Fair Value of Financial Assets and Liabilities (Continued)

Financial assets and liabilities measured at fair value on a recurring basis on the consolidated balance sheet at December 31, 2021 and 2020 were as follows:

		Fair Value Measurement Using:						
Balance Sheet Classification	Type of Instrument		Level 1		Level 2		Level 3	Total
December 31, 2021								
Assets:								
Cash equivalents	Money market funds	\$	32,420	\$	_	\$	_	\$ 32,420
Marketable securities	U.S. treasury bills		5,994		35,937		_	41,931
Marketable securities	U.S. corporate bonds		_		130,155		_	130,155
Marketable securities	Foreign corporate bonds		_		20,561		_	20,561
Total assets		\$	38,414	\$	186,653	\$	_	\$ 225,068
Liabilities:								
Series B preferred shares forward cor	ntracts						13,110	 13,110
Total liabilities		\$		\$	<u> </u>	\$	13,110	\$ 13,110
December 31, 2020								
Assets:								
Cash equivalents	Money market funds	\$	6,858	\$	_	\$	_	\$ 6,858
Marketable securities	U.S. corporate bonds		_		185,884		_	185,884
Marketable securities	Foreign corporate bonds		<u> </u>		37,301		<u> </u>	37,301
Total assets		\$	6,858	\$	223,185	\$	_	\$ 230,043
Liabilities:								
Series B preferred shares forward cor	ntracts						14,190	14,190
Total liabilities		\$		\$		\$	14,190	\$ 14,190

There were no securities transferred between Level 1, 2, and 3 during the years ended December 31, 2021 and 2020.

The following is a description, including valuation methodology, of the financial assets and liabilities measured at fair value on a recurring basis:

# Cash Equivalents

Cash equivalents at December 31, 2021 consisted of cash invested in money market funds. The carrying value of cash equivalents approximates fair value as maturities are less than three months. Since quoted prices are available in an active market, the Company's cash equivalents are classified in Level 1 of the fair value hierarchy.

# Marketable Securities

The fair values of the Company's Level 2 debt securities are obtained from quoted market prices of debt securities with similar characteristics or discounted cash flows to estimate fair value.

# Series B Preferred Shares Forward Contracts

In August 2020, the Company entered into Series B preferred share agreement, whereby RPI will invest in the Company through the purchase of up to 3,992 Series B preferred shares (the "Series B Preferred Shares") at a price of \$50,100 per share (the "RPI Series B Preferred Share Agreement"). The gross proceeds from the transaction with RPI will be used for the clinical development of zavegepant and other general corporate purposes. The shares will be issued in quarterly increments from March 31, 2021 to December 31, 2024.

The holders of the Company's outstanding Series B Preferred Shares will have the right to require redemption of the shares in certain circumstances. If a Change of Control occurs, as defined in the Company's memorandum and article of association, and the Series B Preferred Shares have not previously been redeemed, the holders of a majority of outstanding Series B Preferred Shares will have an option to redeem

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 4. Fair Value of Financial Assets and Liabilities (Continued)

outstanding shares in a single payment at a price equal to 1.77 times the original issuance price of the Series B Preferred Shares.

The Company may redeem the Series B Preferred Shares at its option at any time in a single payment at a price equal to 1.77 times the original issuance price of the Series B Preferred Shares.

The Company is required to redeem the Series B Preferred Shares for 1.77 times the original purchase price, payable beginning March 31, 2025 in equal quarterly installments through December 31, 2030. Accordingly, the Company has concluded that the agreement to issue Series B Preferred Shares at a future date represents a forward contract, and classified as a derivative. The Company initially measured the forward contract at a fair value of zero.

The Company subsequently remeasures the fair value and recognizes any gains or losses through other income (expense) in its consolidated statement of operations. The Company recognized expense of \$2,833 and \$14,190 for the years ended December 31, 2021, and 2020, respectively, related to the RPI Series B Preferred Share Agreement.

The fair value of the derivative recognized in connection with the RPI Series B Preferred Share Agreement was determined based on significant inputs not observable in the market, and therefore represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative primarily relates to the difference between the fair value of the Series B Preferred Shares and the contractual future purchase price. The fair value of the Series B Preferred Shares is calculated based on the cash flows to RPI (1.77 times the original purchase price as scheduled or accelerated upon certain events, as described previously) and the Company's estimated cost of capital for those cash flows. The cash flows to RPI are based on probability adjusted cash flows from certain scenarios outlined in the agreement that would result in accelerated payments modeled using a Monte Carlo simulation. As inputs into the valuation, the Company considered the type and probability of occurrence of certain change of control events, the amount of the payments, the expected timing of certain acceleration of payments, and a risk-adjusted discount rate. Assessing the probability of certain change of control events over a 10-year time period requires significant judgement and the successful completion of a change of control is largely dependent on the outcome of potential negotiations with a third party. Due to this uncertainty, our expectation of the probability of the timing of a change of control event at the reporting date could reasonably be different than the timing of an actual change of control event, and if so, would mean the estimated fair value could be

significantly higher or lower than the fair value determined.

Upon issuance of the Series B Preferred Shares, they qualify as mandatorily redeemable instruments and are classified as preferred shares liabilities. The Company will then measure the liability at fair value, and subsequently accrete the carrying value to the redemption value through interest expense using the effective interest rate method. The Company had 1,406 and no Series B Preferred Shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively.

Any Series B Preferred Shares that are not redeemed on an applicable redemption date described above will accrue interest at 18% per annum, until the shares are redeemed. If Series B Preferred Shares remain unredeemed for a period of one year after the applicable redemption date, the holders of the unredeemed shares will have the right to convert such preferred shares into a number of common shares equal to (a) the redemption price plus any accrued interest, divided by (b) the five day volume-weighted average trading price of the Company's common shares for the five days immediately preceding the conversion date for such unredeemed shares.

The following tables provide roll forwards of the aggregate fair value of the Company's Series B Preferred Shares Forward Contracts for which fair value is determined by Level 3 inputs for the years ended December 31, 2021 and 2020:

	Car	rying Value
Balance at December 31, 2020	\$	14,190
Change in fair value of derivative liability		2,833
Partial settlement of derivative liability	\$	(3,913)
Balance at December 31, 2021	\$	13,110
Beginning balance	\$	_
Beginning balance Change in fair value of derivative liability	\$	 14,190

#### Contingent Value Right Liability

On January 4, 2021, the Company acquired Kleo Pharmaceuticals, Inc. ("Kleo") (see Note 6 for additional information). Included in the purchase consideration transferred was a contingent value right to receive one dollar in cash for each Kleo share if certain specified Kleo biopharmaceutical products or product candidates receive the approval of the FDA prior to the expiration of 30 months following the effective time of the

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 4. Fair Value of Financial Assets and Liabilities (Continued)

transaction. The maximum amount payable pursuant to the contingent value right is approximately \$17,300, and the fair value of the contingent value right was \$1,457 as of the acquisition date. The Company recorded the contingent value right in other long-term liabilities on the consolidated balance sheets.

The fair value of the contingent value right was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company used a discounted cash flow approach to value the contingent value right liability. As inputs into the valuation, the Company considered the probability of FDA approval within the 30 month period, which we estimated at approximately 10%, the amount of the payment, and a discount rate of approximately 7% determined using an implied credit spread adjusted based on companies with similar credit risk.

At December 31, 2021, the Company determined the value of the contingent value right to be immaterial and recognized a gain of \$1,457 related to the contingent value right in other income (expense) in the consolidated statements of operations.

# Valuation of Series A Preferred Shares Derivative Liability

The fair value of the derivative liability recognized in connection with the Series A preferred shares agreement with RPI, as described in Note 8, 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 using credit spreads of biopharmaceutical companies in similar stages of development to the Company. In accordance with ASC 815, Derivatives and Hedging, the fair value of the derivative was recorded on the balance sheet as a Series A preferred shares derivative liability with changes in fair value recorded in other income (expense) in the consolidated statements of operations.

Upon the FDA's approval of NURTEC ODT the Company remeasured the derivative using the inputs noted above. In the first quarter of 2020, the Company partially settled the derivative liability associated with this approval of \$42,821, which modified the timing of the payment obligation related to the redeemable preferred share liability.

The following table provides a roll forward of the aggregate fair value of the Company's Series A preferred shares derivative liability for which fair value is determined by Level 3 inputs for the year ended December 31, 2020:

<u>_</u>	Carı	rying Value
Balance at December 31, 2019	\$	37,690
Change in fair value of derivative liability		5,131
Partial settlement of derivative liability	\$	(42,821)
Balance at December 31, 2020	\$	

The Company had no Series A preferred shares derivative liability for the year ended December 31, 2021.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 4. Fair Value of Financial Assets and Liabilities (Continued)

#### Financial Instruments Not Measured at Fair Value on the Consolidated Balance Sheets

The carrying value and estimated fair value classified by level of fair value hierarchy for financial instruments carried on the consolidated balance sheets at adjusted cost or contract value at December 31, 2021 and 2020 were as follows:

	Carrying		Fair Value Measurer	ment Using:			
	Value	Level 1	Level 2	Level 3	Total		
December 31, 2021							
Assets:							
Series A-2 Preferred Stock investment <sup>(1)</sup>	6,000	N/A	N/A	N/A	N/A		
Liabilities:							
Long-term debt <sup>(2)</sup>	626,720	_	646,159	_	646,159		
December 31, 2020							
Assets:							
Series A-2 Preferred Stock investment <sup>(1)</sup>	6,000	N/A	N/A	N/A	N/A		
Liabilities:							
Long-term debt <sup>(2)</sup>	267,458	_	287,050	_	287,050		

<sup>(1)</sup> It was not practical to estimate the fair value of this investment as it represents Series A-2 Preferred Stock of an unlisted company. On a routine basis the Company will determine if additional preferred shares of the unlisted company have been issued and will adjust the carrying value of its Series A-2 Preferred Stock investment accordingly. The Series A-2 Preferred Stock investment was recorded in other long-term assets on the consolidated balance sheets. See Artizan under Note 14 "License and Other Agreements" for additional details on the Series A-2 Preferred Stock investment.

# 5. Balance Sheet Components

# **Prepaid Expenses**

Prepaid expenses consisted of the following:

	December 31,					
	2021		2020			
Prepaid clinical trial costs	\$ 42,578	\$	21,173			
Prepaid manufacturing	17,448		36,040			
Prepaid commercial costs	15,732		16,448			
Other prepaid expenses	13,080		3,021			
	\$ 88,838	\$	76,682			

# Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,				
		2021		2020	
Building and land	\$	11,728	\$	6,857	
Building improvements		569		_	
Computer hardware and software		3,863		1,574	
Machinery & equipment		1,193		287	
Furniture & fixtures		1,202		1,202	
Office equipment		747		674	
Construction-in-progress		_		860	
	\$	19,302	\$	11,454	
Accumulated depreciation		(4,612)		(2,114)	
	\$	14,690	\$	9,340	

Depreciation expense for property and equipment was \$2,498, \$1,182 and \$629 for the years ended December 31, 2021, 2020 and 2019, respectively.

As of December 31, 2021 and 2020, computer software costs included in property and equipment were

<sup>(2)</sup> The fair value of the Company's long-term debt was determined using observable inputs, such as quoted prices in active markets for similar liabilities and other inputs that are corroborated by observable market data.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 5. Balance Sheet Components (Continued)

\$1,727 and \$238, respectively, net of accumulated amortization of \$566 and \$53, respectively. Depreciation and amortization expense for capitalized computer software costs was \$513 and \$53 for the years ended December 31, 2021 and 2020. There was no depreciation and amortization expense recognized for capitalized computer software during the year ended December 31, 2019.

# **Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following:

	As of December 31,				
		2021		2020	
Accrued development milestones	\$	5,000	\$	667	
Accrued employee compensation and benefits		40,109		29,447	
Accrued clinical trial costs		37,477		19,887	
Accrued commercialization and other professional fees		19,994		6,336	
Accrued sales discounts and allowances		203,760		73,155	
Current obligation to perform R&D services		22,030		846	
Other accrued expenses and current liabilities		91,649		36,292	
	\$	420,019	\$	166,630	

### Inventories

Inventories consisted of the following:

	As of December 31,					
		2021		2020		
Raw materials	\$	_	\$	931		
Work-in-process		159,075		33,266		
Finished goods		9,269		5,366		
Total inventories		168,344		39,563		
Less noncurrent inventories <sup>(1)</sup>	\$	87,736	\$	_		
Total inventories classified as current	\$	80,608	\$	39,563		

(1) Included in other assets on the consolidated balance sheets. There are no recoverability issues for these amounts.

# 6. Business Acquisition

On January 4, 2021, the Company acquired Kleo Pharmaceuticals, Inc. ("Kleo"). Kleo is a development-stage biopharmaceutical company focused on advancing the field of immunotherapy by developing small molecules that emulate biologics. The transaction was accounted for as the acquisition of a business using the acquisition method of accounting.

The total fair value of the consideration transferred was \$20,043, which primarily consisted of the issuance of a total of 115,836 common shares of the Company to Kleo stockholders and contingent consideration in the form of a contingent value right to receive one dollar in cash for each Kleo share if certain specified Kleo biopharmaceutical products or product candidates receive the approval of the FDA prior to the expiration of 30 months following the effective time of the transaction. The maximum amount payable pursuant to the contingent value right was approximately \$17,300. At December 31, 2021, the Company determined the value of the contingent value right to be immaterial and recognized a gain of \$1,457 related to the contingent value right in other income (expense).

Prior to the consummation of the transaction, the Company owned approximately 41.9% of the outstanding shares of Kleo and accounted for it as an equity method investment. As part of the transaction, the Company acquired the remainder of the shares of Kleo, and post-transaction the Company owns 100% of the outstanding shares of Kleo. The carrying value of the Company's investment in Kleo was \$1,176 immediately prior to the acquisition date. The Company determined the fair value of the existing interest was \$6,437, and recognized a gain from our equity method investment of \$5,261 for the year ended December 31, 2021 on the consolidated statement of operations as a result of remeasuring to fair value the existing equity interest in Kleo.

In connection with the transaction, we recorded: net working capital of \$573; property, plant and equipment of \$1,257; intangible assets consisting of in progress research and development assets of \$18,400 which include an oncology therapeutic candidate entering Phase I clinical trials and a COVID-19 therapeutic candidate in the planning stage for clinical development; debt assumed of \$1,577; and goodwill of \$1,390.

Kleo's employees, other than its President and Chief Financial Officer, were retained as part of the transaction. In connection with the transaction agreement, the Company filed a registration statement permitting Kleo stockholders to offer and sell the common shares of the Company issued in the transaction.

