

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

AMENDMENT NO. 1

TO

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BIOHAVEN LTD.

(Exact name of registrant as specified in its charter)

British Virgin Islands
(State or other jurisdiction of incorporation or organization)

2834
(Primary Standard Industrial Classification Code Number)

Not Applicable
(I.R.S. Employer Identification Number)

c/o Biohaven Pharmaceuticals, Inc.
215 Church Street
New Haven, Connecticut 06510
(203) 404-0410

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Vlad Coric, M.D.
Chief Executive Officer
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215 Church Street
New Haven, Connecticut 06510
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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED OCTOBER 20, 2022

BIOHAVEN LTD.

(a British Virgin Islands business company)

20,000,000 Shares

The logo for Biohaven Ltd. features the word "biohaven" in a lowercase, sans-serif font. The "bio" portion is in a light green color, and the "haven" portion is in a dark blue color.

Common Shares

Biohaven Ltd. is selling 20,000,000 of its common shares in this offering.

Our shares trade on The New York Stock Exchange under the symbol “BHVN.” On October 19, 2022, the last sale price of the shares as reported on the New York Stock Exchange was \$12.40 per share.

Investing in our common shares involves risks that are described in the “Risk Factors” section beginning on page [11](#) of this prospectus.

	Per Share	Total
Public offering price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Proceeds before expenses	\$	\$

⁽¹⁾ We have agreed to reimburse the underwriters for certain expenses in connection with this offering. See “Underwriting.”

The underwriters may also exercise their option to purchase up to an additional 3,000,000 common shares from us, at the public offering price, less the underwriting discount, for 30 days after the date of this prospectus.

Vlad Coric, our Chief Executive Officer, Matthew Buten, our Chief Financial Officer, and certain of our directors and their affiliated funds have indicated an interest in purchasing approximately \$100 million, in the aggregate, of our common shares in this offering at the public offering price. Dr. Coric and Mr. Buten have indicated an interest in purchasing approximately \$10 million and \$1 million of those common shares, respectively. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to each of Dr. Coric, Mr. Buten or our directors and their affiliated funds, and any of such persons or their affiliated funds could determine to purchase more, fewer or no shares in this offering.

Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The common shares will be ready for delivery on or about _____, 2022.

J.P. Morgan

The date of this prospectus is _____, 2022.

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The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms or other independent sources. Some data are also based on our good faith estimates.

We have not authorized, and the underwriters have not authorized, anyone to provide you with information other than the information contained in this prospectus. We take no responsibility for, and can provide no assurance as to the reliability of, any information that others may give you. The information contained in this prospectus is accurate only as of the date hereof, regardless of the time of delivery of this prospectus or of any sale of our common shares. It is important for you to read and consider all information contained in this prospectus in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled "Where You Can Find Additional Information" in this prospectus.

We are offering to sell, and seeking offers to buy, our common shares only in jurisdictions where offers and sales are permitted. The distribution of this prospectus and the offering of the common shares in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, this offering of the common shares and the distribution of this prospectus outside the United States. This prospectus does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

PROSPECTUS SUMMARY

This summary highlights selected information that is presented in greater detail elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common shares. You should read this entire prospectus carefully, including the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and our combined financial statements and the related notes included elsewhere in this prospectus, before making an investment decision.

Unless expressly indicated or the context requires otherwise, the terms “Biohaven,” “Company,” “we,” “us,” and “our” in this prospectus refer to Biohaven Ltd., a business company limited by shares incorporated under the laws of the British Virgin Islands (“BVI”), and its subsidiaries, including as a business of Biohaven Pharmaceutical Holding Company Ltd. (the “Former Parent”) to the extent the context requires. All references to “Pfizer” refer to Pfizer Inc., a Delaware corporation.

Spin-Off from Biohaven Pharmaceutical Holding Company Ltd.

Biohaven Ltd. was incorporated on May 2, 2022 as a direct, wholly owned subsidiary of the Former Parent. On October 3, 2022, the Former Parent completed the distribution (the “Distribution”) to holders of its common shares of all of the outstanding common shares of the Company and the spin-off of Biohaven from the Former Parent (the “Spin-Off”) was completed. Immediately following the Spin-Off, the Former Parent and Pfizer Inc. (“Pfizer”) consummated the transactions contemplated by the Agreement and Plan of Merger, dated as of May 9, 2022 (the “Merger Agreement”), by and among the Former Parent, Pfizer and a wholly owned subsidiary of Pfizer, pursuant to which Pfizer acquired the Former Parent (the “Merger”). Each holder of Former Parent common shares received one common share of Biohaven for every two Former Parent common shares held of record as of the close of business, New York City time, on September 26, 2022. In the Distribution, an aggregate of 35,832,557 Biohaven common shares were issued. The aggregate number of common shares issued in connection with the Distribution did not include 2,611,478 common shares to be issued in connection with Former Parent stock options that were exercised on October 3, 2022 and 924,093 common shares to be issued in connection with Former Parent Restricted Stock Units that vested on October 3, 2022. As of October 14, 2022, an aggregate of 39,375,944 Biohaven common shares were issued and outstanding. As of October 3, 2022, we had approximately \$257.8 million in cash.

Following the Distribution, we now own clinical stage assets, including the Kv7 ion channel activators, glutamate modulation and myostatin inhibition platforms, preclinical product candidates, and certain corporate infrastructure previously owned by the Former Parent (the “Biohaven Business”) and have proprietary rights to a number of trademarks used in this prospectus which are important to our business, including the Biohaven logo.

Company Overview

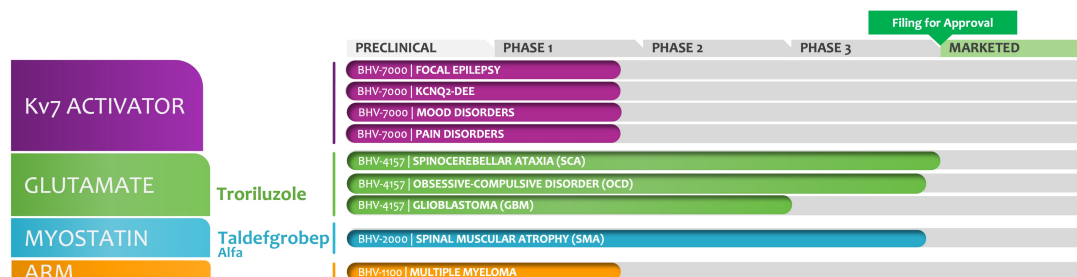
Biohaven Ltd. is a business company limited by shares incorporated under the laws of the BVI. We are a clinical-stage biopharmaceutical company that combines a deep understanding of neuroscience, immunology, disease-related biology, advanced chemistry and expertise in global clinical trials to advance novel therapies for patients. Our experienced management team brings with it a proven track record of delivering new drug approvals for products for diseases such as migraine, depression, bipolar and schizophrenia, and our research programs, built on a deep understanding of disease-related biology and neuropharmacology, are advancing novel therapies with target indications, including epilepsy, mood disorders, Obsessive-Compulsive Disorder (“OCD”), Spinocerebellar Ataxia (“SCA”), Spinal Muscular Atrophy (“SMA”) and pain disorders. Our neuroscience portfolio includes a broad pipeline of drug candidates modulating distinct nervous system targets, including Kv7 ion channels (“Kv7”), glutamate receptors, myostatin, and transient receptor potential (“TRP”) channels.

We are advancing our broad and diverse pipeline with at least five clinical trials currently underway or expected to start by the end of 2022. We have built a highly experienced team of senior leaders and neuroscience drug developers who combine a nimble, results-driven biotech mindset with capabilities in drug discovery and development. In addition, we have several preclinical assets in our early discovery program, targeting neuroscience and immunology indications.

Our net losses for the fiscal years ended December 31, 2021 and 2020 were \$213.8 million and \$118.7 million, respectively. Our net losses for the six months ended June 30, 2022 and 2021 were \$300.3 million and \$107.5 million, respectively. Our net losses reflect the early-stage (pre-revenue) nature of our core clinical-stage biopharmaceutical business.