# 7. Liability Related to Sale of Future Royalties, net

# 2018 RPI Funding Agreement

In June 2018, the Company entered into a funding agreement (the "2018 RPI Funding Agreement") to sell tiered, sales-based royalty rights on global net sales of pharmaceutical products containing the compounds rimegepant or zavegepant (previously known as BHV-3500 and vazegepant) and certain derivative

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 7. Liability Related to Sale of Future Royalties, net (Continued)

compounds thereof ("Products") to 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 2018 RPI Funding Agreement, 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. Pursuant to the Collaboration Agreement with Pfizer, Pfizer will compensate Biohaven for the related royalties on net sales outside of the U.S. owed to RPI under the 2018 RPI Funding Agreement.

Concurrent with the 2018 Funding Agreement, the Company entered into a common stock purchase agreement (the "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.

The Company concluded that there were two units of account for the consideration received comprised of the liability related to sale of future royalties and the common shares. The Company allocated the \$100,000 from the 2018 Funding Agreement and \$50,000 from the Purchase Agreement among the two units of account 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 share price on the transaction date, adjusted for the trading restrictions. The transaction costs of \$377 were allocated in proportion to the allocation of total consideration to the two units of account. The effective interest rate under the 2018 Funding Agreement, including transaction costs, is approximately 27% as of December 31, 2021.

# 2020 RPI Funding Agreement

In August 2020, the Company entered into a funding agreement with RPI 2019 Intermediate Finance Trust ("RPI 2019 IFT") providing for up to \$250,000 of funding in exchange for rights to participation payments based on global net sales of products containing zavegepant and rimegepant and certain payments based on success-based milestones relating to zavegepant (the "2020 RPI Funding Agreement"). Under the 2020 RPI Funding Agreement, RPI 2019 IFT will be entitled to receive tiered, sales based participation rights up to 3.0% of future global net sales of products containing zavegepant, 0.4% of future global net sales of products containing rimegepant, and payments tied to success-based milestones as described below. Pursuant to the Collaboration Agreement with Pfizer, Pfizer will compensate Biohaven for the related royalties on net

sales outside of the U.S. owed to RPI under the 2020 RPI Funding Agreement. The Company received \$150,000 in cash at closing in 2020 and \$100,000 in cash upon achievement of the commencement of the oral zavegepant Phase 3 program in 2021.

The success-based milestone payments range from 0.6x to 2.95x of the funded amount depending on the number of regulatory approvals achieved for zavegepant (including 1.9x for the first zavegepant migraine regulatory approval) and would be paid over a 10-year period. If the Company consummates a Change of Control, and the Buy-Back Option has not previously been exercised, RPI 2019 IFT has the option to accelerate each unpaid milestone payment which has or thereafter occurs.

The Company concluded that there were two units of account for the \$150,000 in initial consideration received, which comprised of a liability related to sale of future royalties for products containing rimegepant, and a research and development arrangement with RPI 2019 IFT for zavegepant. The Company allocated the \$150,000 from the 2020 RPI Funding Agreement among the two units of account based on the present value of probability adjusted net sales at the time of the transaction. The Company allocated \$147,876 in transaction consideration to the liability related to sale of future royalties and \$2,124 to the obligation to perform R&D services liability in the consolidated balance sheets. The transaction costs of \$400 were allocated to the liability related to sale of future royalties. The effective interest rate under the 2020 RPI Funding Agreement, including transaction costs, is approximately 8% as of December 31, 2021.

The following table shows the activity within the liability related to sales of future royalties account for the years ended December 31, 2021 and 2020, respectively, related to the 2018 and 2020 RPI Funding Agreements.

	2021			2020
Beginning balance	\$	335,282	\$	144,111
Additional liability related to the 2020 RPI Funding Agreement, net of issuance costs		_		147,476
Royalty revenues payable to RPI		(11,604)		(1,543)
Non-cash interest expense on liability related to sale of future royalties		60,605		45,238
Ending balance	\$	384,283	\$	335,282

In March 2021, the Company received \$100,000 from RPI 2019 IFT, pursuant to the 2020 RPI Funding Agreement, for the commencement of the oral

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 7. Liability Related to Sale of Future Royalties, net (Continued)

zavegepant Phase 3 clinical program. The Company allocated the proceeds to obligation to perform R&D services liability in the consolidated balance sheets.

Since there is a substantive and genuine transfer of risk to RPI 2019 IFT for the development of zavegepant, the \$102,124 of consideration allocated to the development of zavegepant is being recognized by the Company as an obligation to perform contractual services and therefore is a reduction of research and development expenses as incurred.

The following table shows the activity within the obligation to perform R&D services account for the years ended December 31, 2021 and 2020, respectively, related to the 2020 RPI Funding agreement.

	2021	2020
Beginning balance	\$ 1,778	\$ _
Additional obligations to perform R&D services	100,000	2,124
Reduction to research and development expenses	(29,177)	(346)
Ending balance	\$ 72,601	\$ 1,778

# 8. Mandatorily Redeemable Preferred Shares, net

#### **RPI Series A Preferred Shares**

In April 2019, the Company sold 2,495 Series A Preferred Shares (the "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. The Company was not obligated to issue any additional Series A Preferred Shares, subject to a fee up to \$3,000 if not all of the Series A Preferred Shares were issued. In the third quarter of 2020, the Company determined it will not exercise the option to issue additional Series A Preferred Shares and accordingly recognized the full \$3,000 fee in other expense in the consolidated statement of operations.

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 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.

The Company may redeem the Series A Preferred Shares at its 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.

The Company is required to redeem the Series A Preferred Shares for two times (2x) the original purchase price, payable beginning March 31, 2021 in equal quarterly installments through 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 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 20% as of December 31, 2021. The Company recognized \$30,020, \$27,623, and \$12,711 in noncash interest expense for the years ended December 31, 2021, 2020, and 2019 respectively. The Company had 1,871 and 2,495 Series A preferred shares issued and outstanding as of December 31, 2021 and 2020, respectively.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 8. Mandatorily Redeemable Preferred Shares, net (Continued)

The following table shows the activity within the Series A preferred share liability for the years ended December 31, 2021 and 2020, respectively:

	Car	rying Value
Gross balance at December 31, 2020	\$	174,264
Interest expense recognized, excluding transaction cost amortization		29,976
Redemption of Series A preferred shares		(62,500)
Gross balance at December 31, 2021		141,740
Less: unamortized transaction costs		(130)
Net balance at December 31, 2021		141,610
Gross balance at December 31, 2019		103,864
Partial settlement of Series A preferred share derivative liability		42,821
Interest expense recognized, including transaction cost amortization		27,579
Gross balance at December 31, 2020	\$	174,264
Less: unamortized transaction costs	\$	(173)
Net balance at December 31, 2020	\$	174,091

Certain scenarios as described in the Preferred Share Agreement were determined by the Company to result in a derivative liability (see Note 4 for details on the fair value measurement).

The Company recorded the payment for the PRV as research and development expense in the consolidated statements of operations, and as an operating cash outflow in the consolidated statements of cash flows during the year ended December 31, 2019. During the second quarter of 2019, the Company submitted NDAs for the acute treatment of migraine for the Zydis ODT and tablet formulations of rimegepant. The NDA submission of rimegepant Zydis ODT was submitted using the PRV.

Upon the FDA's approval of NURTEC ODT the Company remeasured the derivative using the inputs noted above. In the first quarter of 2020, the Company partially settled the Series A preferred shares derivative liability associated with this approval of \$42,821, which modified the timing of the payment obligation related to the redeemable preferred share liability. The Company had no Series A preferred shares derivative liability for the year ended December 31, 2021 or 2020.

# **RPI Series B Preferred Shares**

On August 7, 2020, the Company entered into the RPI Series B Preferred Share Agreement, pursuant to which RPI agreed to invest in the Company through the purchase of up to 3,992 Series B Preferred Shares at a price of \$50,100 per share. The shares will be issued in

quarterly increments from March 31, 2021 to December 31, 2024. Upon issuance of the Series B Preferred Shares, they qualify as mandatorily redeemable instruments and are classified as a mandatorily redeemable preferred shares liability on the consolidated balance sheet. The Company measures the liability at fair value, and subsequently accretes the carrying value to the redemption value through interest expense using the effective interest rate method. The effective interest rate under the Series B Preferred Share Agreement was determined to be approximately 8.5%, and the Company recognized \$2,273 in interest expense for the year ended December 31, 2021. The Company had 1,406 and no Series B preferred shares issued and outstanding, as of December 31, 2021 and December 31, 2020, respectively.

The following table shows the activity within the Series B preferred share liability for the year ended December 31, 2021:

	Carr	ying Value
Balance at December 31, 2020	\$	_
Issuance of Series B preferred shares at fair value		74,354
Interest expense recognized		2,273
Balance at December 31, 2021	\$	76,627

#### 9. Warrants

#### 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. The payment was recorded in research and development expense.

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 14). 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 expires May 31, 2029 and has accelerated vesting in the event of a change of control of Biohaven.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 10. Shareholders' Deficit

#### Issuance of Common Shares for Purchase and Sale Agreement

In October 2021, the Company entered into a purchase and sale agreement (the "Purchase and Sale Agreement") to purchase a building located at 221 Church Street, New Haven, Connecticut in exchange for 39,004 shares of Company stock valued at approximately \$4,871. The Purchase and Sale Agreement closed and the shares were issued in December 2021.

#### Issuance of Common Shares for Exercise of Warrant

In September 2021, the Trout Group LLC exercised a warrant granted in June 2017 for the purchase of 6,751 shares through a net share settlement, resulting in an issuance of 5,621 shares.

#### **Issuance of Common Shares for Reliant Agreement**

In July 2021, the Company entered into a development and license agreement (the "Reliant Agreement") with Reliant Glycosciences, LLC ("Reliant"), pursuant to which the Company and Reliant have agreed to collaborate on a program with Biohaven Labs' multifunctional molecules to develop and commercialize conjugated antibodies for therapeutic uses relating to IgA nephropathy and treatment of other diseases and conditions. Under the Reliant Agreement, the Company paid Reliant an upfront share payment of 29,297 shares valued at approximately \$3,686.

#### Issuance of Common Shares for the March 2021 Offering

In March 2021, the Company issued and sold 2,686,409 common shares at a public offering price of \$76.00 per share for net proceeds of approximately \$199,500 after deducting underwriting discounts and commissions of approximately \$4,167 and other offering expenses of approximately \$500. In addition, in March 2021, the underwriter of the March follow-on offering exercised its option to purchase additional shares, and the Company issued and sold 402,961 common shares for net proceeds of approximately \$30,000 after deducting underwriting discounts and commissions of approximately \$625. 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 \$229,500.

# Issuance of Common Share for Acquisition of Kleo Pharmaceuticals, Inc.

On January 4, 2021, the Company acquired Kleo Pharmaceuticals, Inc. In the merger, each share of Kleo common stock issued and outstanding immediately

prior to the effective time of the merger was converted into the right to receive approximately 0.007 of a common share of the Company, rounded up to the nearest whole share. Prior to the consummation of the merger, the Company owned approximately 41.9% of the outstanding shares of Kleo through its subsidiary Therapeutics, resulting in 115,836 common shares of the Company being issued to Kleo stockholders in the merger.

# Issuance of Common Shares for Yale MoDE Agreement

On January 1, 2021, the Company entered into a worldwide, exclusive license agreement for the development and commercialization of a novel Molecular Degrader of Extracellular Protein (MoDEs) platform based on ground-breaking research conducted in the laboratory of Professor David Spiegel at Yale University. Under the agreement, the Company paid Yale University an upfront cash payment of \$1,000 and 11,668 shares valued at \$1,000, both of which were included in research and development expense in the consolidated statements of operations.

# Issuance of Common Shares for Consulting Agreement with Moda Pharmaceuticals LLC

On January 1, 2021, the Company entered into a consulting services agreement with Moda Pharmaceuticals LLC to further the scientific and commercial advancement of technology, drug discovery platforms, product candidates and related intellectual property owned or controlled by the Company. Under the agreement, the Company paid Moda Pharmaceuticals LLC an upfront cash payment of \$2,700 and 37,836 shares valued at \$3,243, both of which were included in research and development expense in the consolidated statements of operations.

### **Issuance of Common Shares for Equity Distribution Agreement**

In December 2020, the Company entered into the Equity Distribution Agreement. In accordance with the terms of the Equity Distribution Agreement, we may offer and sell common shares having an aggregate offering price of up to \$400,000 from time to time through or to the sales agents, acting as our agents or principals. Sales of our common shares, if any, will be made in sales deemed to be "at the market offerings" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, in ordinary brokers' transactions, to or through a market maker, on or through the New York Stock Exchange or any other market venue where the securities may be traded, in the over-the-counter market, in privately negotiated transactions, or through a combination of any

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 10. Shareholders' Deficit (Continued)

such methods of sale. The sales agents may also sell our common shares by any other method permitted by law. The sales agents are not required to sell any specific amount of securities but will act as our sales agents using commercially reasonable efforts consistent with their normal trading and sales practices, on mutually agreed terms between the sales agents and us. The Company issued and sold 939,328 common shares for net proceeds of approximately \$78,743 during the year ended December 31, 2021. The Company did not issue any shares under the Equity Distribution Agreement during the year ended December 31, 2020.

# Issuance of Common Shares for Sosei Heptares License Agreement

In November 2020, the Company entered into a global collaboration and license agreement with Sosei Heptares. Under the agreement, the Company paid Sosei Heptares an upfront cash payment of \$5,000 and 54,617 shares valued at \$4,858. In addition, Sosei Heptares will be eligible to receive additional development, regulatory and commercialization milestone payments of up to \$370,000, as well as tiered royalties equal to zero to ten percent of net sales of products resulting from the collaboration. In return, the Company will receive exclusive global rights to develop, manufacture and commercialize a portfolio of novel, small-molecule CGRP receptor antagonists discovered by Sosei Heptares for the treatment of CGRP-mediated disorders.

# Issuance of Series A Preferred Shares and Employee Share Options by Consolidated Subsidiary

In September 2020, the Company's Asia-Pacific Subsidiary, BioShin Limited, authorized, issued and sold 15,384,613 BioShin Series A Preferred Shares at a price of \$3.90 per share for a total of \$60,000 to a group of investors led by OrbiMed, with participation from Cormorant Asset Management LLC, HBM Healthcare Investments Ltd, Surveyor Capital (a Citadel Company), and Suvretta Capital Management, LLC (the "BioShin Investors"). The BioShin Series A Preferred Shares contained both a call option by the Company and a put option held by the BioShin Investors. Due to the contingently redeemable features, the Company had classified the BioShin Series A Preferred Shares in mezzanine equity since the redemption was out of the Company's control.

In connection with the BioShin Series A Preferred Shares issuance, BioShin Limited executed the 2020 Equity Incentive Plan ("BioShin 2020 Equity Incentive Plan") and granted options under the BioShin 2020 Equity Incentive Plan to certain employees. The compensation expense 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 years) using the straight-line method. The Company is accounting for the expense being recognized over the requisite service period as non-controlling interest in shareholder's equity. The Company recognized \$1,810 and \$1,819 in non-controlling interest relating to the options for the years ended December 31, 2021 and 2020.

In November 2021, Biohaven Pharmaceutical Holding Company LTD. ("Biohaven HoldCo"), Biohaven Therapeutics Ltd., Atlas Merger Sub ("Merger Sub") and BioShin entered into an Agreement and Plan of Merger (the "Merger Agreement"). The Merger Agreement provided for the merger of Merger Sub with and into BioShin, with BioShin surviving the merger as a wholly owned indirect subsidiary of Biohaven Holdco, in accordance with Section 233 of the Cayman Islands Companies Act. As a result of the satisfaction of the closing conditions described in the Merger Agreement, on January 6, 2022, each Series A convertible preferred share of BioShin, no par value, other than Excluded Shares (as defined in the Merger Agreement), was converted into the right to receive 0.080121 of a Biohaven Holdco common share.

# 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.

# 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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 10. Shareholders' Deficit (Continued)

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.

Issuance of Common Shares for Exercise of Related Party Warrants

In connection with a guarantee of its obligations under a certain 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. The exercise resulted in cash proceeds to the Company of \$1,998 and the issuance of 215,000 common shares.

# 11. Accumulated Other Comprehensive Income (Loss)

Shareholders' deficit included the following activity in accumulated other comprehensive income (loss) for the years ended December 31, 2021 and 2020:

	0004	2020
	2021	2020
Net unrealized investment gains (losses):		
Beginning of period balance	\$ (125)	\$ —
Other comprehensive loss before reclassifications <sup>(1)</sup>	(217)	(113)
Amounts reclassified from accumulated other comprehensive income (loss) <sup>(2)</sup>	19	(12)
Other comprehensive loss	(198)	(125)
End of period balance	(323)	(125)
Foreign currency translation adjustments:		
Beginning of period balance	439	_
Other comprehensive income (loss) <sup>(1)</sup>	(189)	439
Other comprehensive income (loss)	(189)	439
End of period balance	250	439
Total beginning of period accumulated other comprehensive income	314	
Total other comprehensive income (loss)	(387)	314
Total end of period accumulated other comprehensive income (loss)	\$ (73)	\$ 314

<sup>(1)</sup> There was no tax on other comprehensive income (loss) during the period.

The Company had no accumulated other comprehensive income (loss) included in shareholders' deficit as of December 31, 2019.

# 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.

Upon effectiveness of the 2017 Equity Incentive Plan, there are no further common shares authorized for grant under the 2014 Plan.

<sup>(2)</sup> Amounts reclassified from accumulated other comprehensive income for specifically identified debt securities are included in other expense, net under other income (expense) in the consolidated statements of operations.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 12. Share-Based Compensation (Continued)

#### 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. As of December 31, 2021, the 2017 Plan allows for a maximum of 15,329,403 shares of the Company's common stock to be reserved and available for grants. Also as of December 31, 2021, there were 1,462,699 shares of the Company's common stock available for future grants under the 2017 Plan. In January 2022, the Board of Directors approved an additional increase in the number of common shares reserved for future issuance under the 2017 Plan of 2.677.252.

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.

#### 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 stock options, RSUs, and the 2017 Employee Share Purchase Plan (the "ESPP") was classified in the consolidated statements of operations as follows:

	Year Ended December 31,					
		2021		2020		2019
Research and development expenses	\$	52,135	\$	23,734	\$	26,284
Selling, general and administrative expenses		74,992		33,680		28,688
	\$	127,127	\$	57,414	\$	54,972
Less: Share-based compensation expense attributable to non-controlling interests		1,810		1,819		_
Share-based compensation expense attributable to Biohaven Pharmaceutical Holding Company Ltd.	\$	125,317	\$	55,595	\$	54,972

As of December 31, 2021, total unrecognized compensation cost related to the unvested share-based awards was \$118,683, which is expected to be recognized over a weighted average period 1.85 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 the Company's common shares at December 31, 2021. The total intrinsic value of outstanding stock options for the years ended December 31, 2021, 2020 and 2019 was \$692,428, \$433,879 and \$284,300, respectively. The total intrinsic value of stock options exercised for the year ended December 31, 2021 was \$160,095.

The assumptions that the Company used to determine the grantdate fair value of stock options granted under the 2014 Plan and the 2017 Plan (collectively, the "Plans") were as follows, presented on a weighted average basis:

	Ye	ar Ended December	31,
	2021	2020	2019
Risk-free interest rate	0.60%	0.72%	1.93%
Expected term (in years)	5.74	7.62	6.24
Expected volatility	67.28%	68.68%	72.27%
Expected dividend yield	—%	—%	—%
Exercise price	\$83.23	\$57.76	\$50.46

As of December 31, 2021, unrecognized compensation expense related to unvested stock options totaled \$50,945, which the Company expects to be recognized over a weighted-average period of 1.57 years. The Company expects approximately 2,034,528 of the unvested stock options to vest over the requisite service period.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 12. Share-Based Compensation (Continued)

The following table is a summary of the Company's stock option activity for the year ended December 31, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2020	7,545,907	\$ 24.58		
Granted	1,277,280	\$ 83.23		
Exercised	(1,647,170)	\$ 17.83		
Forfeited	(86,290)	\$ 60.13		
Outstanding as of December 31, 2021	7,089,727	\$ 40.15	6.78	\$ 692,428
Options exercisable as of December 31, 2021	5,055,199	\$ 31.18	6.21	\$ 539,053
Vested and expected to vest as of December 31, 2021	7,089,727	\$ 40.15	6.78	\$ 692,428

#### 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, 2021, there was \$67,738 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 2.06 years. The total fair value of RSUs vested during the years ended December 31, 2021, 2020 and 2019 was \$34,819, \$7,056 and \$1,702, respectively.

The following table is a summary of the RSU activity for the year ended December 31, 2021:

	Number of Shares	Wei Grant	ghted Average Date Fair Value
Unvested restricted stock outstanding as of December 31, 2020	467,160	\$	56.00
Granted	1,246,200	\$	86.94
Forfeited	(45,913)	\$	75.79
Vested	(449,377)	\$	77.48
Unvested restricted stock outstanding as of December 31, 2021	1,218,070	\$	78.98

# Employee Share Purchase Plan

In April 2020, the Company's board of directors approved the rules and procedures of the 2017 Employee Share Purchase Plan (the "ESPP") approved

by shareholders of the Company on May 3, 2017. The ESPP allows each eligible employee who is participating in the plan to purchase shares by authorizing payroll deductions of up to 15% of eligible earnings. Unless the participating employee has previously withdrawn from the offering, accumulated payroll deductions will be used to purchase shares on the last business day of the offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Under applicable tax rules, an employee may purchase no more than \$25 worth of ordinary shares, valued at the start of the purchase period, under the ESPP in any calendar year. There is no minimum holding period associated with shares purchased pursuant to this plan. An employee's purchase rights terminate immediately upon termination of employment.

The number of shares reserved for issuance under the ESPP automatically increases on January 1 of each calendar year, beginning on January 1, 2018 through January 1, 2027. As of December 31, 2021, 2,057,085 shares remained available for future issuance under the ESPP. In January 2022, 600,000 additional shares were authorized to be issued under the ESPP.

The Company accounts for employee share purchases made under its ESPP using an estimate of the grant date fair value, which is determined in accordance with ASC 718, Stock Compensation. The purchase price discount and the look-back feature cause the ESPP to be compensatory and the Company to recognize compensation expense. The compensation cost is recognized on a straight-line basis over the requisite service period. The Company recognized compensation expense of \$2,696 and \$2,815 for the years ended December 31, 2021 and 2020. The Company values ESPP shares using the Black-Scholes model

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 12. Share-Based Compensation (Continued)

As of December 31, 2021, there was \$1,359 of unrecognized share compensation expense related to the ESPP, which is expected to be recognized over the remaining offering period ending May 31, 2022. During the year ended December 31, 2021, 104,230 shares were issued under the ESPP.

#### Bioshin 2020 Equity Incentive Plan

In 2020 the Company executed the Bioshin 2020 Equity Incentive Plan, which awards non-public subsidiary stock as compensation. The Company

recognized stock based compensation expense of \$1,810 and \$1,819 in the years ended December 31, 2021 and 2020, respectively, for the Bioshin 2020 Equity Incentive Plan. Upon employee vesting of subsidiary stock, the Company recognizes a noncontrolling equity interest. Employees are restricted from selling vested subsidiary stock to anyone other than the Company and the Company has discretion on the amount of stock to repurchase. Therefore, the subsidiary stock is classified as equity because it is not mandatorily redeemable. The Company has not repurchased any subsidiary stock.

# 13. 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,					
		2021		2020		2019
Numerator:						
Net loss	\$	(848,396)	\$	(768,615)	\$	(528,805)
Net loss attributable to non-controlling interests		(1,810)		(1,819)		_
Net loss attributable to Biohaven Pharmaceutical Holding Company Ltd.	\$	(846,586)	\$	(766,796)	\$	(528,805)
Denominator:						
Weighted average common shares outstanding—basic and diluted		64,677,823		58,732,415		48,489,890
Net loss per share attributable to Biohaven Pharmaceutical Holding Company Ltd.—basic and diluted	\$	(13.09)	\$	(13.06)	\$	(10.91)

The Company's potential dilutive securities, which include stock options, restricted share units, 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 of the Company 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,			
	2021	2020	2019		
Options to purchase common shares	7,089,727	7,545,907	9,423,015		
Warrants to purchase common shares	100,000	106,751	106,751		
Restricted Share Units	1,218,070	467,160	88,950		
	8.407.797	8.119.818	9.618.716		

#### 14. License and Other Agreements

# Yale University Agreements

In September 2013, the Company entered into an exclusive license agreement (the "Yale Agreement") with Yale University 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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 14. License and Other Agreements (Continued)

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.

In January 2021, the Company entered a worldwide, exclusive license agreement with Yale University for the development and commercialization of a novel Molecular Degrader of Extracellular Protein ("MoDE") platform (the "Yale MoDE Agreement"). Under the license agreement, Biohaven acquired exclusive, worldwide rights to Yale's intellectual property directed to its MoDE platform. The platform pertains to the clearance of disease-causing protein and other biomolecules by targeting them for lysosomal degradation using multi-functional molecules. As part of consideration for this license, the Company paid Yale University an upfront cash payment of \$1,000 and 11,668 common shares valued at approximately \$1,000. Under the agreement, the Company may develop products based on the MoDE platform. The agreement includes an obligation to pay a minimum annual royalty of up to \$1,000 per year, and low single digit royalties on the net sales of licensed products. 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. In addition, Yale University will be eligible to receive additional development milestone payments of up to \$800 and commercial milestone payments of up to \$2,950. The agreement terminates on the later of twenty years from the effective date, twenty years from the filing date of the first investigational new drug application for a licensed product or the last to expire of a licensed patent.

For the year ended December 31, 2021, in addition to the development milestone payments noted above, the Company recorded \$150 in research and development expense related to Yale MoDE Agreement following the initiation of a certain Phase 1 clinical trial. For the years ended December 31, 2020 and 2019, the

Company did not record any material expense, or make any milestone or royalty payments under the Yale Agreement or the Yale MoDE Agreement.

# ALS Biopharma Agreement

In August 2015, the Company entered into an agreement (the "ALS Biopharma Agreement") with ALS Biopharma and Fox Chase Chemical Diversity Center Inc. ("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.

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.

For the years ended December 31, 2021, 2020 and 2019, the Company did not record any expense or make any milestone or royalty payments under the ALS Biopharma Agreement.

# **Catalent Agreements for Rimegepant**

In January 2018, the Company entered into an exclusive worldwide license and development agreement with Catalent U.K. Swindon Zydis Limited, a subsidiary of Catalent, Inc. ("Catalent") pursuant to which the Company obtained certain license rights to the Zydis ODT technology for use with NURTEC ODT. Since NURTEC ODT 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.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 14. 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 NURTEC ODT, 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 or by Catalent. 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 the agreement on a country-by-country basis if, among other things, the Company fails to meet specified development timelines, which the Company may extend in certain circumstances.

In connection with the agreement with Catalent, upon FDA approval of NURTEC ODT on February 27, 2020, the Company became obligated to pay Catalent up to \$1,500 upon the achievement of specified regulatory and commercial milestones. The Company recorded the \$1,500 in milestone payments as an intangible asset in its consolidated balance sheets in the first quarter of 2020, and is amortizing the expense to cost of goods sold on its consolidated statement of operations over the patent life. The Company paid the \$1,500 in milestone payments to Catalent during the year ended December 31, 2020. The Company did not make any milestone payments to Catalent during the year ended December 31, 2021.

#### 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 not material based on 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.

For the years ended December 31, 2021, 2020 and 2019, the Company did not record any material expense or make any milestone or royalty payments under the Rutgers Agreement.

#### **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 zavegepant, 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 BMS

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 14. License and Other Agreements (Continued)

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 BMS 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 filling, 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-bylicensed product and country-by-country basis upon the expiration of the royalty term with respect to each licensed product in each country and can also be terminated if certain events occur, e.g., material breach or insolvency.

In March 2018, the Company entered into an amendment to the BMS Agreement (the "2018 BMS Amendment"). Under the 2018 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 zavegepant, which was recorded in research and development expense in the consolidated statements of operations.

The 2018 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.

In August 2020, the Company entered into a further amendment of the BMS Agreement (the "August 2020 BMS Amendment"). Under the August 2020 BMS Amendment, the Company paid BMS an upfront payment of \$5,000 in return for a reduction in the royalties payable on net sales of rimegepant and zavegepant in China, with percentages in the low- to mid-single digits. In addition, the Company is obligated to pay up to \$22,500 for each licensed product upon the achievement of commercial milestones in China. The August 2020 BMS Amendment also amended the BMS Agreement to remove sales in China from the commercial milestone payment obligations.

In November 2020, the Company entered into a further amendment of the BMS Agreement (the "November 2020 BMS Amendment"). Under the November 2020 BMS Amendment, certain exclusivity provisions under the BMS Agreement are waived which permits the Company to develop certain CGRP compounds licensed by the Company from Heptares Therapeutics Limited ("Heptares"). Under the November 2020 Amendment, if the Company initiates clinical development of a Heptares compound prior to July 8, 2023, the Company is obligated to pay BMS certain fees based on net sales of the Heptares compounds from low single percentage to 10% and pay up to \$17,500 for each Heptares compound upon the achievement of certain development milestones and up to \$150,000 for each Heptares compound upon the achievement of certain commercial milestones. No fees or milestones are due by the Company to BMS for Heptares compounds that begin clinical trials after July 8, 2023

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

In connection with the BMS Agreement, upon FDA approval of NURTEC ODT on February 27, 2020, the Company became obligated to pay BMS \$40,000 in milestone payments. The Company recorded the \$40,000 in milestone payments as an intangible asset on its consolidated balance sheets in the first quarter of 2020, and will amortize the expense to cost of goods sold on its consolidated statement of operations over the patent life. The Company paid the \$40,000 in milestone payments to BMS during the year ended December 31, 2020.