Product Candidates

The following table summarizes some of our key clinical programs in addition to upcoming potential clinical development milestones for our product candidates. We hold the worldwide rights to all of our product candidates. See the section entitled “Business” included in this prospectus for an in-depth discussion of our development programs and product candidates.



Our Strategy

Our goal is to develop innovative therapies for neurological and immunological diseases that have the potential to change current treatment paradigms. The key elements of our strategy to achieve this goal include:

- **Establish our position as a leader in neuroscience drug discovery and development through the advancement of a diverse and innovative pipeline, including our Kv7 targeting and glutamate modulating platforms.** We leverage our differentiated understanding of neuroscience as well as our proven innovative clinical trial design and execution to develop our assets across multiple indications. In addition, we are investing in future areas of neuroscience and immunoscience research, including the discovery and development of compounds with disease-modifying potential.
- **Rapidly develop our clinical-stage neurology and neuropsychiatry assets, with at least five clinical trials either underway or expected to start by the end of 2022.**
- **Focus development efforts on our recently acquired Kv7 platform by advancing BHV-7000 to at least one Phase 2/3 registrational trial in 2023.** Our Phase 1 study with BHV-7000 is currently underway and we expect results by the first half of 2023. If our Phase 1 study with BHV-7000 is successfully completed, we expect to initiate at least one pivotal trial in patients with epilepsy in the second half of 2023.
- **Advance our early discovery portfolio across multiple neuroscience and immunoscience indications.** Our preclinical pipeline includes molecular degraders of extracellular proteins, CD38 targeting antibody recruiting molecules (ARMs), TRP channels, TDP-43 targeting small molecules, and other undisclosed targets, including those with disease-modifying potential.
- **Efficiently allocate capital to maximize the impact of our assets.** We seek to efficiently allocate capital with the goal of step-wise value creation: driving speed to proof-of-principle, speed to proof-of-concept and speed to market. For example, our early-stage clinical trials are designed to elucidate the potential of our compounds and inform future clinical trials, thereby strengthening our probability of success and our efficiency in bringing our therapies to patients. We aim to be resource- and capital-efficient in the development of our product candidates by selectively accessing complementary expertise and infrastructure through strategic partnerships or other collaborations. We believe that our drug development team with particular experience in neuroscience and immunoscience have a differential ability to identify high-

potential assets for acquisition or in-licensing to unlock their full value. We plan to opportunistically pursue such assets from time to time and strategically expand our portfolio.

- ***Opportunistically match sources and uses of capital.*** Our broad portfolio both requires and provides a basis for diverse financing options. We will seek to maximize growth opportunities, which may include raising additional capital through a combination of private or public equity offerings, debt financings, collaborations, strategic alliances, marketing, distribution or licensing arrangements with third parties or through other sources of financing. By matching sources and uses of capital, we can maximize our value creation opportunities while mitigating operational risk through partnerships.
- ***Maximize the commercial potential of our product candidates and bring new therapies to underserved patient populations.*** Our development and commercialization strategy will be driven by our understanding of existing treatment paradigms along with patient, physician and payor needs. We expect to build a focused and efficient medical affairs and commercial organization to maximize the commercial potential of our portfolio. Our current plan is to commercialize our product candidates, if approved, in the United States and international markets, either alone or in collaboration with others.

Our Team

We have assembled a seasoned management team with expertise in clinical research, development, regulatory affairs, medical affairs, operations, manufacturing, commercialization and financing. Our team includes industry veterans who have collectively driven numerous drug approvals, with prior experience at large pharmaceutical companies and a demonstrated ability to operate in smaller, more efficient organizations to drive value for investors. We have an experienced research and development team focused on utilizing our differentiated understanding of the complexity of human drug development including an advanced understanding of neuroscience and immunoscience, receptor pharmacology and genetics that underlie many diseases. This allows us to develop investigational agents with target selectivity and indication-appropriate pharmacology, which we believe are key to enhancing activity and improving tolerability in the treatment of these diseases. We believe that the distinctive combination of our proven management team and our existing pipeline has the potential to bring to patients the next generation of transformative neuroscience therapies.

Summary of Risk Factors

An investment in our common shares is subject to a number of risks, including risks related to our product candidates, risks related to our business and risks related to our common shares. The following list of risk factors is not exhaustive. Please read the information in the section captioned “Risk Factors” for a more thorough description of these and other risks.

Risks Related to the Development of Our Product Candidates

- We depend entirely on the success of a limited number of product candidates.
- Clinical trials are very expensive, time consuming and difficult to design and implement, involve uncertain outcomes and may not be predictive of results of future trials.
- 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.
- 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 have never commercialized a product candidate and may lack the necessary expertise, personnel and resources to successfully commercialize any product candidate 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.
- Our product candidates, if approved, will be 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.

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.
- An inability to raise capital when needed or on terms favorable to us could force us to curtail our planned operations and growth strategy.

Risks Related to Our Dependence on Third Parties

- 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, which may expose our business to risks.
- We may not establish or maintain collaborations with third parties to develop or commercialize product candidates.

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 to federal and state healthcare and other laws.
- We may not 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.
- If we were unable to obtain licenses from third parties on commercially reasonable terms or lose our rights to licensed intellectual property, we may not be able to continue developing or commercializing our product candidates.
- Patent terms may not provide exclusivity for our product candidates for an adequate amount of time to realize sufficient commercial benefits.
- Third parties may seek to invalidate our patents.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

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

- 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 improper activities.

Risks Related to Ownership of Our Common Shares

- Substantially all of our total outstanding shares may be sold freely into the market. This could cause the market price of our common shares to drop significantly, even if our business is doing well.
- 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.
- The trading price of our common shares may be volatile and may fluctuate.
- If we are or become a passive foreign investment company, there could be adverse U.S. federal income tax consequences to U.S. holders.
- Our historical financial results as a part of Former Parent and our unaudited pro forma combined financial statements may not be representative of our results as a separate, stand-alone company.

Risks Related to this Offering

- We have broad discretion in the use of net proceeds from this offering.
- You will experience dilution as a result of this offering, which may adversely affect the per share trading price of our common shares.

Company Information

We are a business company limited by shares incorporated under the laws of the BVI. Our registered office is located at Kingston Chambers, P.O. Box 173, Road Town, Tortola, British Virgin Islands. Our U.S. office is located at 215 Church Street, New Haven, CT 06510 with additional facilities in Yardley, PA, Pittsburgh, PA, and New Haven, CT. Our telephone number is (203) 404-0410 and our website address is www.biohaven.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in making an investment decision regarding our common shares.

Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act (the “JOBS Act”), enacted in 2012. As an emerging growth company, we expect to take advantage of reduced reporting requirements otherwise applicable to public companies. These provisions include, but are not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”);
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may rely on the relief provided by these provisions until the last day of our fiscal year following the fifth anniversary of the completion of the Distribution. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), our annual gross revenues exceed \$1.235 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our shareholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Section 107 of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the “Securities Act”), for complying with new or revised accounting standards. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Implications of Being a Smaller Reporting Company

Additionally, we are a “smaller reporting company” as defined in Rule 12b-2 under the Exchange Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies, including, but not limited to, reduced disclosure obligations regarding executive compensation. We will continue to be a smaller reporting company as long as either (i) the market value of our common shares held by non-affiliates is less than \$250 million as of the last business day of our most recently completed second fiscal quarter or (ii) our annual revenue is less than \$100 million during the most recently

completed fiscal year and the market value of our common shares held by non-affiliates is less than \$700 million as of the last business day of our most recently completed second fiscal quarter.

THE OFFERING

Issuer	Biohaven Ltd.
Common shares outstanding before this offering	39,375,944 shares ⁽¹⁾
Common shares offered by us	20,000,000 shares (or 3,000,000 common shares if the underwriters exercise in full their option to purchase additional common shares).
Total common shares to be outstanding immediately after this offering	59,375,944 shares ⁽¹⁾ (or 62,375,944 common shares if the underwriters exercise in full their option to purchase additional common shares).
Use of proceeds	<p>We estimate that our net proceeds from this offering will be approximately \$233.1 million (or approximately \$268.1 million if the underwriters exercise their option to purchase additional common shares in full), after deducting the underwriting discount and prior to paying any offering expenses, based on an offering price of \$12.40 per share (the closing price for our common shares on the New York Stock Exchange (“NYSE”) on October 19, 2022).</p> <p>We intend to use the net proceeds that we receive in this offering for general corporate purposes.</p> <p>See “Use of Proceeds” for further details.</p>
Dividend policy	We do not expect to pay any cash dividends on our common shares in the foreseeable future. All decisions regarding the payment of dividends will be made by our Board of Directors (our “Board”) from time to time in accordance with applicable law.
Insider participation	Vlad Coric, our Chief Executive Officer, Matthew Buten, our Chief Financial Officer, and certain of our directors and their affiliated funds have indicated an interest in purchasing approximately \$100 million, in the aggregate, of our common shares in this offering at the public offering price. Dr. Coric and Mr. Buten have indicated an interest in purchasing approximately \$10 million and \$1 million of those common shares, respectively. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to each of Dr. Coric, Mr. Buten or our directors and their affiliated funds, and any of such persons or their affiliated funds could determine to purchase more, fewer or no shares in this offering.
Risk factors	Please read the section entitled “ Risk Factors ” beginning on page 11 of this prospectus for a discussion of some of the factors you should carefully consider before deciding to invest in our common shares.

(1) The number of shares is based on the number outstanding as of October 14, 2022 and does not include:

- 9,110,000 common shares issuable upon the exercise of stock options outstanding as of October 14, 2022, at an exercise price of \$7 per share;
- 80,000 common shares reserved for future issuance of awards under our 2022 Equity Incentive Plan (the “2022 Plan”); and
- 393,769 common shares reserved for future issuance under our 2022 Employee Share Purchase Plan (the “ESPP”).

SUMMARY HISTORICAL AND UNAUDITED PRO FORMA COMBINED FINANCIAL DATA

The following tables present our summary historical and unaudited pro forma combined financial data as of the dates and for the periods presented. The summary historical combined financial data of the Company as of and for the years ended December 31, 2021 and 2020, were derived from the audited combined financial statements of the Company, which are included elsewhere in this prospectus. We derived the summary historical combined financial data as of and for the six months ended June 30, 2022 from our unaudited condensed combined financial statements included elsewhere in this prospectus. The summary combined financial data presented below should be read in conjunction with the audited and unaudited combined financial statements and related notes included elsewhere in this prospectus, “Management’s Discussion and Analysis of Financial Condition and Results Operations” and “Unaudited Pro Forma Combined Financial Information.”

The summary historical combined financial data does not necessarily reflect what our results of operations and financial position would have been if we had operated as a separate publicly traded entity during all periods presented, including changes that will occur in our operations and capitalization as a result of the Distribution. Accordingly, the historical results should not be relied upon as an indicator of our future performance.

Our unaudited pro forma combined statement of operations data for the year ended December 31, 2021 and the six months ended June 30, 2022 assumes that the Spin-Off and Distribution occurred as of January 1, 2021. The unaudited pro forma combined balance sheet as of June 30, 2022 gives effect to the Spin-Off and the Distribution as if it had occurred on June 30, 2022. The unaudited transaction accounting and autonomous entity adjustments are based on assumptions that management believes are reasonable under the circumstances and given the information available at this time. The summary unaudited pro forma combined financial information is for illustrative and informational purposes only and does not purport to represent what the financial position or results of operations would have been if the Company had operated as an independent company during the periods presented or if the transactions described therein had actually occurred as of the date indicated, nor does it project the financial position at any future date or the results of operations for any future period. See the notes to the unaudited pro forma combined financial statements included elsewhere in this prospectus for a discussion of adjustments reflected in the unaudited pro forma combined financial statements.

	Year Ended December 31,		
	Pro Forma	Historical	
	2021	2021	2020
Combined Statement of Operations Data: (Amounts in thousands)			
Research and development	\$ 193,172	\$ 181,486	\$ 98,460
General and administrative	54,223	37,414	16,046
Net loss	(224,829)	(213,796)	(118,668)

	Six Months Ended June 30,		
	Pro Forma	Historical	
	2022	2022	2021
Combined Statement of Operations Data: (Amounts in thousands)			
Research and development	\$ 249,884	\$ 247,183	\$ 92,695
General and administrative	49,522	39,700	19,830
Net loss	(314,322)	(300,319)	(107,545)

As of June 30,

	As of June 30,	
	Pro Forma	Historical
	2022	2022
Combined Balance Sheet Data: (Amounts in thousands)		
Cash	\$ 257,799	\$ 23,209
Working capital ⁽¹⁾	\$ 218,131	\$ (19,099)
Total assets	\$ 332,810	\$ 98,220
Total liabilities	\$ 70,582	\$ 73,222

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

RISK FACTORS

In connection with any investment decision with respect to our securities, you should carefully consider the risk factors described below, as well as general economic and business risks and the other information contained in this prospectus. The occurrence of any of the events or circumstances described below or other adverse events could have a material adverse effect on our business, results of operations and financial condition and could cause the trading price of our common shares to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

Risks Related to Our Financial Position and Need for Additional Capital

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

We were incorporated on May 2, 2022 as a direct, wholly-owned subsidiary of Former Parent. Our operations to date have been largely focused on organizing and staffing, raising capital and in-licensing the rights to, and advancing the development of, our product candidates, including conducting preclinical studies and clinical trials. We have not yet demonstrated an ability to obtain marketing approvals for any product candidates, manufacture products on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

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

We have incurred significant operating losses since our inception as a business of Former Parent 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 as a business of Former Parent, we have incurred significant operating losses. Our net loss was \$213.8 million for the year ended December 31, 2021 and \$300.3 million for the six months ended June 30, 2022. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. None of our product candidates has been approved for marketing in the United States, or in any other jurisdiction, and may never receive such approval. It could be several years, if ever, before we have a commercialized product that generates significant revenues. As a result, we are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- 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 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;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- hire additional clinical, medical, commercial, and development personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

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

We may never succeed in any or all of these activities and, even if we do, we may never generate sufficient revenue to achieve profitability.

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

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

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

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to develop our product candidates. Our expenses could increase beyond our current expectations if the FDA requires us to perform clinical trials and other studies in addition to those that we currently anticipate. For example, for our troriluzole clinical program, we are conducting a Phase 2/3 clinical trial in SCA incorporating feedback from the FDA in response to discussion that we had with the FDA regarding proposed modifications to the scale for assessment and rating of Ataxia, 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.

In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. Additionally, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution and, with respect to certain of our product candidates, the

payment of milestone and royalty fees. Furthermore, we expect to incur additional costs associated with operating as a public company.

As of October 3, 2022, we had approximately \$257.8 million in cash. We expect that our existing cash will be sufficient to fund our planned operating expenses, financial commitments and other cash requirements for at least 12 months from the date of filing of this report. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the 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;
- 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 costs and timing of future commercialization activities, including drug manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish strategic collaborations for the development or commercialization of some of our product candidates; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims brought by third parties against us.

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

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

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

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

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

Risks Related to the Development of Our Product Candidates

Our current business depends entirely on the success of a limited number of product candidates, which are in clinical development. If we do not obtain or are delayed in obtaining regulatory approval for and successfully commercialize one or more of our product candidates, our business, financial condition and results of operations could be materially impacted and we may never become profitable.

Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We do not have any products that have received regulatory approval, and therefore we have never generated any revenue from product sales, and we may never be able to develop product candidates that receive regulatory approval or are successfully commercialized after regulatory approval is received. Consequently, the revenue-generating potential of our business is unproven and uncertain. 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, completion of our Phase 3 clinical trials of troriluzole in OCD, execution of clinical trials for BHV-7000, including late-stage studies in epilepsy and mood disorders, completion of a Phase 2/3 clinical trial of troriluzole in glioblastoma, and completion of a Phase 3 clinical trial of BHV-2000 in SMA. 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 a new drug application (“NDA”), biologics license application (“BLA”) or comparable applications in other jurisdictions for any of our product candidates within the timeframes we expect, or that any NDA, BLA or similar application we submit will be accepted by the FDA or comparable foreign regulators for filing in a timely manner or at all. 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. The success of our product candidates will depend on various factors, including:

- completing clinical trials that demonstrate our product candidates’ 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. Our failure to achieve one or more of these factors in a timely manner or at all could 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.