In connection with the BMS Agreement, the Company was required to pay \$2,000 to BMS on commencement of a Phase 1 clinical trial, \$4.000 on

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 14. License and Other Agreements (Continued)

commencement of a Phase 2 clinical trial, and \$6,000 on commencement of a Phase 3 clinical trial, for certain milestones relating to the development of zavegepant. Accordingly, the Company recognized these liabilities in accrued expenses within the consolidated balance sheets in the fourth guarter of 2018, first guarter of 2019, and fourth quarter of 2019, respectively. Per the BMS Agreement, the \$2,000 and \$4,000 payment obligations under the agreement were deferred until the earlier of FDA approval of rimegepant or the discontinuation of the rimegepant development program. Upon FDA approval of NURTEC ODT on February 27, 2020, the Company became obligated to pay BMS the \$2,000 and \$4,000 milestone payments for the commencement of the Phase 1 and Phase 2 clinical trials of zavegepant, respectively, and made the milestone payments in the second guarter of 2020. The Company paid the \$6,000 milestone payment following the commencement of the Phase 3 clinical trial of zavegepant in the fourth guarter of 2020. In the first guarter of 2021, the Company accrued a \$5,000 development milestone expense following the regulatory filing for rimegepant in Europe, which was paid in the second quarter of 2021. In the fourth quarter of 2021, the Company accrued a \$5,000 development milestone expense for the planned submission of a New Drug Application to the FDA for intranasal zavegepant in the first half of 2022.

The Company recorded \$10,000, \$5,000, and \$17,500 of research and development expense related to the BMS Agreement during the years ended December 31, 2021, 2020 and 2019, respectively. In addition, for the years ended December 31, 2021 and 2020, the Company recorded \$46,420 and \$6,346, respectively, in royalty expense in cost of goods sold on the consolidated statement of operations under the BMS agreement. The Company recorded no royalty expense related to the BMS agreement in 2019.

# 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 2016 AstraZeneca 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 2016 AstraZeneca 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. 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 or on a country-by-country basis ten years after the first commercial sale and can also be terminated if certain events occur. e.g., material breach or insolvency.

For the years ended December 31, 2021, 2020 and 2019, the Company did not record any expense or make any milestone or royalty payments under the 2016 AstraZeneca Agreement.

# **RPI** Agreements

In June 2018, pursuant to the 2018 RPI 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 2018 RPI Funding Agreement, in exchange for \$100,000 in cash. Specifically, the participation rate commences at 2.1 percent on annual global net sales of up to and equal to \$1,500,000, declining to 1.5 percent on annual global net sales exceeding \$1,500,000.

In connection with the 2018 RPI Funding Agreement, the Company recorded \$50,094, \$41,908, and \$26,580 in interest expense on its liability related to sale of future royalties for the years ended December 31, 2021, 2020 and 2019, respectively. The Company paid \$6,458 and \$597 under the 2018 RPI Funding Agreement during the years ended December 31, 2021 and 2020, and no payments under the 2018 RPI Funding Agreement in 2019.

In August 2020, pursuant to the 2020 RPI Funding Agreement, the Company sold sales-based participation rights on global net sales of products containing zavegepant and rimegepant to RPI 2019 IFT for

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 14. License and Other Agreements (Continued)

aggregate funding of \$250,000, payable in two tranches. For further details on the transaction see Note 7 "Liability Related to Sale of Future Royalties, net."

In connection with the 2020 RPI Funding Agreement, the Company recorded \$10,511 and \$3,330 in interest expense on its liability related to sale of future royalties for the years ended December 31, 2021 and 2020. The Company paid \$1,230 and \$70 under the 2020 RPI Funding Agreement during years ended December 31, 2021 and 2020.

# 2018 License Agreement with AstraZeneca

In September 2018, the Company entered into an exclusive license agreement (the "2018 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-3241. 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 were 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 salesbased 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.

The Company plans to conduct a Phase 3 clinical trial of this product candidate, which is now 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. The Company is solely responsible, and has agreed to use commercially reasonable efforts, for all development, regulatory and commercial activities related to verdiperstat. The Company 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 sublicense to AstraZeneca in addition to any milestone payments it would otherwise be obligated to pay.

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 and can also be terminated if certain events occur, e.g., material breach or insolvency.

For the years ended December 31, 2021, 2020 and 2019, the Company did not record any material expense

or make any milestone or royalty payments under the 2018 AstraZeneca Agreement.

#### 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. The payment was recorded in research and development expense in the consolidated statements of operations for the year ended December 31, 2019.

In addition, the Company 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.

In connection with the FCCDC Agreement, Biohaven and FCCDC have established a TDP-43 Research Plan, which was amended in November 2020, that provides for certain milestones to be achieved by FCCDC, and milestone payments to be made by the Company up to approximately \$3,800 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 0% to 10% 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 terminates on a country-by-country basis and product-by-product basis upon expiration of the royalty term for such product in such country and can also be terminated if certain events occur, e.g., material breach or insolvency.

The Company recorded \$1,746 and \$1,500 in research and development expense in the consolidated statements of operations related to the Research Plan milestones with FCCDC during the years ended

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 14. License and Other Agreements (Continued)

December 31, 2021 and 2020, respectively. Excluding the upfront payments noted above, the Company recorded no expense related to this agreement in 2019.

# **Heptares Agreement**

In November 2020, the Company entered into a global collaboration and license agreement with Heptares Therapeutics Ltd. (the "Heptares Agreement") to obtain rights to develop, manufacture and commercialize a portfolio of novel, small-molecule CGRP receptor antagonists discovered by Sosei Heptares for the treatment of CGRPmediated disorders. The portfolio includes the lead candidate BHV-3100 (also known as "HTL0022562"), which has advanced through preclinical development demonstrating promising and differentiated properties for further investigation in human trials. As part of consideration for this license, the Company paid Sosei Heptares an upfront cash payment of \$5,000 and 54,617 shares valued at \$4,858, both of which were included in research and development expense on the consolidated statement of operations. In addition, Sosei Heptares will be eligible to receive additional development, regulatory and commercialization milestone payments of up to \$370,000, as well as earned royalties equal to zero to ten percent of net sales of products resulting from the collaboration. The royalty payments are payable on a country-by-country and licensed product-by-licensed product basis from the date of commercial launch of a licensed product by Biohaven until the later of: (a) the expiration of the last valid claim covering the composition of matter of such licensed product, or its use or manufacture, in such country; (b) expiration of the regulatory exclusivity period for such licensed product in the relevant country; and (c) ten (10) years following the date of the commercial launch of such licensed product in the relevant country.

Biohaven has the right to terminate the Heptares Agreement for any reason or no reason: (a) in its entirety during the research term on one hundred and eighty (180) days' written notice to Sosei Heptares; and (b) following the end of the research term, in its entirety or on a country-by-country basis, on ninety (90) days' prior written notice to Sosei Heptares. Biohaven will remain liable to pay (a) any milestone payments that have become due for payment and/or (b) royalty payments on net sales by Biohaven, in each case (a) and (b) on or before the termination date.

Heptares has the right to terminate the Heptares Agreement on thirty (30) days' written notice to Biohaven if after the end of the research term, for a continuous period of not less than three hundred and sixty five (365) days, no material Development activities have been undertaken by or on behalf of Biohaven on any licensed product; provided that, at least three (3) months prior to

exercising such termination right Heptares must notify Biohaven of its concerns and the parties shall discuss in good faith the reasons why Biohaven is not undertaking such material development activities and its plans for recommencing such activities.

In the second quarter of 2021, the Company accrued a \$500 development milestone expense following the initiation of a Phase I clinical trial, which was paid in the third quarter of 2021.

For the year ended December 31, 2021 and 2020, excluding the upfront and development milestone payments noted above, the Company recorded \$7,658 and \$800, respectively, in research and development expense related to the Heptares Agreement.

# Artizan Agreement

In December 2020, Biohaven entered into an Option and License Agreement with Artizan Biosciences Inc (the "Artizan Agreement"). Pursuant to the Artizan Agreement, Biohaven acquired an option ("Biohaven Option") to obtain a royalty-based license from Artizan to manufacture, use and commercialize certain products in the United States. The Biohaven Option is exercisable throughout the development phase of the products at an exercise price of approximately \$4,000 to \$8,000, which varies based on the market potential of the products. Biohaven and Artizan have also formed a JSC to oversee, review and coordinate the product development activities with regard to all products for which Biohaven has (or has exercised in the future) the Biohaven Option.

In December 2020, simultaneously with the Option and License Agreement, the Company entered into a Series A-2 Preferred Stock Purchase Agreement with Artizan. Under the agreement, the Company paid Artizan 61,494 shares valued at \$6,000, which were issued in January 2021. In exchange, the Company acquired 34,472,031 shares of series A-2 preferred stock of Artizan. The Company recorded the fair value of the Series A-2 Preferred Stock as an other asset on its consolidated balance sheets and a corresponding liability in other current liabilities as of December 31, 2020.

For the year ended December 31, 2021, the Company did not record any research and development expense or make any milestone payments related to the Artizan Agreement.

# Moda Agreement

On January 1, 2021, the Company entered into a consulting services agreement with Moda Pharmaceuticals LLC (the "Moda Agreement") to further the scientific advancement of technology, drug discovery platforms (including the technology licensed under the

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 14. License and Other Agreements (Continued)

Yale MoDE Agreement), product candidates and related intellectual property owned or controlled by the Company.

Under the Moda Agreement, the Company paid Moda an upfront cash payment of \$2,700 and 37,836 shares valued at approximately \$3,243. In addition, Moda will be eligible to receive additional development milestone payments of up to \$81,612 and commercial milestone payments of up to \$30,171. The Moda Agreement has a term of four years and may be terminated earlier by the Company or Moda under certain circumstances including, for example, the Company's discontinuation of research on the MoDE platform or default.

For the year ended December 31, 2021, the Company did not record any material research and development expense or make any milestone payments related to the Moda Agreement.

# Reliant Agreement

In July 2021, the Company entered into the Reliant Agreement pursuant to which the Company and Reliant have agreed to collaborate on a program with Biohaven Labs' multifunctional molecules to develop and commercialize conjugated antibodies for therapeutic uses relating to IgA nephropathy and treatment of other diseases and conditions. Under the Reliant Agreement, the Company paid Reliant an upfront payment in the form of issuance of common shares valued at approximately \$3,686, which the Company recorded as research and development expense on its consolidated statement of operations. In addition, Reliant will be eligible to receive development and regulatory milestone payments of up to \$36,500, and royalties of a low single-digit percentage of net sales of licensed products.

For the year ended December 31, 2021, excluding the upfront payment noted above, the Company recorded \$167 in research and development expense related to the Reliant Agreement.

# **Purchase and Sale Agreement**

In October 2021, the Company entered into the Purchase and Sale Agreement to purchase the building located at 221 Church Street, New Haven, Connecticut (see Note 10).

# KU Leuven Agreement

In January 2022, Biohaven and Katholieke Universiteit Leuven ("KU Leuven") entered into an Exclusive License and Research Collaboration Agreement (the "KU Leuven Agreement") to develop and commercialize first-in-class TRPM3 antagonists to

address the growing proportion of people worldwide living with chronic pain disorders. The TRPM3 antagonist platform was discovered at the Centre for Drug Design and Discovery ("CD3") and the Laboratory of Ion Channel Research ("LICR") at KU Leuven. Under the KU Leuven Agreement, Biohaven receives exclusive global rights to develop, manufacture and commercialize KU Leuven's portfolio of small-molecule TRPM3 antagonists. The portfolio includes the lead candidate, henceforth known as BHV-2100, which has demonstrated promising efficacy in preclinical pain models and will be the first to advance towards Phase 1 studies. Biohaven will support further basic and translational research at KU Leuven on the role of TRPM3 in pain and other disorders. As consideration, KU Leuven received an an upfront cash payment of \$3,000 and 15,340 shares valued at \$1,779, and is eligible to receive additional development, regulatory, and commercialization milestones payments of up to \$327,750. In addition, KU Leuven will be eligible to receive mid-single digit royalties on net sales of products resulting from the collaboration.

### Taldefgrobep Alfa License Agreement

In February 2022, following the transfer of intellectual property the Company announced that we entered into a worldwide license agreement with BMS for the development and commercialization rights to taldefgrobep alfa (also known as BMS-986089), a novel, Phase 3-ready anti-myostatin adnectin (the "Taldefgrobep Alfa License Agreement"). Under the terms of the Taldefgrobep Alfa License Agreement, the Company will receive worldwide rights to taldefgrobep alfa and BMS will be eligible for regulatory approval milestone payments of up to \$200,000, as well as tiered, sales-based royalty percentages from the high teens to the low twenties. There were no upfront or contingent payments to BMS related to the Taldefgrobep Alfa License Agreement.

#### 15. 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.

As a company principally subject to taxation in the BVI, the Company's foreign income relates to the operations of our non-BVI subsidiaries operating in the U.S., Ireland, and China. The Company has historically outsourced all of the research and clinical development for its programs under a master services agreement

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 15. Income Taxes (Continued)

with Biohaven Pharmaceuticals, Inc., a Delaware corporation ("BPI"). As a result of providing services under this agreement and profit from US commercial sales of NURTEC ODT, BPI was profitable during the years ended December 31, 2021, 2020 and 2019, and BPI is subject to taxation in the United States.

Loss before provision for income taxes consisted of the following:

	Yea	r End	ded December	31,	
	2021		2020		2019
BVI	\$ (285,697)	\$	(421,948)	\$	(541,625)
Foreign	(557,626)		(336,440)		13,239
Loss before provision for income taxes	\$ (843,323)	\$	(758,388)	\$	(528,386)

The provision for income taxes consisted of the following:

	Year Ended December 31,					
		2021		2020		2019
Current income tax provision:						
BVI	\$	_	\$	_	\$	_
Foreign		5,073		10,227		419
Total current income tax provision		5,073		10,227		419
Deferred income tax provision (benefit):						
BVI		_		_		_
Foreign		_		_		_
Total deferred income tax provision (benefit)		_		_		_
Total provision for income taxes	\$	5,073	\$	10,227	\$	419

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,				
	2021	2020	2019		
BVI statutory income tax rate	0.0 %	0.0 %	0.0 %		
Foreign tax rate differential	(8.2)	(121.2)	0.3		
Tax credits	(1.8)	(1.4)	(2.2)		
Tax reserves	0.0	0.7	0.0		
Change in valuation allowance	10.2	124.6	1.9		
Share-based compensation	(0.6)	(0.9)	0.0		
Nondeductible expenses	0.9	0.0	0.0		
Other	0.1	(0.5)	0.1		
Effective income tax rate	0.6 %	1.3 %	0.1 %		

Net deferred tax assets (liabilities) consisted of the following:

(	December 31,				
		2021	inei		
		2021		2020	
Deferred tax assets:					
Tax credits	\$	26,590	\$	17,321	
Accrued bonus		7,772		5,422	
Net operating losses		98,537		44,839	
Interest expense carryforward		27,491		8,241	
Intangible assets		875,000		875,000	
Share-based compensation		27,562		16,737	
Lease liabilities		867		3,522	
Other		5,848		610	
Valuation allowance		(1,063,314)		(965,338)	
Total deferred tax assets		6,353		6,354	
Deferred tax liabilities:					
Right-of-use assets		(867)		(3,522)	
Other		(5,486)		(2,832)	
Total deferred tax liabilities		(6,353)		(6,354)	
Net deferred tax asset (liability)	\$		\$		
` ,,	_		_		

In August 2020, the Company completed an intra-entity asset transfer of certain of its intellectual property to the Company's Irish subsidiary. As a result of the transfer, the Company recorded a deferred tax asset of \$875,000. The recognized deferred tax benefit represents the difference between the basis of the intellectual property for financial statement purposes and the basis of the intellectual property for Irish tax purposes. The increase in the Company's foreign net operating losses and interest expense carryforward is a result of the Company centralizing its operating company in Ireland. Based on its analysis of all available objective evidence, the Company concluded that it was more likely than not that the deferred tax assets from the intra-entity transfer will not be realized due to the lack of net operating income history of its subsidiary. Therefore, the Company established a full valuation allowance against its net deferred tax asset in Ireland.