Clinical testing is expensive and can take many years to complete, and delay or 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. In September 2022, we reported negative topline results from the Phase 2/3 HEALEY ALS Platform trial evaluating verdiperstat compared to placebo for the treatment of participants with ALS. At this time, we have no plans to continue development of verdiperstat in ALS, and we are evaluating whether or not to pursue any additional clinical trials evaluating other disease indications.

In addition, 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.

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.

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.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

We have limited experience in drug discovery and drug development.

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

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 need to be redesigned, enroll an adequate number of patients on time or begin 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 or other regulators disagreeing as to the design, protocol or implementation of our clinical trials;
- the delay or refusal of regulators (including the FDA) or institutional review boards (“IRBs”) to authorize us to commence a clinical trial;
- regulators (including the FDA), IRBs, ethics committees of the institutions at which trials are being conducted or the data safety monitoring board for such trials requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements (including the FDA’s current Good Clinical Practice (“GCP”) regulations) or our clinical protocols, safety concerns, adverse side effects, or lack of adequate funding to continue the clinical trial, among others;
- 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 (including due to reports from testing of similar therapies) that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- 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.

Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue from product sales. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The regulatory approval processes of the FDA and comparable foreign regulatory agencies are lengthy, time-consuming and unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be materially harmed.

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 or BLA from the FDA or approval from the EMA, NMPA or other applicable foreign regulatory agency. 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 those beyond our control, such as 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.

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. 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, or that the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's, EMA's, NMPA's or the applicable foreign regulatory agency's disagreement with the interpretation of data from preclinical studies or clinical trials;

- actions by the CROs that we retain to conduct our preclinical studies and clinical trials, which are outside of our control and that materially adversely impact our preclinical studies and clinical trials;
- the FDA's, EMA's, NMPA's or 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; and
- 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, with respect to our randomized, controlled clinical trial of troriluzole for the treatment of SCA, we undertook discussions with the FDA regarding the acceptability of the primary endpoint and necessary secondary endpoints, including our proposal to use a modified SARA scale. In our first Phase 2/3 clinical trial, the FDA stated that while certain items measured by the SARA scale appeared capable of reflecting a clinically meaningful benefit for patients depending on how the scoring of those items is defined, the use of the SARA scale was not appropriate as a primary endpoint in the trial. Based on our post-hoc analyses of data from the open-label extension phase of the trial, we proposed modifications to the SARA scale that we believe may address some of these shortcomings. Based on feedback received from the FDA, we incorporated trial design modifications that include utilization of a modified SARA scale. However, notwithstanding the feedback that we have received from the FDA, there remains substantial risk that the FDA or any foreign regulatory agency may nevertheless conclude that results obtained using the modified SARA scale would not be an adequate basis for approval.

In addition, in our Phase 3 clinical trial evaluating the efficacy and safety of troriluzole in adult patients with SCA, the primary endpoint, change from baseline to week 48 on the modified SARA scale, did not reach statistical significance in the overall SCA population as there was less than expected disease progression over the course of the study. Post-hoc analysis of efficacy measures by genotype suggests a treatment effect in patients with the SCA Type 3 ("SCA3") genotype. There is substantial risk that the FDA, EMA, NMPA or the applicable foreign regulatory agency may disagree with the interpretation of our data, and there can be no assurance that any such regulatory agency will find the data sufficient to support approval, or that we will not be required to conduct additional testing on the safety and efficacy of troriluzole.

We intend to interact with the FDA and/or EMA in the first half of 2023 but have not yet decided on the format of such an interaction. We could seek advice through various formal or informal interactions with regulatory agencies or we could choose to submit an NDA if we believe that is warranted from the results of our ongoing post-hoc analyses.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and other key global markets, which requires compliance 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. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited.

Moreover, even if we were to obtain approval to market any product candidate we develop, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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

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

For example, in 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. In September 2022, we reported negative topline results from the Phase 2/3 HEALEY ALS Platform trial evaluating verdiperstat compared to placebo for the treatment of participants with ALS. At this time, we do not have plans to pursue any additional clinical trials evaluating verdiperstat in ALS but we are evaluating its potential in other disease indications.

Moreover, undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, the limitation of commercial potential or the delay or denial of regulatory approval by the FDA or a foreign regulatory agency. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Accordingly, we may need to abandon the development of certain product candidates 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. 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.

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, delay the clinical trial, and prevent receipt of regulatory approval from the FDA and other regulators. 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 receives marketing approval and we, or others, later discover that the drug is 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 by their nature 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.

We have monitored the subjects in our studies for certain safety concerns and we have not seen evidence of significant safety concerns in our clinical trials. However, if one or more of our product candidates receives regulatory approval, and we, or others, later discover that they are less effective than previously believed, or cause undesirable side effects that had not previously been identified, 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 similar program 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;
- 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 depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be adversely affected.

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

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

- the proximity and availability of clinical trial sites for prospective patients.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

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

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. The current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. In addition, we have agreed to indemnify the licensors of the intellectual property related to our product candidates against certain intellectual property infringement claims. Any claims against us, or with respect to which we are obligated to provide indemnification, regardless of their merit, could be difficult and costly to defend or settle, and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved.

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

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

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

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

Risks Related to Commercialization of Our Product Candidates

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

We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring the rights to our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have no sales force, marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to a third party.

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

To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution of any approved product, our product revenue may be lower than if we directly marketed or sold such product. 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.

We operate in a highly competitive and rapidly changing industry. Failure to compete successfully could adversely affect our business, financial condition and results of operations.

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 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 other indications. If we continue to pursue these indications, 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.

Many of the companies which we are competing with or which we may compete with 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 our competitors.

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

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

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidates 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, are essential for most patients to be able to afford products such as our 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 our product candidates, if approved, and attract additional collaboration partners to invest in the development of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and adequate reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that 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.

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 payors, 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 healthcare providers who use such devices or therapies.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and

clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

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

Even if we obtain regulatory approval for any of our product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promoting, 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 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.

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. We may not be able to adapt to changes in existing requirements or the adoption of new requirements or policies. 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;
- refusal to permit the import or export of products; or
- requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization.

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

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

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if the FDA approves the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. 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. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing. The degree of market acceptance of our product candidates that are approved for commercial sale will depend on a variety of factors, including:

- the efficacy, cost, convenience and ease of administration, and other potential advantages compared to alternative treatments, including any similar generic treatments;
- effectiveness of sales and marketing efforts;
- 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; and
- any restrictions on the use of our products, if approved, together with other medications.

In addition, the potential market opportunity for our 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, our revenue from product sales may be limited and we may be unable to achieve or maintain profitability.

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

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

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

While we believe that troriluzole, a prodrug of riluzole will be treated as NCEs under current FDA interpretations and, therefore, if approved, should be afforded five years of data exclusivity, the FDA may disagree with that conclusion and may approve generic products after a period that is less than five years. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

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

Risks Related to Our Dependence on Third Parties

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 medical institutions, clinical investigators, contract laboratories and other third parties, such as contract research organizations (“CROs”) as appropriate. We are reliant upon such third parties to assist us in conducting GCP-compliant clinical trials on our product candidates properly and on time, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-parties, we will have only limited control over their actual performance of these activities.

We and our CROs and other vendors are required to comply with cGMP, GCP and good laboratory practices (“GLP”), which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Union and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections

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

While we will have agreements governing their activities, we are not, and will not be able to control whether or not our CROs devote sufficient time and resources to our future preclinical and clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. If our CROs do not successfully carry out their contractual duties or obligations, or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, the clinical data generated in our clinical trials may be deemed unreliable, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

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

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

Our ability to develop our product candidates depends and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the active pharmaceutical ingredients (“APIs”) and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates. In addition, our results of operations and cash flows could be adversely impacted by any inability to obtain favorable terms from our suppliers, including any acceleration of payment terms to our suppliers and/or the imposition of more restrictive credit terms and other contractual requirements.