In January 2021, we completed the acquisition of Kleo. We recorded a full valuation allowance against our Kleo deferred tax assets and periodically review our position. Due to Kleo's cumulative loss history, we determined that a full valuation allowance on these assets was appropriate. We will continue to evaluate the need for a valuation allowance on our deferred tax assets until there is sufficient positive evidence to support the reversal of all or some portion of these allowances.

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 15. Income Taxes (Continued)

As of December 31, 2021, the Company had foreign net operating loss carryforwards of \$747,156, which can be carried forward indefinitely and \$26,401 which begin to expire in 2037. The Company has federal and state research and development credits of \$12,825 and \$6,467, respectively, as December 31, 2021, which begin to expire in 2037. As of December 31, 2021, the Company had federal orphan drug credits of \$7,298, which begin to expire in 2038. As of December 31, 2021, we evaluated our U.S. deferred tax assets and determined that a full valuation allowance on these assets was appropriate.

The change in the valuation allowance for deferred tax assets during the year ended December 31, 2021 was primarily due to generation of excess tax credits, losses in foreign jurisdictions and the acquisition of Kleo. The change in the valuation allowance for deferred tax assets during the year ended December 31, 2020 was primarily due to the intra-entity transfer of certain intellectual property for which the Company has established a full valuation allowance. The changes for the year ended December 31, 2019 were due to the generation of excess credits.

The following table represents a roll-forward of our valuation allowance on deferred tax assets:

	Year Ended December 31,					
		2021		2020		2019
Valuation allowance as of beginning of year	\$	965,338	\$	20,728	\$	10,957
Decreases recorded as benefit to income tax provision		_		_		_
Increases recorded to income tax provision		92,845		944,610		9,771
Increases recorded in other balance sheet accounts		5,131		_		_
Valuation allowance as of end of year	\$	1,063,314	\$	965,338	\$	20,728

The Company followed the authoritative guidance for recognizing and measuring uncertainty in income taxes for tax positions taken or expected to be taken in a tax return.

The beginning and ending amounts of unrecognized tax benefits reconciles as follows:

	Year	Ende	ed Decemb	er 31	Ι,
	2021		2020		2019
Beginning of period balance	\$ 5,790	\$	_	\$	_
Increase for tax positions taken during the current period	1,100		5,790		_
Revaluation of tax positions taken in a prior period	200		_		_
End of period balance	\$ 7,090	\$	5,790	\$	

The unrecognized tax benefits relate primarily to issues common among multinational corporations. All of these unrecognized tax benefits, if recognized, would impact the Company's effective income tax rate. 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, 2021 and 2020, the total amount of accrued interest and penalties were not significant. We estimate that it is reasonably possible that within the next 12 months, \$320 of our gross unrecognized tax benefits, could reverse affecting the effective income tax rate in future periods.

The Company files income tax returns in the U.S. federal, state and several foreign jurisdictions. The U.S. federal and foreign jurisdictions returns are subject to tax examinations for the tax year ended December 31, 2018 and subsequent years. The Company's subsidiary, BPI, is currently under examination for the tax period ending December 31, 2019.

# 16. Debt

In August 2020, the Company and Biohaven Pharmaceuticals, Inc., the Company's wholly-owned subsidiary (together with the Company, the "Borrowers"), entered into a financing agreement, as amended, with Sixth Street Specialty Lending, Inc., as administrative agent, and the lenders party thereto (the "Lenders") pursuant to which the Lenders agreed to extend a senior secured credit facility to the Company providing for term loans in an aggregate principal amount up to \$500,000, plus any capitalized interest paid in kind. The Borrowers drew an initial term loan of \$275,000 at closing in August 2020 (the "Initial Term Loan") and had \$100,000 of immediately available delayed draw term loan commitments and \$125,000 of

delayed draw term loan commitments available upon achievement of the Delay Draw Sales Milestone (as defined in the Sixth Street Financing Agreement).

In March 2021, the Borrowers and certain other of the Company's subsidiaries entered into Amendment No. 1 (the "First Amendment") to the financing agreement pursuant to which the parties agreed to, among other things, remove the Delayed Draw Sales Milestone tied to the availability of the \$125,000 tranche of delayed draw term loans. In August 2021, the Borrowers drew the \$125,000 tranche of delayed draw term loans (the "DDTL-2).

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 16. Debt (Continued)

In September 2021, the Borrowers and certain other of the Company's subsidiaries entered into Amendment No. 2 (the "Second Amendment") to the financing agreement. Pursuant to the Second Amendment, the parties agreed to, among other things, increase the size of the credit facility by providing for additional term loans in an aggregate principal amount of \$250,000 for a total facility size of \$750,000 plus any capitalized interest paid in kind. At the closing of the Second Amendment, the Borrowers drew an initial term loan of \$125,000 (the "2021 Term Loan") and \$100,000 of delayed draw term loan commitments (the "DDTL-1"). The remaining \$125,000 in delayed draw term loan commitments (the "2021 DDTL Commitment") was available to be drawn by the Borrowers until December 31, 2021 (the "Delayed Draw Term Loan Commitment Termination Date").

In November 2021, the Company entered into Amendment No. 3 and Limited Consent to Financing Agreement ("the Third Amendment and Limited Consent") to our Sixth Street Financing Agreement. Pursuant to the Third Amendment and Limited Consent, the Lenders consented to the Company's entry into the Collaboration Agreement with Pfizer.

In December 2021, the Company entered into Amendment No. 4 (the "Fourth Amendment") to the financing agreement (as previously amended and as amended by the Fourth Amendment, the "Sixth Street Financing Agreement"), pursuant to which the parties agreed to, among other things, extend the Delayed Draw Term Loan Commitment Termination Date to June 30, 2022.

The Company has the right to elect to pay up to 4.00% per annum of the interest on the term loans comprising such borrowing in the form of payment-in-kind for the first eight fiscal quarters after the date of such borrowing. For the loans drawn under the 2021 DDTL Commitment, the payment-in-kind election cannot exceed seven fiscal quarters after the Delayed Draw Term Loan Commitment Termination Date. Interest on amounts borrowed under the facility will be payable quarterly.

The Company will have the right to prepay borrowings under the facility in whole or in part at any time, subject to a customary prepayment fee on the principal amount prepaid, which declines over time. The Company paid customary fees with respect to amounts drawn on each credit date. The Company also agreed to pay customary fees on the funding of any delayed draw term loans.

The Sixth Street Financing Agreement contains mandatory prepayments, restrictions, and covenants applicable to the Company and its subsidiaries that are

customary for financings of this type. Among other requirements, the Borrowers are required to maintain a minimum unrestricted cash balance of \$80,000. At the Borrowers' request, the minimum unrestricted cash balance will be waived for any fiscal quarter in which the Borrowers achieve \$400,000 of net sales of the Company's products in the four consecutive quarterly periods prior to such fiscal quarter. The Sixth Street Financing Agreement also includes representations, warranties, indemnities, and events of default that are customary for financings of this type, including an event of default relating to a change of control of the Company. Upon or after an event of default, the administrative agent and the lenders may declare all or a portion of our obligations under the Sixth Street Financing Agreement to be immediately due and payable and exercise other rights and remedies provided for under the Sixth Street Financing Agreement.

The obligations under the Sixth Street Financing Agreement are and will be guaranteed by each of the Company's existing and future direct and indirect subsidiaries, subject to certain exceptions. The obligations of the Company and its subsidiaries under the Sixth Street Financing Agreement are secured, subject to customary permitted liens, and other agreed-upon exceptions, by a security interest in certain existing and after-acquired assets of the Company and its subsidiaries.

#### 2020 Loans

In August 2020, the Company borrowed the Initial Term Loan for total proceeds of \$262,200, net of discounts and issuance costs. In August 2021, the Company borrowed the DDTL-2 for total proceeds of \$123,750. net of discounts and issuance costs. The DDTL-2 contained the same financing terms as the Initial Term Loan. The Initial Term Loan and the DDTL-2 (collectively, the "August 2020 Loans") become due and payable in August 2025. The August 2020 Loans bear floating interest on the unpaid principal amount at a rate per annum equal to the three-month LIBOR rate, adjusted for applicable reserve requirements, and subject to a floor of 1.00%, plus 9.00%. As of December 31, 2021, the contractual interest rate for the August 2020 Loans was 10.00%, and the effective interest rate is approximately 11.60% and 10.90% for Initial Term Loan and DDTL-2, respectively. The interest expense on the August 2020 Loans, including amortization of loan discounts and issuance costs, was \$34,898 and \$11,975 for the years ended December 31, 2021, and 2020, respectively. For the August 2020 Loans, the Company elected to pay in kind the maximum amount for its interest payments made through December 31, 2021.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

# 16. Debt (Continued)

#### **2021 Loans**

In September 2021, the Company borrowed the 2021 Term Loan and DDTL-1 (collectively, the "September 2021 Loans") and received \$119,722 and \$97,778, respectively, both net of discounts and issuance costs. The September 2021 Loans are due and payable in September 2026. If drawn, loans drawn under the 2021 DDTL Commitment will be borrowed under the same financing terms as the September 2021 Loans. The September 2021 Loans will bear floating interest on the unpaid principal amount at a rate per annum equal to the three-month LIBOR rate, adjusted for applicable

reserve requirements, and subject to a floor of 1.00%, plus 8.25%. As of December 31, 2021, the contractual interest rate for the September 2021 Loans was 9.25%, and the effective interest rate is approximately 10.80% and 10.20% for 2021 Term Loan and DDTL-1, respectively. The interest expense on the September 2021 Loans, including amortization of loan discounts and issuance costs, was \$5,578 for the year ended December 31, 2021. For the September 2021 Loans, the Company elected to pay in kind the maximum amount for its interest payments made through December 31, 2021.

The following table is a summary of the Company's borrowing as of December 31, 2021 and 2020:

, , ,	,		
	2	021	2020
Long-term debt			
Floating rate loans due August 2025 (10.00% at December 31, 2021) <sup>(1)</sup>	\$	417,685 \$	279,478
Floating rate loans due September 2026 (9.25% at December 31, 2021) <sup>(2)</sup>		227,300	_
Total debt principal	<del></del>	644,985	279,478
Unamortized debt discount and issuance costs		(18,265)	(12,020)
Long-term debt	\$	626,720 \$	267,458

(1) Includes \$13,207 and \$4,478 of paid-in-kind interest that was added to the principal balances during the years ended December 31, 2021, and 2020, respectively. (2) Includes \$2,300 of paid-in-kind interest that was added to the principal balances during the year ended December 31, 2021.

The following is a summary of the Company's required repayments of debt principal due during each of the next five years and thereafter, as of December 31, 2021:

2022	\$ —
2023	10,386
2024	36,661
2025	393,368
2026	204,570
	\$ 644,985

# 17. Commitments and Contingencies

# Lease Agreements

During the second quarter of 2020, the Company took occupancy of the premises associated with its Yardley office lease, which the Company determined to be an operating lease. Before the Yardley lease, the Company had no active leases in 2020 other than a short-term lease of temporary office space. The short-term lease terminated when the Company took occupancy of the premises. Also, during 2020, the Company took delivery of most of its commercial fleet leases, which were determined to be finance leases. See "Real Estate Lease" and "Commercial Fleet Leases" below for additional details related to the office lease and commercial fleet leases, respectively.

# BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 17. Commitments and Contingencies (Continued)

The following table is a summary of the components of total lease cost for the years ended December 31, 2021 and 2020:

	Statement of Operations Loss Location	2021		2020	
Lease cost					
Finance lease cost:					
Amortization of right-of-use assets	Selling, general and administrative expense	\$ 5,318	\$	2,284	
Interest on lease liabilities	Interest expense	568		331	
Operating lease cost	Selling, general and administrative expense	1,042		676	
Total lease cost		\$ 6,928	\$	3,291	

The Company recognized no material short-term or variable lease costs for the years ended December 31, 2021 and 2020. The Company recognized no material lease costs in 2019.

The following table summarizes supplemental cash flow information for the years ended December 31, 2021 and 2020:

		2021	2020
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows paid for operating leases	\$	672	\$ 202
Operating cash flows paid for interest portion of finance leases	\$	592	\$ 266
Financing cash flows paid for principal portion of finance leases	\$	4,863	\$ 2,240
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	\$	478	\$ 16,184
Right-of-use assets obtained in exchange for new finance lease liabilities		369	\$ 3,681

<sup>(1)</sup> This figure excludes \$2,850 of opening adjustments to the right-of-use operating asset due to leasehold improvements originally classified in other assets and transferred to the right-of-use operating asset at lease commencement in 2020.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 17. Commitments and Contingencies (Continued)

Supplemental balance sheet information related to leases as of December 31, 2021 and 2020 is as follows:

In thousands, except remaining lease term and discount rate	Balance Sheets Location	2021	2020
Operating lease:			
Operating lease right-of-use assets	Other assets	\$ 5,222	\$ 5,98
Current portion of operating lease liabilities	Accrued expenses and other current liabilities	\$ 439	\$ 675
Noncurrent operating lease liabilities	Other long-term liabilities	 2,797	2,929
Total operating lease liabilities		\$ 3,236	\$ 3,604
Finance leases:			
Finance lease right-of-use assets		\$ 16,363	\$ 16,184
Accumulated amortization		7,632	2,284
Total finance lease right-of-use assets	Other assets	\$ 8,731	\$ 13,900
Current portion of finance lease liabilities	Accrued expenses and other current liabilities	\$ 5,410	\$ 5,640
Noncurrent finance lease liabilities	Other long-term liabilities	3,728	8,361
Total finance lease liabilities		\$ 9,138	\$ 14,001
Weighted average remaining lease term (in years)			
Operating leases		5.75	6.75
Finance leases		1.63	2.56
Weighted average discount rate			
Operating leases		9.07%	9.07%
Finance lease		5.15%	5.19%

The following table summarize maturities of lease liabilities as of December 31, 2021:

	Finance leases	Operating leases	Total
2022	\$ 5,714	\$ 689	\$ 6,403
2023	3,741	703	4,444
2024	62	717	779
2025	_	731	731
2026	_	746	746
Thereafter	_	569	569
Total lease payments	9,517	4,154	13,671
Less: imputed interest	379	918	1,297
Total lease liabilities	\$ 9,138	\$ 3,236	\$ 12,374

#### Real Estate Leases

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 NURTEC ODT commercial launch. The lease commenced in the

second quarter of 2020. It has a term of 88 months, with the ability to extend to 148 months. The Company continuously reassesses its strategic objectives and resulting capital deployment strategy. Therefore, at lease commencement the Company determined that the extension was not reasonably certain and did not include the extension in the lease term when calculating the

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 17. Commitments and Contingencies (Continued)

right-of-use asset and lease liability. The Company had restricted cash of \$1,000, as of December 31, 2021, of which \$250 is included in other current assets and \$750 is included in other assets in the consolidated balance sheets, 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 provided the Company with a temporary space to occupy while leasehold improvements were 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 was 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 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 expected to occupy the temporary space for less than 12 months, the Company did not record a right-of-use asset and lease liability in its consolidated balance sheets for the temporary space. The Company recognized no material expense related to the temporary space. Since there were no cash payments for use of the temporary space, the rent expense recognized for the use of the temporary space is being treated as a deferred rent liability in other long-term liabilities in the Company's consolidated balance sheets. As the Company makes lease payments on the premises, a portion of each lease payment will be used to reduce the deferred rent liability.

During the second quarter of 2020, the Company began occupying the premises after the landlord substantially completed all agreed upon improvements to the office space. The Company determined the lease to be an operating lease and used an estimate of its incremental borrowing rate at lease commencement to discount the future lease commitments.

In November 2020, the Company's Irish subsidiary entered into a license agreement in Dublin, Ireland for approximately 1,000 square feet of office space to support its operations. Upon execution of the agreement, the licensor agreed to provide the Company a temporary space to occupy at no additional cost until building improvements are complete. The license commenced on January 2021. Once the license commences, the license term is 36 months, with an automatic renewal option equal to the current term of the license but no less than 3 months until the license is terminated by Biohaven or the licensor. Since the license gives the Company the right to control the use of

the office space, the Company determined that the license should be accounted for as an operating lease.

#### Commercial Fleet

During 2020, the Company took delivery of a majority of its commercial car fleet. Each commercial fleet lease has a term of 36 months, and the wholesale value of the vehicle at lease termination is guaranteed by the Company. In addition, the Company can terminate the vehicle leases at any time without a significant penalty. For the discount rate, the Company used its incremental borrowing rate, which it believes approximates the rate implicit in the commercial fleet leases.

#### **Other Commercial Commitments**

The Company's commercial commitments in excess of one year primarily relate to manufacturing preparation services that are enforceable and legally binding on us and that specify all significant terms, including applicable milestone payments and target completion dates. The Company had commercial commitments in excess of one year of \$21,037, \$11,072, and \$6,000 for 2022, 2023, and 2024, respectively.

#### **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 may commit to minimum payments under these arrangements. The Company did not have material unpaid minimum commitments in excess of one year as of December 31, 2021 or 2020.

#### 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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 17. Commitments and Contingencies (Continued)

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, 2021 or 2020.

#### 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, 2021, there were no matters which would have a material impact on the Company's financial results.

#### 18. Related Party Transactions

#### License Agreements with Yale

On September 30, 2013, the Company entered into the Yale Agreement with Yale (see Note 14 for detail). 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.

In January 2021, the Company entered into the Yale MoDE Agreement with Yale (see Note 14 for detail). Under the license agreement, Biohaven acquired exclusive, worldwide rights to Yale's intellectual property directed to its MoDE platform. As part of consideration for this license, the Company paid Yale University an upfront cash payment of \$1,000 and 11,668 common shares valued at approximately \$1,000. Additionally, in the fourth quarter of 2021, the Company paid a \$150 development milestone to Yale following the initiation of a Phase I clinical trial.

For the year ended December 31, 2021, excluding the development milestone payment noted above, the Company did not record any material research and development expense related to the Yale MoDE Agreement and Yale Agreement (the "Yale Agreements"). For the years ended December 31, 2020 and 2019, the Company did not record any material expense, or make any milestone or royalty payments under the Yale Agreements. As of December 31, 2021, 2020 and 2019, the Company owed no amounts to Yale.

#### Kleo Pharmaceuticals, Inc.

Prior to the acquisition in January 2021, the Company had an investment in the common stock of Kleo (see Note 6 for acquisition details). Kleo was a related party because the Company had determined that

it exercised 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, purchasing 1,420,818 shares for cash consideration of \$5,000. As of December 31, 2020, the Company owned approximately 42% of Kleo's outstanding capital stock. The Company had also entered into a clinical development master services agreement with Kleo to assist Kleo with clinical development. As of December 31, 2020, the Company had not performed material services or received any payments under this agreement.

#### 19. Subsequent Events

#### Pfizer Collaboration and BioShin Merger Agreement

In November 2021, the Company and Pfizer Inc. entered into a Subscription Agreement (the "Subscription Agreement"). On December 31, 2021, the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, expired with respect to the reportable transactions contemplated by the Subscription Agreement. As a result of such expiration of the waiting period and satisfaction of the other closing conditions described in the Subscription Agreement, on January 4, 2022, the Company closed the sale of 2,022,581 of its common shares to Pfizer Inc. for \$350,000, representing an approximately 25% market premium at \$173 per share (the "Share Purchase"), pursuant to the terms of the Subscription Agreement.

In November 2021, the Company and Pfizer entered into a Collaboration and License Agreement (the "Collaboration Agreement"), pursuant to which Pfizer was granted the exclusive right to commercialize product candidates containing Biohaven's proprietary compound rimegepant (BHV-3000) and may elect to commercialize zavegepant (BHV-3500), in each case, in all countries worldwide outside of the United States. On January 4, 2022, following the expiration or termination of applicable waiting periods under all applicable antitrust laws and the completion of the Share Purchase, the Collaboration Agreement with Pfizer became effective.

In November 2021, Biohaven HoldCo, Biohaven Therapeutics Ltd., Atlas Merger Sub ("Merger Sub") and BioShin entered into an Agreement and Plan of Merger (the "Merger Agreement"). The Merger Agreement provides for the merger of Merger Sub with and into BioShin, with BioShin surviving the merger as a wholly

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share amounts)

#### 19. Subsequent Events (Continued)

owned indirect subsidiary of Biohaven Holdco, in accordance with Section 233 of the Cayman Islands Companies Act. As a result of the satisfaction of the closing conditions described in the Merger Agreement, on January 6, 2022, each Series A convertible preferred share of BioShin, no par value, other than Excluded Shares (as defined in the Merger Agreement), was converted into the right to receive 0.080121 of a Biohaven Holdco common share.

#### **Kv7 Platform Acquisition**

In February 2022, the Company entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with Knopp Biosciences LLC ("Knopp") and Channel Biosciences, LLC, a newly formed wholly owned subsidiary of Knopp ("Channel"), pursuant to which (a) Knopp will contribute its assets related to its Kv7 channel targeting platform, and (b) the Company will subsequently acquire all of the equity interests in Channel (the "Transaction").

In consideration for the Transaction, the Company will make an upfront payment comprised of \$35,000 in cash and \$65,000 in common shares of Biohaven ("Biohaven Shares") issued through a private placement. The Company has also agreed to pay additional successbased payments comprised of (i) up to \$325,000 based on developmental and regulatory milestones through approvals in the United States, EMEA and Japan for the lead asset, BHV-7000 (formerly known as KB-3061). (ii) up to an additional \$250,000 based on developmental and regulatory milestones for the Kv7 pipeline development in other indications and additional country approvals, and (iii) up to \$562,500 for commercial sales based milestones of BHV-7000. These contingent milestone payments may be paid in cash or Biohaven Shares at the election of the Company, but if the Company elects to pay in Biohaven Shares, such amounts are subject to increases of a mid-single-digit percentage increase (or in one case, a ten-percent increase). Additionally, the Company has agreed to make scaled royalty payments in cash for BHV-7000 and the pipeline programs, starting at high single digits and peaking at low teens for BHV-7000 and starting at mid-single digits and peaking at low double digits for the pipeline programs.

The Company has also given Knopp the option to request a onetime cash true-up payment from the Company in December 2022 in the event that Knopp continues to hold Biohaven Shares issued as a component of the upfront payment and the value of such shares has declined, subject to certain conditions.

The requisite approvals of Knopp equityholders have been obtained. The Transaction is subject to the

satisfaction of certain customary closing conditions, including the receipt of select third-party consents.

At the closing of the Transaction, 493,254 common shares of Biohaven will be issued as part of the initial consideration. The contemplated issuances and sales of that initial consideration payable in common shares and those contingent payments payable in Biohaven Shares have not been registered under the Securities Act or any state securities laws. Biohaven has relied on the exemption from the registration requirements of the Securities Act under Section 4(a)(2) thereof, for a transaction by an issuer not involving any public offering.

#### AMENDMENT NO. 1 TO DELAWARE EMPLOYMENT AGREEMENT

This Amendment No. 1 to Delaware Employment Agreement (this "Amendment") is dated as of December 14, 2021, by and between Biohaven Pharmaceutical, Inc., a Delaware corporation (the "Company"), and James Engelhart, an individual (the "Executive").

**WHEREAS**, the Company and the Executive entered into an Employment Agreement, effective as of May 5, 2017 (the "Original Employment Agreement"), pursuant to which the Company employed the Executive in the capacity as Chief Financial Officer on the terms and conditions set forth therein; and

**WHEREAS**, the Biohaven Pharmaceutical Holding Company Ltd. ("Parent") and the Executive entered into an Employment Agreement, effective as of May 2, 2016 (the "BVI Employment Agreement"), pursuant to which the Parent employed the Executive in the capacity as Chief Financial Officer on the terms and conditions set forth therein; and

WHEREAS, the Executive has discussed with the Company that the Executive would like to advise and assist in the transition of the new CFO and the Company is amenable to such proposal and therefore the parties desire to amend the Original Employment Agreement in accordance with the terms and conditions hereinafter set forth and Executive shall not be the Chief Financial Officer of the Company and Parent as of the date hereof;

**NOW, THEREFORE**, in consideration of the premises and mutual covenants and agreements herein contained, the undersigned parties (each a "<u>Party</u>" and collectively, the "<u>Parties</u>") agree to amend the Original Employment Agreement as follows:

- 1. The foregoing recitals are incorporated herein by reference.
- 2. <u>Capitalized Terms</u>. Capitalized terms used in this Amendment and not otherwise defined herein shall have the respective meanings given such terms in the Original Employment Agreement.
- 3. <u>Employment and Duties</u>. The Parties agree that Section 1 of the Original Employment Agreement shall be amended and restated in its entirety to read as follows:
  - 1. EMPLOYMENT AND DUTIES. As of December 15, 2021, the Company hereby employs the Executive to be its Advisor of Strategic Initiatives to assist the Company the transition of the new CFO and in strategic financial, tax, economic substance initiatives and other mutually agreeable strategic assignments as are from time to time delegated to the Executive by the Chief Executive Officer of the Company. During the Term (as defined below), the Executive agrees that he will devote time, attention and skills to these strategic initiatives (as defined below) of the Company and that he will perform such duties, responsibilities and authority in connection with the foregoing as are from time to time delegated to the Executive by the Chief Executive Officer of the Company. For purposes of this Agreement, the "Business" of the Company shall be defined as the development and commercialization of neuropsychiatric drug candidates and related technology based products.

- 3. <u>Compensation</u>. The Original Employment Agreement Section 2 is amended as follows: (a) Base Salary shall be \$452,569.92 as of the Effective Date; and (b) the Bonus Percentage for Section 2(b) shall be forty-five percent (45%).
  - 4. <u>Term of Employment</u>. Section 6 of the Original Employment Agreement is hereby replaced in its entirety as follows:

Term. The initial term of the Agreement shall commence upon execution and continue until December 31, 2022 (the "Initial Term") and shall thereafter automatically renew for twelve (12) month periods (each a "Renewal Term" and together with the Initial Term, the "Term") unless either Party provides written notice of non-renewal at least thirty (30) days prior to the applicable anniversary date. The Executive shall have the right to terminate the Agreement upon thirty (30) days prior written notice to the Company. The Company shall have the right to terminate the Agreement upon ninety (90) days' notice after the ninth (9th) month of the Initial Term, in which case Executive will be entitled to compensation for the balance of the year including contractual bonus for the calendar year. No bonus shall accrue if Executive exercises his right to terminate the agreement before the completion of a given 12 month calendar year. In the event this Employment Agreement is terminated by either party for any reason (the "Termination Date") the Consulting Agreement attached as Exhibit A shall immediately commence and there shall be no gap in the provision of Services to the Company as defined in the Company's Incentive Equity Plan of 2017.

- 5. <u>Termination of BVI Employment Agreement</u>. The Parties agree that on the Effective Date, the BVI Employment Agreement shall terminate as of December 15, 2021 and be of no further force or effect.
- 6. <u>Miscellaneous</u>. Except as provided herein, the terms of the Original Employment Agreement shall remain in full force and effect. The Original Employment Agreement (together with <u>Exhibit A</u> to the Original Employment Agreement), as amended hereby, 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 the Agreement, as amended hereby, shall be valid or effective unless the same is in writing and signed by both Parties hereto.
- 7. Prior Travel and Entertainment expense claims. Executive shall be reimbursed for prior travel related expenses incurred performing Executive's duties as Chief Financial Officer, provided, where applicable, receipts are furnished for these expenses.

**IN WITNESS WHEREOF**, the Parties have executed this Amendment No. 1 to the Original Employment Agreement as of the day and year first above written.

#### BIOHAVEN PHARMACEUTICAL, INC.

By: /s/ Vladimir Coric

Name: Vladimir Coric

Title: Chief Executive Officer and Director

#### **EXECUTIVE**

By: /s/ Jim Engelhart

James Engelhart

# EXHIBIT A ENGELHART CONSULTING AGREEMENT

#### BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD. CONSULTING AGREEMENT

This Consulting Agreement ("<u>Agreement</u>") is dated as of December 14, 2021 to go into effect as set forth in Section 7 of this Agreement (the "<u>Effective Date</u>") by and among James Engelhart ("<u>Consultant</u>") and Biohaven Pharmaceutical, Inc., a Delaware corporation ("<u>Biohaven</u>"). Biohaven and Consultant are sometimes referred to collectively as the "<u>Parties</u>" and individually as a "<u>Party</u>" to this Agreement.