While we have auditing rights with all our current manufacturing counterparties, 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 our contract suppliers or manufacturers fail to achieve and maintain compliance with applicable laws and regulatory requirements, our business could be adversely affected in a number of ways, and cause, among other things:

- 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.

Further, if the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws and regulatory requirements, 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.

We may rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. We may also have sole-source suppliers for one or more of our other product candidates. Some of the APIs and other substances and materials used in our product candidates are currently available only from one or a limited number of domestic or foreign suppliers and foreign manufacturers and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers.

In the event an existing supplier or manufacturer fails to supply or manufacture, as applicable, product on a timely basis or in the requested amount, fails to meet regulatory requirements or our specifications, 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 suppliers, 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 manufacturers, and this process of approval could delay production of our products or development of product candidates indefinitely. We and our manufacturers do not currently maintain inventory of these APIs and other substances and materials. Any interruption in the supply of an API or other substance or material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects.

In addition, these contract manufacturers are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory agency does not

approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

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

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

In addition, the manufacturing facilities of certain of our suppliers are located outside of the United States. This may give rise to difficulties in importing our products or product candidates or their components into the United States or other countries as a result of, among other things, regulatory agency approval requirements or import inspections, incomplete or inaccurate import documentation or defective packaging.

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

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates, which may include transferring production to new third-party suppliers or manufacturers. In order to conduct larger or late-stage scale clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product. If we, or any of our manufacturers, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

We may in the future enter into collaborations with third parties to develop and commercialize our product candidates. If these collaborations are not successful, or if we are not able to establish or maintain these collaborations, our business could be harmed.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund expenses. For some of our product candidates, we may decide to collaborate

with pharmaceutical and biotechnology companies for the future development and potential commercialization of those product candidates. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. Collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements, and the terms of any collaborations or other arrangements that we may establish may not be favorable to us.

We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing or alternative products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us.

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.

Risks Related to Regulatory Compliance

We are required to comply with a wide variety of laws and regulations, and are subject to regulation by various federal, state and foreign agencies, and our failure to comply with existing and future regulatory requirements could adversely affect our results of operations and financial condition. 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 operations are subject to a broad array of regulatory requirements globally. We are subject to federal, state, local, international and transnational laws and regulations, including the operating, quality and security standards of the FDA, the U.S. Department of Health and Human Services ("HHS"), and other regulatory authorities such as the EMA, and in the future, any changes to such laws and regulations could adversely affect us. In particular, changes in the FDA's regulation of drug discovery and development or manufacturing processes could adversely affect our results of operations and financial condition. We may be required to register for permits and/or licenses with the FDA, HHS, or other regulatory authorities such as the EMA, and there can be no assurance that we will be able to maintain or renew existing permits, licenses or other regulatory approvals or obtain, without significant delay, future permits, licenses or other approvals needed for the operation of our business. Any noncompliance by us with

applicable laws and regulations or the failure to maintain, renew or obtain necessary permits and licenses could have an adverse effect on our results of operations and financial condition.

In the United States, the European Union, and other foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Affordable Care Act (“ACA”), as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states, without specifically ruling on the ACA’s constitutionality. 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 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 (“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. HHS moved 30% of Medicare payments to alternative payment models tied to the quality or value of services in 2016. Additionally, HHS had set a goal of moving 50% of Medicare payments into these alternative payment models by the end of 2018, but 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 May 2019, CMS finalized 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. However, this rule was struck down by a federal court before it went into effect. Although some of these and other proposals will require authorization through additional legislation to become effective, members of Congress and the Biden Administration have stated that they will continue to seek new legislative and administrative measures to control drug costs. In response to an Executive Order from President Biden, the Secretary of HHS recently issued a comprehensive plan for addressing high drug prices that describes a number of legislative approaches and identifies administrative tools to address the high cost of drugs. And Democrats recently included drug pricing reform provisions reflecting elements of the plan in a broader spending package in late 2021—such as capping Medicare Part D patients’ out-of-pocket costs, establishing penalties for drug prices that increase faster than inflation in Medicare, and authorizing the federal government to negotiate prices on certain select, high-cost drugs under Medicare Parts B and D. 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 (“EU”), 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 healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing

approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback

Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) enacted as part of the American Recovery and Reinvestment Act of 2009, 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, on 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, to safeguard the privacy, security and transmission of individually identifiable health information from any unauthorized use or disclosure;
- the FDCA, 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;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers;
- state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources;
- state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities;
- state and local laws that require the registration of pharmaceutical sales representatives; and
- state laws governing the privacy and security of personal information, including personal 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.

Ensuring that our internal operations and current and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. Further, defending against any

such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

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

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

We are subject to changing law and regulations regarding regulatory matters, corporate governance and public disclosure that have increased both our costs and the risk of non-compliance.

We are subject to rules and regulations by various governing bodies, including, for example, the SEC, which is charged with the protection of investors and the oversight of companies whose securities are publicly traded, and to new and evolving regulatory measures under applicable law, including the laws of the BVI. Our efforts to comply with new and changing laws and regulations have resulted in and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices. If we fail to address and comply with these regulations and any subsequent changes, we may be subject to penalty and our business may be harmed.

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

As the global regulatory and tax environment evolves, we may be subject to new or different statutory and regulatory requirements. For example, on January 1, 2019, the Economic Substance (Companies and Limited

Partnerships) Act, 2018 of the British Virgin Islands (the “Economic Substance Act”) came into force and was amended on October 1, 2019 and June 29, 2021 and remains subject to further amendments, additional regulations and guidance on interpretation from the regulator. It is difficult to predict what impact the Economic Substance Act and its associated regulations and guidance or changes in the interpretation of these laws or regulations could have on us. However, compliance with various additional obligations may create additional costs that may be borne by us or otherwise affect our management and operation.

Risks Related to Our Intellectual Property

We could lose market exclusivity earlier than expected.

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.

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 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 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, are 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 five-year 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 Authorisation Application (“MAA”) with the EMA. After the EMA evaluates the MAA, it provides a recommendation to the EC and the EC then approves or denies the MAA. 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 biologically-derived 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.

Rest of the World

In countries outside of the U.S., the EU and Japan, 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.

We are dependent on licensed intellectual property in our business. If we are unable to obtain licenses from third parties on commercially reasonable terms or lose our rights to such licensed intellectual property, or if our rights are determined to be narrower than we understand them to be, we may not be able to continue developing or commercializing our product candidates.

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, including, for example, a license agreement with ALS Biopharma and Fox Chase Chemical Diversity Center, Inc., pursuant to which we were assigned intellectual property rights relating to troriluzole, license agreements with AstraZeneca, pursuant to which we were granted exclusive licenses relating to BHV-5500 and verdiperstat, a license agreement with Bristol-Myers Squibb, pursuant to which we were granted an exclusive license to BHV-2200, and a license agreement with KU Leuven, pursuant to which we were granted an exclusive license to develop and commercialize the TRPM3 antagonist platform. We may 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, such as non-compete periods for certain collaboration targets and rights of first negotiation for development of certain programs. Typically, in our licenses, we have control over the filing, prosecution, maintenance and enforcement of the licensed intellectual property. However, in some cases, we may not control prosecution of the licensed intellectual property, or may not have the first right to enforce such intellectual property. In those cases, we may not be able to adequately influence patent prosecution or enforcement, or prevent inadvertent lapses of coverage due to failure to pay maintenance fees.

If we fail to comply with any of our obligations under a current or future license agreement, the licensor may allege that we have breached our license agreement, and may seek to terminate our license. Termination of any of our current or future licenses could result in our loss of the right to use the licensed intellectual property, which could materially adversely affect our ability to develop, manufacture or commercialize a product candidate or product, if approved, as well as harm our competitive business position and our business prospects. Under some license agreements, termination may also result in the transfer of or granting of rights under certain of our intellectual property and information related to the product candidate being developed under the license, such as regulatory information. If our licensors fail to comply with their obligations under these agreements, such as, for example, by failing to maintain or enforce patents licensed to us, exclusivity relating to the products covered by the license may be diminished or lost. Our rights under license agreements could be determined to be narrower than we understand them to be. Also, if it is found that our licensors were not the original inventors of the licensed intellectual property, or were not the first to file patent applications, then we may lose rights to the licensed intellectual property.

Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues. Disputes between us and our licensors have arisen and may arise in the future. For example, 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, including our right to sublicense patents and other rights to third parties;
- 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 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, manufacture or commercialize the affected product candidates.

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

Patent terms may not provide exclusivity for our product candidates for an adequate amount of time for us to realize commercial benefits.

Patents have a limited lifespan. In the United States and most of the world, the statutory expiration of a patent is generally 20 years from the first 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 products, including generic products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates may not provide us with exclusivity for an adequate amount of time for us to realize commercial benefits.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process, subject to a statutory maximum of fourteen (14) years from the regulatory approval and an additional six months of pediatric exclusivity if available. Similar regulations regarding patent term extensions, or supplementary protection certificates, are available in some countries such as the European Union, United Kingdom, Japan and Korea.

However, we may not receive a patent term restoration, a supplementary protection certificate or extension if we fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain a patent term restoration, a supplementary protection certificate or extension, or the term is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced.

Third parties may seek to invalidate our patents.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation actions in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time,

the patent owner may be compelled to limit the scope of the allowed or granted claims which are the subject of the challenge, or may lose the allowed or granted claims altogether.

Generic manufacturers seeking to launch a generic substitute of small molecule drug in the U.S. typically engage in patent challenges. We expect that as early as four (4) years after the approval of our products, one or more generic manufacturers may allege that one or more of the patents listed in the Orange Book under our NDA is either invalid or not infringed (a Paragraph IV certification). We then must decide whether to file a patent infringement suit against such generic manufacturer(s). Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could.

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

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our technology, such as our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. If, in the context of seeking approval for one of our product candidates subject to approval via Section 505(b)(2), we were required to file a Paragraph IV certification against any patents of a third party, we would additionally be at risk of an automatic stay if litigation is initiated, thereby potentially delaying our approval or market entry. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of resources from our business.

In the event of a successful claim of infringement against us, we may have to pay substantial damages, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

In addition to claims of infringement made by third parties against us, we may file claims of infringement against third parties who infringe, or misappropriate, our patents or those of our licensors. This can occur as a counter claim in an infringement suit against us or as a direct claim against the third party. Our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable or claims challenging the scope of the intellectual property rights we own or control. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Other risk factors relating to our intellectual property

In addition to the risk factors described above, we consider the items below to be relevant for consideration in the assessment of the Company's intellectual property position.

- Changes in intellectual property laws or regulations in the U.S. or other countries could negatively affect our business. Similarly, changes in the interpretation of such laws or regulations could have an impact on our business. For example, U.S. Supreme Court has ruled on several patent cases in recent years, such as *Impression Products, Inc. v. Lexmark International, Inc.*, *Association for Molecular Pathology v. Myriad Genetics, Inc.*, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, and *Alice Corporation Pty. Ltd. v. CLS Bank International*, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, decisions by courts may lead to legislation impacting our ability to obtain or enforce our intellectual property.
- Our ability to enforce our intellectual property outside of the U.S. is dependent on the laws of jurisdiction in which the alleged infringement occurred, the ability to engage in discovery to obtain evidence and the availability of meaningful recoveries, e.g., damages and injunctions. The laws of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. As a result, our business may be harmed by limitations on our ability to protect our technology through the enforcement of our intellectual property in certain countries outside the U.S.
- The U.S. government may seek to exercise its rights under the Bayh-Dole Act of 1980 in programs that have received government funding. This exercise of rights could require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party the U.S. Government 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").
- We rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, third party collaborators, contract manufacturers, consultants, advisors and other third parties. An unauthorized disclosure or use of our trade secrets can have an adverse impact on our business.
- Other innovator companies may independently develop alternative technologies to our technologies without infringing our intellectual property rights, such as, for example, by developing compounds that function according to the same mechanism of action as our compounds, but are chemically distinct from ours and are not covered by the claims of the patents that we own or control.
- Litigation involving intellectual property can be generally time consuming and expensive. Litigation or other legal proceedings relating to intellectual property claims is unpredictable and generally expensive and time-consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on our valuation.

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

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

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

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

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

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

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

- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

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

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

As we expand our operations outside of the United States, we will be required to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. We are subject to U.S. laws governing international business activities, including U.S. economic sanctions, export controls and anti-corruption laws, including the 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. If our employees or agents violate our policies or we fail to maintain adequate record keeping and internal accounting practices to accurately record our transactions, we may be subject to regulatory sanctions. 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. Violations of U.S. economic sanctions, export controls and anti-corruption laws, or allegations of such acts, could damage our reputation and subject us to civil or criminal investigations in the United States and in other jurisdictions and related shareholder lawsuits, could lead to substantial civil and criminal, monetary and nonmonetary penalties and could cause us to incur significant legal and investigatory fees which could adversely affect our business, combined financial condition and results of operations.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As our clinical development progresses, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of clinical operations, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our 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. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation.

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

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

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

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

Despite the implementation of security measures, our internal computer systems, and those of our CROs and other third parties on which we rely, are vulnerable to damage from computer viruses, unauthorized access, cyberattacks, natural disasters, fire, terrorism, war and telecommunication and electrical failures. If such an event were to occur and interrupt our operations, it could result in a material disruption of our development programs. For example, the loss of clinical trial data from ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, loss of trade secrets or inappropriate disclosure of confidential or proprietary information, including individually identifiable health information or the 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 data concerning health, is subject to the EU General Data Protection Regulation, or 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 data concerning health and other sensitive data, obtaining consent of the individuals to whom the personal data relates to process their personal data, 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 turnover, 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.

Risks Related to Ownership of Our Common Shares

An active trading market for our common shares may not be sustained, or be liquid enough for investors to resell our common shares quickly or at the market price.

Our common shares began trading on the NYSE on October 4, 2022. Although trading in our common shares has developed, we cannot assure you that an active trading market will continue to develop or be sustained or that any trading market will be liquid. If an active market for our common shares is not sustained, it may be difficult for our shareholders to sell shares without depressing the market price for the shares or to sell their shares at all. An inactive market may also impair our ability to raise capital to continue to fund operations by selling our common shares and may impair our ability to acquire other companies or technologies by using our common shares as consideration.

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

Our share price may 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, our shareholders and 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 and commercialize any of our product candidates;
- developments, announcements or changes in government regulations relating to drug products, including related to drug pricing, reimbursement and healthcare coverage;
- delays in in-licensing or acquiring additional complementary product candidates;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions, or inability to obtain additional funding;
- announcements relating to our arrangements with AstraZeneca;
- failure to meet or exceed expectations of the investment community;
- actual or anticipated variations in our operating results;
- changes in financial estimates by us or by any securities analysts who might cover our shares;
- announcements by therapeutic drug product providers related to pricing of therapeutics;
- announcements of significant licenses, acquisitions, strategic partnerships or joint ventures by us or our competitors;
- publication of research reports or comments by securities or industry analysts;
- failure to attract or retain of key personnel;

- sales of our common shares, including sales by our directors and officers or specific shareholders;
- general market or regulatory conditions in the pharmaceutical industry or in the economy as a whole;
- other events and factors, many of which are beyond our control; and
- other factors described in this “Risk Factors” section and elsewhere in this prospectus.

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

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

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

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

Anti-takeover provisions in our amended memorandum and articles of association (“Amended 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 Amended Memorandum and Articles of Association 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 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. Among other things, these provisions:

- establish a classified Board 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;
- 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;

- require that shareholder actions must be effected at a duly called shareholder meeting and prohibit actions by our shareholders by written consent;
- limit the ability of members to requisition and convene general meetings of members; and
- authorize our Board to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preferred shares without any further vote or action by our members 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.

Any provision of our Amended 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.

Substantially all of our total outstanding shares may be sold freely into the market. This could cause the market price of our common shares to drop significantly, even if our business is doing well.