#### RECITALS

**WHEREAS**, Consultant and Biohaven had previously entered into that certain Employment Agreement dated as of May 5, 2017, as amended (the "<u>DE Employment Agreement</u>") which governed Consultant's employment relationship with Biohaven;

WHEREAS, Consultant and Biohaven Pharmaceutical Holding Company Ltd., a company formed under the laws of the Territory of the British Virgin Islands and the ultimate parent company of Biohaven ("BHVN"), had previously entered into that certain Employment Agreement dated as of March 8, 2016 (the "BVI Employment Agreement") which governed Consultant's employment relationship with BHVN;

**WHEREAS**, the Parties mutually desire to change the employment relationship to that of a consultant pursuant to the terms and conditions of this Agreement;

WHEREAS, Consultant has significant knowledge and experience in the financial, tax and economic substance area for pharmaceutical companies (the "Covered Services"), and Biohaven would like Consultant to assist in its evaluation of opportunities, including new products and compounds, with the Covered Services.

**NOW, THEREFORE**, in consideration of the mutual covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto, intending legally to be bound, agree as follows:

- 1. Biohaven hereby engages Consultant to render the Covered Services for up to eight (8) hours each week during the Term (as defined in Section 7 herein) and such additional hours as may be mutually agreed by Consultant and Biohaven from time to time (the "Services").
  - 2. As full and complete consideration for Consultant's Covered Services, Biohaven shall pay Consultant as consideration as follows:
    - (a) A weekly amount of Three Thousand Six Hundred Dollars (\$3,600.00), plus an amount equal to Four Hundred Fifty Dollars (\$450.00) per hour for any Services worked by Consultant in excess of eight (8) hours per week, all payable at the normal pay intervals for Biohaven's other employees; provided, that after January 1, 2024 Consultant will be paid only for hours actually worked and no longer receives the weekly minimum stated above;
    - (b) A travel stipend in the amount of Four Hundred Dollars (\$400.00) per day for travel in the United States, Bermuda, Ireland and Canada;
    - (c) Consultant shall be reimbursed for reasonable travel, meals and accommodation expenses actually incurred by Consultant; provided, that Consultant has received the prior written consent to such travel by Biohaven;

- (d) All of Consultant's existing options and restricted Share units that have been previously granted or will be granted to Consultant by Biohaven shall remain outstanding in accordance with their terms and shall continue to vest during the Term. Biohaven represents and agrees that the Covered Services and the Services provided by Consultant pursuant to this Agreement constitute continued services under all applicable equity plans and agreements. In addition to the foregoing, by execution of this Agreement, Biohaven and Consultant hereby agree that all existing option and RSU grants from Biohaven to Consultant are hereby amended to provide for an exercise period of up to one (1) year after the later of the termination of this Agreement or a later cessation of services by Consultant to Biohaven or any related entities but in no event after the ten (10) year expiration of the applicable option; and
- (e) Consultant shall either continue to receive the same medical insurance benefits that Consultant most recently received as an employee with Biohaven or, if different plans are then provided to executive officers, he shall receive a comparable plan to such executive officers, including medical and dental coverage, with Biohaven paying the same portion of all premiums for such benefits as it paid as an employer immediately prior to the Effective Date.
- 3. Consultant acknowledges and agrees that all of the inventions, discoveries, developments, improvements, techniques, designs and data which Consultant conceives of, reduces to practice or otherwise creates while performing the Covered Services and the Services during the Term, and which either utilize any of Biohaven's Confidential Information, are made at the request or direction of Biohaven or are made in conjunction with any other Biohaven employees or assets (the "Material") are works made for hire for Biohaven and owned by Biohaven. Accordingly, Biohaven shall be considered the author and, at all stages of completion, the sole and exclusive owner of the Material and have all right, title and interest therein (the "Rights"). The Rights shall include, without limitation, all copyrights, trademarks, patents, intellectual property, trade secrets and any and all other ownership and exploitation rights in the Material now or hereafter recognized in any and all territories and jurisdictions including, by way of illustration, the right to exploit the Material throughout the universe in perpetuity in all media, markets, languages and in any manner now known or hereafter devised. If under any applicable law the fact that the Material is a work made for hire is not effective to place authorship and ownership of the Material and all rights therein in Biohaven, then to the fullest extent allowable and for the full term of protection otherwise accorded to Consultant under such applicable laws, Consultant hereby assigns and transfers to Biohaven the Rights and, in connection therewith, any and all right, title and interest of Consultant in the Material, the Work and any other works now or hereafter created containing the Material. Notwithstanding the foregoing, the Material and Rights referenced above are solely related to new information and ideas that are developed by Consultant for Biohaven during the Term in conjunction with the provision of the Covered Services and Services and do not limit in anyway the Consultant's ownership or use of his current knowledge, ideas and abilities as long as they did not originate or were derived from the Material and Rights without the written consent from Biohaven.
- 4. Consultant shall, upon reasonable request and at Biohaven's expense, execute, acknowledge and deliver to Biohaven any and all documents Biohaven may deem reasonably necessary or desirable to evidence the Rights and assist Biohaven, at Biohaven's expense, in filing for any and all copyrights, trademarks, patents, intellectual property, trade secrets and any and all other ownership and exploitation rights in the Material related to the Rights.
- 5. Consultant hereby represents and warrants that: (a) the Covered Services and Services provided by Consultant do not, and will not, violate any third party rights or any agreement in favor of a third party; (b) the results and products of Consultant's Covered Services

and Services and the use thereof by Biohaven do not, and will not, violate any non-disclosure or other contractual obligation of Consultant to any third party and are not the subject of any litigation or claim that might give rise to litigation; and (c) Consultant has all necessary rights, power and authority to enter into this Agreement and provide the Covered Services and Services to Biohaven.

- 6. Consultant shall defend, indemnify and hold harmless Biohaven and its affiliates, and its officers, directors, shareholders, employees and agents (each, a "Biohaven Indemnified Party") from and against any and all claims which any Biohaven Indemnified Party may suffer or incur as a result of or which arises under, in connection with or pursuant to or is based upon any claim (a) arising from any intentional, reckless or grossly negligent act of Consultant first occurring and only having occurred after the date hereof; (b) arising from any intentional, reckless or grossly negligent omission of Consultant first failing to occur and only having failed to occur after the date hereof; or (c) alleging any material breach by Consultant of any of his obligations, representations or warranties herein. This Agreement is personal to Consultant and may not be assigned by Consultant. Any purported assignment of rights or delegation of duties by Consultant shall be deemed void from the outset. Biohaven may assign this Agreement.
- 7. <u>Term.</u> The initial term of this Agreement shall commence immediately upon the termination of the DE Employment Agreement, as amended, and shall continue until December 31, 2024 (the "<u>Initial Term</u>") and shall thereafter automatically renew for twelve (12) month periods (each a "<u>Renewal Term</u>" and together with the Initial Term, the "<u>Term</u>") unless either party was provided written notice of non-renewal at least thirty (30) days prior to the applicable anniversary date.
- 8. Consultant acknowledges that Consultant may have access to and become acquainted with various trade secrets and confidential information of Biohaven which are used in connection with the business and intended business of Biohaven (individually and collectively the "Confidential Information"). Consultant shall not disclose any Confidential Information, directly or indirectly, or use it in any way, except as authorized in writing in advance by Biohaven. The Confidential Information shall not include any information that is generally available to the public through no breach of this Agreement by Consultant, or that is independently developed by Consultant while not providing the Covered Services without use of or reference to the Confidential Information. Further, nothing herein shall restrict Consultant from disclosing the Confidential Information to the extent required by judicial process after seeking guidance from the Company legal advisors in connection with any judicial, regulatory or administrative investigation, process or proceeding. All files, records, documents, drawings, specifications, equipment and similar items embodying the Confidential Information, whether prepared by Consultant or otherwise coming into the Consultant's possession, shall remain the exclusive property of Biohaven. Consultant hereby to prevent any disclosure of the Confidential Information to any person or entities. Upon the completion of Consultant's business dealings with Biohaven, Consultant shall immediately return to Biohaven all original and duplicate copies of the Confidential Information and any related information.
- 9. Consultant acknowledges that he is an independent contractor and that he shall only be provided with the benefits expressly set forth in this Agreement and shall not be entitled to any additional benefits that may be provided by Biohaven to Biohaven's employees generally. Consultant further acknowledges that he does not have the unilateral right, power or authority to bind, contract for or on behalf of Biohaven or otherwise act on Biohaven's behalf.
- 10. As of the Effective Date, Consultant irrevocably confirms that he has no claims (whether under common law, contract, equity, statute or otherwise and whether present, future, actual, contingent or otherwise) against Biohaven, or its directors, officers, employees or shareholders (excluding any amounts for the current payroll cycle that are due as of the

Effective Date and payable in the next regular payroll thereafter). To the extent that any such claims may exist as of the Effective Date, Consultant irrevocably and unconditionally waives it or them and releases Biohaven and its directors, officers, employees and shareholders from any liability in respect thereof. As of the Effective Date, Biohaven also irrevocably confirms that it has no claims (whether under common law, contract, equity, statute or otherwise and whether present, future, actual, contingent or otherwise) against the Consultant. To the extent that any claims may exist as of the Effective Date, Biohaven irrevocably and unconditionally waives it or them and releases the Consultant from any liability in respect thereof.

11. This Agreement shall be governed by the internal laws of the State of Connecticut without regard to its conflict of laws provisions. This Agreement sets forth the complete understanding of the Parties with respect to the subject matter and may be modified only by written agreement signed by the Parties. This Agreement supersedes and replaces the DE Employment Agreement and the BVI Employment Agreement which shall be of no further force or effect.

The signature of the Parties in the spaces provided below will confirm their agreement to the foregoing.

#### BIOHAVEN PHARMACEUTICAL, INC.

By: /s/ Vladimir Coric

Name: Vladimir Coric

Title: Chief Executive Officer and Director

#### **CONSULTANT**

By: /s/ Jim Engelhart

James Engelhart

#### **AMENDMENT NO. 4 TO FINANCING AGREEMENT**

This AMENDMENT NO. 4 TO FINANCING AGREEMENT, dated as of December 28, 2021 (this "Amendment"), is made by and among BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD., a BVI business company limited by shares incorporated under the laws of the British Virgin Islands with company number 1792178 (the "Company" or "BVI Borrower"), BIOHAVEN PHARMACEUTICALS, INC., a corporation organized under the laws of Delaware ("US Borrower" and, together with BVI Borrower, the "Borrowers", and each individually, a "Borrower"), the Guarantors party hereto, the Lenders party hereto (constituting the Required Lenders), and SIXTH STREET SPECIALTY LENDING, INC., a Delaware corporation, as administrative agent for the Lenders (in such capacity, the "Administrative Agent").

WHEREAS, the Borrowers are party to that certain Financing Agreement, dated as of August 7, 2020, with certain Subsidiaries of BVI Borrower from time to time party thereto (the "<u>Guarantors</u>"), the lenders from time to time party thereto (the "<u>Lenders</u>"), and the Administrative Agent (as amended, restated, amended and restated, supplemented or otherwise modified from time to time prior to the date hereof, the "<u>Financing Agreement</u>"), pursuant to which the Lenders have made Loans to the Borrowers which remain outstanding.

WHEREAS, pursuant to and in accordance with <u>Section 10.5</u> of the Financing Agreement, the Loan Parties have requested that the Administrative Agent and the Lenders make the amendments to the Financing Agreement as set forth herein and in the Fee Letter, and the Administrative Agent and the Lenders signatory hereto (collectively constituting the Required Lenders) are willing to so amend the Financing Agreement and the Fee Letter on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and other good and valuable consideration, the parties hereto hereby agree as follows:

- 1. <u>Defined Terms</u>. Any capitalized term used herein and not defined shall have the meaning assigned to it in the Financing Agreement.
- 2. <u>Amendments to Financing Agreement</u>. In reliance upon the representations and warranties made by the Loan Parties set forth in <u>Section 4</u> below and subject to the satisfaction of the conditions set forth in <u>Section 3</u> hereof, the Financing Agreement is hereby <u>amended</u> on the Effective Date (as defined below) as follows:
- (a) New <u>Defined Terms in Section 1.1: Definitions</u>. Section 1.1 of the Financing Agreement is hereby amended by inserting the following definitions in appropriate alphabetical order as follows:
  - "Amendment No. 4" means that certain Amendment No. 4 to Financing Agreement, dated as of the Amendment No. 4 Effective Date, by and among the Borrowers, the Guarantors, the Lenders party thereto and the Administrative Agent.

"Amendment No. 4 Effective Date" means December 28, 2021.

"Amendment No. 4 Security Confirmation (BVI)" means a BVI law security confirmation deed in relation to the Equitable Share Mortgages, the Fixed and Floating Charges and the Amendment No. 2 Security Confirmation (BVI), dated the Amendment No. 4 Effective Date, duly executed by the Company, BHVN Therapeutics, BHVN CGRP and the Administrative Agent.