Sales of substantially all of our common shares in the public market, or the perception that these sales might occur, could depress the market price of our common shares and could impair our ability to raise capital through the sale of additional equity securities. Immediately following the Distribution, substantially all of our common shares became freely tradable, without restrictions or further registration under the Securities Act, subject to certain restrictions applicable to shares held by our affiliates as defined in Rule 144 under the Securities Act.

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 after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. Accordingly, investors cannot rely on dividend income from our common shares and any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares.

We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to “emerging growth companies” will make our common shares less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an “emerging growth company,” we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an “emerging growth company,” we are required to report only two years of financial results in certain Securities Act registration statements. We may take advantage of these exemptions until we are no longer an “emerging growth company.” We will remain an “emerging growth company” for up to five years after the effective date of the registration statement of which this prospectus forms a part, although we will lose that status sooner if our revenues exceed \$1.235 billion, if we issue more than \$1 billion in non-convertible debt in a three-year period, or if the market value of our common shares that are held by non-affiliates exceeds \$700 million as of June 30 of a fiscal year. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the price of our common shares may be more volatile than that of an otherwise comparable company that does not avail itself of the same or similar exemptions.

We are a smaller reporting company, and the reduced reporting requirements applicable to smaller reporting companies may make our common shares less attractive to investors.

We are a “smaller reporting company” as defined in Rule 12b-2 under the Exchange Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced financial statement and other financial information disclosure, and reduced disclosure obligations regarding executive compensation in our annual and periodic reports and proxy statements. We will remain a smaller reporting company as long as either (i) the market value of our common shares held by non-affiliates is less than \$250 million or (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our common shares held by non-affiliates is less than \$700 million. Our public float is measured as of the last business day of our most recently completed second fiscal quarter, and annual revenues are as of the most recently completed fiscal year for which audited financial statements are available. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and our share price may be more volatile than that of an otherwise comparable company that does not avail itself of the same or similar exemptions.

We are a BVI business company limited by shares and, the holders of our common shares may have fewer protections as a shareholder of our company, because judicial precedent regarding the rights of shareholders is more limited under BVI law than that under U.S. law.

Our corporate affairs are governed by our Amended Memorandum and Articles of Association as amended and restated from time to time, the BVI Business Companies Act (As Revised) (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. 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 exhaustive 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 than the BVI. There is no statutory recognition in the BVI of judgments obtained in the U.S., although the courts of the BVI will in certain circumstances recognize and enforce a non-penal judgment of a foreign court of competent jurisdiction without retrial on the merits.

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 controlling 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 the BVI’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 Amended Memorandum and 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, dispositions of assets, takeover efforts, and other corporate decision making.

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

While statutory provisions do exist in BVI law for derivative actions to be brought in certain circumstances, shareholders in BVI business companies may not have standing to initiate a shareholder derivative action in a federal court of the United States. The circumstances in which any such action may be brought, and the procedures and defenses that may be available in respect to any such action, may result in the rights of shareholders of a BVI business company being more limited than those of shareholders of a company organized in the United States. Accordingly, shareholders may have fewer alternatives available to them if they believe that corporate wrongdoing

has occurred. The BVI courts are also unlikely to: (i) recognize or enforce against us judgments of courts in the United States based on certain civil liability provisions of U.S. securities law; or (ii) to impose liabilities against us, in original actions brought in the BVI, based on certain civil liability provisions of U.S. securities laws that are penal in nature or that relate to taxes or similar fiscal or revenue obligations or would be viewed as contrary to BVI public policy or the proceedings pursuant to which judgment was obtained were contrary to natural justice.

There is no statutory recognition in the BVI of judgments obtained in the United States. However, the courts of the BVI will in certain circumstances recognize such a foreign judgment and treat it as a cause of action in itself which may be sued upon as a debt at common law so that no retrial of the issues would be necessary, provided that:

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

The British Virgin Islands courts are unlikely:

- to recognize or enforce against the Company, judgments of courts of the U.S. predicated upon the civil liability provisions of the securities law of the U.S.; and
- to impose liabilities against the Company, predicated upon the certain civil liability provisions of the securities laws of the U.S. so far as the liabilities imposed by those provisions are penal in nature.

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

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

- If the company or a director of the company engages in or proposes to engage in conduct, that contravenes the BVI Act or our Amended Memorandum and Articles of Association, a shareholder may apply to the BVI court for an order directing the company or its director(s) to comply with or restraining the company or a director from engaging in conduct that contravenes the BVI Act or our Amended Memorandum and Articles of Association.
- Under the BVI Act, minority shareholders have a statutory right to bring a derivative action in the name of and on behalf of the company in circumstances where the company has a cause of action against its directors. This remedy is available at the discretion of the BVI court which will take a number of factors into account before granting or refusing a leave to proceed to the relevant shareholder, including whether such action is in the interests of the company, the cost of such action and whether there are alternative remedies that the shareholder concerned may rely upon.
- A shareholder of the company may bring an action against the company for breach of duty owed to him or her as a shareholder. This would typically be relevant in a situation where a shareholder is aggrieved by the

company for breach of an entitlement or right under the company's Amended Memorandum and Articles of Association.

- A shareholder of the company who considers that the affairs of the company have been, are being or likely to be, conducted in a manner that is, or any act or acts of the company have been, or are, likely to be oppressive, unfairly discriminatory, or unfairly prejudicial to him in that capacity, may apply to the BVI court for an order to remedy the situation. Again, this is a discretionary remedy and the BVI court will only award it if they are satisfied that it is just and equitable to do so.
- A shareholder may, in certain circumstances, apply for liquidators to be appointed over the affairs of a company under the BVI's Insolvency Act 2003 (as amended) (the "BVI Insolvency Act"). Shareholders can also by resolution appoint a liquidator of a BVI business company under the BVI Act if the company is solvent or under the BVI Insolvency Act if the company is insolvent.

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

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

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

As a BVI business company, it may be difficult for a shareholder to effect service of process within the United States upon us, our directors and officers, or to enforce against us, or them, judgments obtained in U.S. courts, including judgments predicated upon the civil liability provisions of the securities laws of the United States or any state therein. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a U.S. securities law claim because foreign courts may not be the most appropriate forums in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides. Accordingly, it may be difficult or impossible for you to bring an action against us in the BVI if you believe your rights under the U.S. securities laws have been infringed. In addition, there is uncertainty as to whether the courts of the BVI would recognize or enforce judgments of U.S. courts against us or such persons predicated upon the civil liability provisions of the securities laws of the U.S. or any state and it is uncertain whether such British Virgin Islands courts would hear original actions brought in the British Virgin Islands against us or such persons predicated upon the securities laws of the U.S. or any state.

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

Under current law, we expect to be treated as a non-U.S. corporation for U.S. federal income tax purposes. The tax laws applicable to our business activities, however, are subject to change and uncertain interpretation. Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in jurisdictions in which we do business. Our actual tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) our ability to use net operating loss carryforwards to offset future taxable income and any adjustments to the amount of the net operating loss carryforwards we can utilize; and (5) changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles. We may also become subject to income, withholding or other taxes in jurisdictions by reason of our activities and operations, and it is possible that taxing authorities in such jurisdictions could assert that we are subject to greater taxation than we currently anticipate. Since 2017, the G20/OECD Inclusive Framework has been working on addressing the tax challenges arising from the digitalization of the economy and has proposed a two-pillar tax approach with pillar one referring to the re-allocation of taxing rights, addressing issues such as where tax should be paid and on what basis (i.e., where sustained and significant business is conducted, regardless of a physical presence), and pillar two ensuring a minimum tax to be paid by multinational enterprises. We are unable to predict when and how the Inclusive Framework agreement will be enacted into law in the countries in which we operate, and it is possible that the implementation of the Inclusive Framework agreement, including the global minimum corporate tax rate, could have a material effect on our liability for corporate taxes and our consolidated effective tax rate.

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

If we are or become a passive foreign investment company (“PFIC”) for any taxable year during which a U.S. holder holds our shares, the U.S. holder would 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.

Under the Code, we would be a PFIC for any taxable year in which (1) 75% or more of our gross income consisted of passive income or (2) 50% or more of the average quarterly value of our assets consisted of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes, but is not limited to, dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations and subject to certain exceptions, 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.