- "Amendment No. 4 Security Confirmation (Ireland)" means an Irish law security confirmation deed in relation to the Debenture, the Debenture 2021, the Share Charge (BHVN Bio Ireland), the Share Charge (BHVN Bio Ireland) 2021, the Share Charge (BHVN Pharma Ireland) and the Share Charge (BHVN Pharma Ireland) 2021, dated the Amendment No. 4 Effective Date, duly executed by the Irish Loan Parties, BHVN Therapeutics, the Company and the Administrative Agent.
- (b) <u>Amendments to Section 1.1: Definitions</u>. Section 1.1 of the Financing Agreement is hereby amended by amending and restating each of the following defined terms as follows:
  - "2021 Delayed Draw Term Loan Commitment Termination Date" means the earliest to occur of (a) the date the Term Loan Commitments are permanently reduced to zero pursuant to Section 2.1(a), (b) the date of the termination of the 2021 Delayed Draw Term Loan Commitments pursuant to Section 8.2, and (c) June 30, 2022.
  - "Collateral Documents (BVI)" means the Equitable Share Mortgages, the Fixed and Floating Charges, the Amendment No. 1 Security Confirmation (BVI), the Amendment No. 2 Security Confirmation (BVI), the Amendment No. 4 Security Confirmation (BVI) and all other instruments, documents and agreements governed by the laws of the British Virgin Islands and delivered by any Loan Party pursuant to this Agreement or any of the other Loan Documents in order to grant to Administrative Agent, for the benefit of Secured Parties, a Lien on any real, personal or mixed property of such Loan Party as security for the Obligations, in each case, as such Collateral Documents (BVI) may be amended or otherwise modified from time to time.
  - "Collateral Documents (Ireland)" means the Debenture, the Share Charge (BHVN Pharma Ireland), the Share Charge (BHVN Bio Ireland), the Debenture 2021, the Share Charge (BHVN Pharma Ireland) 2021, the Share Charge (BHVN Bio Ireland) 2021, the Amendment No. 1 Security Confirmation (Ireland), the Amendment No. 2 Security Confirmation (Ireland), the Amendment No. 4 Security Confirmation (Ireland) and all other instruments, documents and agreements governed by the laws of Ireland and delivered by any Loan Party pursuant to this Agreement or any of the other Loan Documents in order to grant to Administrative Agent, for the benefit of Secured Parties, a Lien on any real, personal or mixed property of such Loan Party as security for the Obligations, in each case, as such Collateral Documents may be amended or otherwise modified from time to time.
  - "Fee Letter" means the Third Amended and Restated Fee Letter, dated December 28, 2021, among the Loan Parties and Administrative Agent.
- 3. <u>Conditions to Effectiveness</u>. The effectiveness of this Amendment is subject to the fulfillment, in a manner satisfactory to the Administrative Agent, of each of the following conditions precedent (the date such conditions are fulfilled (or waived) is hereinafter referred to as the "<u>Effective Date</u>"):
- (a) <u>Representations and Warranties; No Event of Default</u>. (i) The representations and warranties set forth in <u>Section 4</u> hereof shall be true and accurate; and (ii) as of the date hereof, no event shall have occurred and be continuing or would result from the consummation of the transactions contemplated herein that would constitute an Event of Default or a Default.
  - (b) <u>Execution of Loan Documents</u>. The Administrative Agent shall have received:
- (i) a counterpart to this Amendment, duly executed by each Loan Party and the Lenders constituting the Required Lenders:

- (ii) a counterpart to the Fee Letter, duly executed by each Loan Party;
- (iii) the Amendment No. 4 Security Confirmation (BVI), duly executed by the parties thereto; and
- $\hbox{(iv)} \qquad \hbox{the Amendment No. 4 Security Confirmation (Ireland), duly executed by the parties thereto.}$
- (c) Secretary's or Director's Certificate. The Administrative Agent shall have received a Secretary's or Director's Certificate for each Loan Party (i) confirming that there has been no change to any Organizational Document of such Loan Party since the Organizational Documents delivered to the Administrative Agent on the Amendment No. 2 Effective Date, (ii) confirming that there has been no change to any incumbency certificate since the incumbency certificate delivered to the Administrative Agent on the Amendment No. 2 Effective Date, (iii) attaching a copy of the resolutions of the Board of Directors or similar governing body of each Loan Party approving and authorizing the execution, delivery and performance of this Amendment, the Fee Letter and the other Loan Documents to which it is a party or by which it or its assets may be bound as of the Effective Date, certified as of the Effective Date by its secretary, assistant secretary or a director as being in full force and effect without modification or amendment; (iv) a good standing certificate (to the extent such concept exists) from the applicable Governmental Authority of such Loan Party's jurisdiction of incorporation, organization or formation, each dated a recent date prior to the Effective Date, (v) a registered agent of each Loan Party incorporated in the British Virgin Islands dated no more than one month prior to the Amendment No. 4 Effective Date together with certified copies of such Loan Party's register of directors, register of members and register of charges (if any); and (vi) such other documents as the Administrative Agent may reasonably request.
- (d) Governmental Authorizations and Consents. Each Loan Party shall have obtained all Governmental Authorizations and all consents of other Persons, in each case that are necessary or advisable in connection with the transactions contemplated by this Amendment and the other Loan Documents and each of the foregoing shall be in full force and effect and in form and substance reasonably satisfactory to the Administrative Agent. All applicable waiting periods shall have expired without any action being taken or threatened by any competent authority which would restrain, prevent or otherwise impose adverse conditions on the transactions contemplated by this Amendment or the other Loan Documents and no action, request for stay, petition for review or rehearing, reconsideration, or appeal with respect to any of the foregoing shall be pending, and the time for any applicable agency to take action to set aside its consent on its own motion shall have expired.
- (e) <u>Payment of Fees, Etc.</u> The Borrowers shall have paid on or before the Effective Date all fees, costs and expenses then payable by the Borrowers pursuant to the Loan Documents.
- 4. <u>Representations and Warranties</u>. Each Loan Party represents and warrants as follows: (i) the representations and warranties contained in <u>ARTICLE IV</u> of the Financing Agreement and in each other Loan Document, certificate or other writing delivered to any Agent or any Lender pursuant hereto or thereto on or prior to the Effective Date are true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to "materiality" or "Material Adverse Effect" in the text thereof, which representations and warranties shall be true and correct in all respects subject to such qualification) on and as of the Effective Date, except to the extent such representations and warranties specifically relate to an earlier date, in which case such representations and warranties shall have been true and correct in all material respects (except that such materiality qualifier shall not be applicable to any representations or warranties that already are qualified or modified as to "materiality" or "Material Adverse Effect" in the text thereof, which representations and

warranties shall be true and correct in all respects subject to such qualification) on and as of such earlier date and (ii) no Default or Event of Default (x) shall have occurred and be continuing on the Effective Date or (y) would result from this Amendment becoming effective in accordance with its terms or from the consummation of the transactions contemplated herein.

5. Reaffirmation and Confirmation. Each Loan Party hereby (a) acknowledges and reaffirms its obligations as set forth in each Loan Document, as modified hereby, (b) agrees to continue to comply with, and be subject to, all of the terms, provisions, conditions, covenants, agreements and obligations applicable to it (including each guarantee and indemnity) set forth in each Loan Document, as modified hereby, which remain in full force and effect, and (c) confirms, ratifies and reaffirms that the security interest granted to the Administrative Agent, for the benefit of the Secured Parties, pursuant to the Loan Documents, as modified hereby, in all of its right, title, and interest in all then existing and thereafter acquired or arising Collateral in order to secure prompt payment and performance of the Obligations, is continuing and the Lien created under such Loan Documents is and shall remain unimpaired and continue to constitute a First Priority Lien on, and security interest in, all such right, title and interests (subject to Permitted Liens) in favor of the Administrative Agent, for the benefit of the Secured Parties, with the same force, effect and priority in effect both immediately prior to and after entering into this Amendment.

#### 6. <u>Miscellaneous</u>.

(a) <u>Continued Effectiveness of the Financing Agreement and the Other Loan Documents.</u> Except as otherwise expressly provided herein, the Financing Agreement and the other Loan Documents are, and shall continue to be, in full force and effect and are hereby ratified and confirmed in all respects, except that on and after the Amendment No. 4 Effective Date (i) all references in the Financing Agreement to "this Agreement", "hereto", "hereof", "hereof" or words of like import referring to the Financing Agreement shall mean the Financing Agreement as modified by this Amendment, and (ii) all references in the other Loan Documents to the "Financing Agreement", "thereto", "thereof", "thereunder" or words of like import referring to the Financing Agreement shall mean the Financing Agreement as modified by this Amendment. To the extent that the Financing Agreement or any other Loan Document purports to pledge to the Administrative Agent, or to grant to the Administrative Agent, a security interest or lien, such pledge or grant is hereby ratified and confirmed in all respects. Except as expressly provided herein, the execution, delivery and effectiveness of this Amendment shall not operate as an amendment of any right, power or remedy of the Administrative Agent and the Lenders under the Financing Agreement or any other Loan Document, nor constitute an amendment of any provision of the Financing Agreement or any other Loan Document, nor constitute a waiver by the Administrative Agent or any Lender of any Default or Event of Default, whether now existing or hereafter arising.

#### (b) Reserved

(c) <u>Counterparts</u>. This Amendment may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, but all such counterparts together shall constitute but one and the same instrument. The words "execution," "execute", "signed," "signature," and words of like import in or related to any document to be signed in connection with this Amendment and the transactions contemplated hereby shall be deemed to include electronic signatures, the electronic matching of assignment terms and contract formations on electronic platforms approved by the Administrative Agent, or the keeping of records in electronic form, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act.

- (d) <u>Headings</u>. Section headings herein are included herein for convenience of reference only and shall not constitute a part hereof for any other purpose or be given any substantive effect.
- (e) <u>Costs and Expenses</u>. Company agrees to pay promptly all fees, costs and expenses of the Administrative Agent and the Lenders in connection with the preparation, execution and delivery of this Amendment.
- (f) Amendment as Loan Document. Each Loan Party hereby acknowledges and agrees that this Amendment constitutes a "Loan Document" under the Financing Agreement, as amended hereby. Accordingly, it shall be an Event of Default under the Financing Agreement, as amended hereby if (i) any representation or warranty made by any Loan Party under or in connection with this Amendment, which representation or warranty is (x) subject to a materiality or a Material Adverse Effect qualification, shall have been incorrect in any respect when made or deemed made, or (y) not subject to a materiality or a Material Adverse Effect qualification, shall have been incorrect in any material respect when made or deemed made or (ii) any Loan Party shall fail to perform or observe any term, covenant or agreement contained in this Amendment.
- (g) <u>Severability.</u> In case any provision in or obligation hereunder shall be invalid, illegal or unenforceable in any jurisdiction, the validity, legality and enforceability of the remaining provisions or obligations, or of such provision or obligation in any other jurisdiction, shall not in any way be affected or impaired thereby.
- (h) <u>Governing Law.</u> THIS AMENDMENT AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL BE GOVERNED BY, AND SHALL BE CONSTRUED AND ENFORCED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK APPLICABLE TO CONTRACTS MADE AND TO BE PERFORMED IN THE STATE OF NEW YORK.
- (i) Waiver of Jury Trial. EACH OF THE PARTIES HERETO HEREBY AGREES TO WAIVE ITS RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING HEREUNDER. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT AND THAT RELATE TO THE SUBJECT MATTER OF THIS AMENDMENT, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS AND ALL OTHER COMMON LAW AND STATUTORY CLAIMS. EACH PARTY HERETO ACKNOWLEDGES THAT THIS WAIVER IS A MATERIAL INDUCEMENT TO ENTER INTO A BUSINESS RELATIONSHIP, THAT EACH HAS ALREADY RELIED ON THIS WAIVER IN ENTERING INTO THIS AMENDMENT, AND THAT EACH WILL CONTINUE TO RELY ON THIS WAIVER IN ITS RELATED FUTURE DEALINGS. EACH PARTY HERETO FURTHER WARRANTS AND REPRESENTS THAT IT HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL AND THAT IT KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL. THIS WAIVER IS IRREVOCABLE, MEANING THAT IT MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING (OTHER THAN BY A MUTUAL WRITTEN WAIVER SPECIFICALLY REFERRING TO THIS CLAUSE (I). IN THE EVENT OF LITIGATION, THIS AMENDMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

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**IN WITNESS WHEREOF**, the parties hereto have caused this Amendment to be executed and delivered by their respective duly authorized officers as of the date first written above.

## BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD., as a Borrower

By: /s/ Vlad Coric, M.D.

Vladimir Coric Director

#### BIOHAVEN PHARMACEUTICALS, INC.,

By: /s/ Vlad Coric, M.D.

Vladimir Coric

President

as a Borrower

#### BIOHAVEN BIOSCIENCE IRELAND LIMITED,

as a Guarantor Subsidiary

By: /s/ John Gleeson

John Gleeson Director

#### BIOHAVEN THERAPEUTICS LTD,

By: /s/ Vlad Coric, M.D.

Vladimir Coric

as a Guarantor Subsidiary President

## BIOHAVEN PHARMACEUTICAL IRELAND DESIGNATED ACTIVITY COMPANY,

By: /s/ John Gleeson

John Gleeson

Director

as a Guarantor Subsidiary BIOHAVEN CGRP IP LTD,

as a Guarantor Subsidiaty

By: /s/ Vlad Coric, M.D.

Vladimir Coric Director

#### KLEO PHARMACEUTICALS, INC.,

as a Guarantor Subsidiary

By: /s/ Vlad Coric, M.D.

Vladimir Coric

President

Signature Page to Amendment No. 4 to Financing Agreement

# SIXTH STREET SPECIALTY LENDING, INC., as Administrative Agent and a Lender

By: /s/ Joshua Easterly

Joshua Easterly

Title: Chief Executive Officer

#### TAO TALENTS, LLC,

as a Lender

By: /s/ Joshua Peck

Joshua Peck Title: Vice President

Signature Page to Amendment No. 4 to Financing Agreement

# SUBSIDIARIES OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD. As of December 31, 2021

Name	Jurisdiction of Incorporation		
Biohaven Specialty Pharmaceutical Ltd.	British Virgin Islands		
Biohaven Therapeutics Ltd.	British Virgin Islands		
Biohaven Pharmaceuticals, Inc.	Delaware		
BioShin Limited	Cayman Islands		
BioShin Hong Kong Limited	Hong Kong		
BioShin (Shanghai) Consulting Services Co., Limited	China		
Biohaven Bioscience Ireland Limited	Ireland		
Biohaven Therapeutics IP Ltd.	British Virgin Islands		
Biohaven CGRP IP Ltd.	British Virgin Islands		
Biohaven Pharmaceutical Ireland Designated Activity Company	Ireland		
Kleo Pharmaceuticals, Inc.	Delaware		
Kleo Pharmaceuticals Pty Ltd.	Australia		
Atlas Merger Sub	Cayman Islands		

#### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

- 1. Registration Statement (Form S-3 Nos. 333-253946 and 333-232167) of Biohaven Pharmaceuticals Holding Company Ltd.,
- 2. Registration Statement (Form S-8 Nos. 333-253748, 333-233197 and 333-225224) pertaining to the 2017 Equity Incentive Plan and the 2017 Employee Stock Purchase Plan of Biohaven Pharmaceutical Holding Company Ltd., and
- 3. Registration Statement (Form S-8 No. 333-218193) pertaining to the 2014 Equity Incentive Plan, the 2017 Equity Incentive Plan and the 2017 Employee Stock Purchase Plan of Biohaven Pharmaceutical Holding Company Ltd.;

of our reports dated February 25, 2022, with respect to the consolidated financial statements of Biohaven Pharmaceuticals Holding Company Ltd. and the effectiveness of internal control over financial reporting of Biohaven Pharmaceuticals Holding Company Ltd. included in this Annual Report (Form 10-K) of Biohaven Pharmaceuticals Holding Company Ltd. for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Hartford, Connecticut February 25, 2022

#### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-253946 and 333-232167) and Form S-8 (Nos. 333-253748, 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, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP Boston, Massachusetts February 25, 2022

## 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, 2021 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:
  - 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
  - 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, 2022

/s/ VLAD CORIC, M.D.

Vlad Coric, M.D.

President and Chief Executive Officer (principal executive officer)

## CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

- I, Matthew Buten, certify that:
- 1. I have reviewed this Annual Report on Form 10-K for the year ended December 31, 2021 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:
  - 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
  - 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, 2022

/s/ MATTHEW BUTEN

Matthew Buten Chief Financial Officer (principal financial officer)

# 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., President and Chief Executive Officer of Biohaven Pharmaceutical Holding Company Ltd. (the "Company"), and Matthew Buten, 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, 2021, 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 2022.

/s/ VLAD CORIC, M.D.

Vlad Coric, M.D.

President and Chief Executive Officer
(principal executive officer)

/s/ MATTHEW BUTEN

Matthew Buten
Chief Financial Officer
(principal financial officer)

<sup>\*</sup> 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.