Although we believe our common shares should not currently be stock of a PFIC for U.S. federal income tax purposes and do not expect to become a PFIC in the foreseeable future, we cannot provide any assurances regarding our PFIC status for any 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 determination of whether we are a PFIC and the characterization of our assets as active or passive may depend in part on (i) our current and intended future business plans which are subject to change, (ii) the application of certain “look-through” rules and (iii) the applicability of the “start-up exception.” Under the start-up exception, a foreign corporation that would otherwise be treated as a PFIC will not be a PFIC for the first taxable year the corporation has gross income (the “start-up year”), if: (A) no predecessor of the corporation was a PFIC; (B) the corporation satisfies the IRS that it will not be a PFIC for either of the first two taxable years following the start-up year; and (C) the corporation is not in fact a PFIC for either of those years. The applicability of the startup exception to us is uncertain and will not be known until after the end of the two taxable years following such startup year. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may fluctuate considerably from time to time, and is dependent on

our application (which inherently involves an element of judgment) of the relevant valuation assumptions and methodologies. 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. Therefore, we cannot provide any assurance regarding our PFIC status for any past, current or future taxable years.

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 QEF 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 U.S. holders of our common shares should assume that a QEF election will not be available.

Please see “Material U.S. Federal Income Tax Considerations” for further information. U.S. holders should consult their own tax advisors with respect to the operation of the PFIC rules and related reporting requirements in light of their particular circumstances, including the advisability of making any election that may be available.

Mail addressed to us may not reach us in a timely manner.

Mail addressed to the Company and received at its registered office will be forwarded unopened to the forwarding address supplied by Company to be dealt with. None of the Company, its directors, officers, advisors or service providers (including the organization which provides registered office services in the BVI) will bear any responsibility for any delay howsoever caused in mail reaching the forwarding address. Such risk will be borne solely by the Company’s shareholders.

Our Amended Memorandum and Articles of Association provide that unless we consent in writing to the selection of an alternative forum, the courts of the British Virgin Islands shall, with certain limited exceptions, be the sole and exclusive forum for certain disputes between us and our shareholders, which could limit our shareholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Amended Memorandum and Articles of Association provide that unless we consent in writing to the selection of an alternative forum, the courts of the British Virgin Islands shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company to the Company or the Company’s members, (iii) any action asserting a claim arising pursuant to any provision of British Virgin Islands law or the Amended Memorandum and Articles of Association, or (iv) any action asserting a claim against the Company governed by the internal affairs doctrine, and that each shareholder consents to the exclusive jurisdiction of the courts of the British Virgin Islands over all such claims or disputes. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over actions brought under the Securities Act or the rules and regulations promulgated thereunder. Furthermore, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the forum selection provision in our Amended Memorandum and Articles of Association will not apply to actions or suits brought to enforce any liability or duty created by the Securities Act, Exchange Act or any claim for which the federal district courts of the United States of America are, as a matter of the laws of the United States of America, the sole and exclusive forum for determination of such a claim.

This choice of forum provision may increase a shareholder’s cost, impose additional litigation costs and limit the shareholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees, although our shareholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder and may therefore bring certain claims in another appropriate forum. Any person or entity purchasing or otherwise acquiring any of our shares or other securities, whether by transfer, sale, operation of law or otherwise, shall be deemed to have notice of and have irrevocably agreed and consented to

these provisions. It is possible that a court could find such a choice of forum provision to be inapplicable or unenforceable, and if a court were to find this provision in our Amended Memorandum and Articles of Association to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could have an adverse effect on our business, results of operations and financial condition.

Because our common shares have only traded on the public market for a limited period of time, the market price and trading volume of our common shares may be volatile.

Prior to the Distribution, there had not been a regular-way trading market for our common shares. We cannot predict the extent to which investors' interest will lead to a liquid trading market or whether the market price of our common shares will be volatile. The market price of our common shares could fluctuate significantly for many reasons, including in response to the risk factors listed in this prospectus or for reasons unrelated to our specific performance, such as reports by industry analysts, investor perceptions, or negative developments for our customers, competitors or suppliers, as well as general economic and industry conditions.

Our historical financial results as a part of Former Parent and our unaudited pro forma combined financial statements may not be representative of our results as a separate, stand-alone company.

The historical financial information we have included in this prospectus has been derived from the combined financial statements and accounting records of Former Parent and does not necessarily reflect what our financial position, results of operations or cash flows would have been had we been a separate, stand-alone company during the periods presented. The historical costs and expenses reflected in our combined financial statements include an allocation for certain corporate functions historically provided by Former Parent, including general corporate expenses and employee benefits and incentives. These allocations were based on what we and Former Parent considered to be reasonable reflections of the historical utilization levels of these services required in support of our business. The historical information does not necessarily indicate what our results of operations, financial position, cash flows or costs and expenses will be in the future. Our pro forma financial information set forth under "Unaudited Pro Forma Combined Financial Information" reflects changes to our operations as a result of the separation. However, there can be no assurances that this unaudited pro forma combined financial information will appropriately reflect our costs as a publicly traded company.

We have incurred, and expect to continue to incur, material costs and expenses as a result of our separation from Former Parent.

We have incurred, and will expect to continue to incur, costs and expenses greater than those we previously incurred while part of Former Parent as a result of our separation from Former Parent. These increased costs and expenses arise from various factors, including financial reporting and costs associated with complying with federal securities laws (including compliance with the Sarbanes-Oxley Act). In addition, we have increased corporate and administrative costs and expenses compared to those we incurred while part of Former Parent, even though we are now a smaller, stand-alone company. These costs may be material to our business.

If we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, or our internal control over financial reporting is not effective, the reliability of our financial statements may be questioned and our share price may suffer.

Section 404 of the Sarbanes-Oxley Act requires any company subject to the reporting requirements of the U.S. securities laws to do a comprehensive evaluation of its and its consolidated subsidiaries' internal control over financial reporting. To comply with this statute, we may eventually be required to document and test our internal control procedures, our management will be required to assess and issue a report concerning our internal control over financial reporting, and our independent auditors will be required to issue an opinion on the Company's internal controls over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. If our management cannot favorably assess the effectiveness of our internal control over

financial reporting or our auditors identify material weaknesses in our internal controls, investor confidence in our financial results may weaken, and our share price may suffer.

Risks Related to this Offering

We have broad discretion in the use of the net proceeds from this offering.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways with which you may not agree. Accordingly, you will be relying on the judgment of our management with regard to the use of the net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that the net proceeds will be invested or otherwise used in a way that does not yield a favorable, or any, return for us.

You will experience dilution as a result of this offering, which may adversely affect the per share trading price of our common shares.

This offering may have a dilutive effect on our earnings per share after giving effect to the issuance of our common shares in this offering and the receipt of the expected net proceeds. The actual amount of dilution from this offering will be based on numerous factors, particularly the use of proceeds and the return generated by such investment, and cannot be determined at this time. The per share trading price of our common shares could decline as a result of sales of a large number of common shares in the market pursuant to this offering.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would” or the negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following:

- our plans to develop and commercialize our product candidates;
- disruption from the Separation making it more difficult to maintain business and operational relationships;
- unknown liabilities;
- the risk of litigation and/or regulatory actions related to the separation or our business;
- risks and costs related to the implementation of the Separation, including any changes to the configuration of the businesses included in the Separation, if implemented;
- future business combinations or disposals;
- risks related to diverting management’s attention from the Company’s ongoing business operation;
- 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;
- the clinical utility of our product candidates;
- 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.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. We cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

INDUSTRY AND MARKET DATA

This prospectus contains statistical data, estimates, and forecasts that are based on independent industry publications, or other publicly available information, as well as other information based on our internal sources. Although we believe that the third-party sources referred to in this prospectus are reliable, neither we nor the underwriters have independently verified the information provided by these third parties. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section titled “Risk Factors” and elsewhere in this prospectus.

USE OF PROCEEDS

We estimate that our net proceeds from this offering will be approximately \$233.1 million (or approximately \$268.1 million if the underwriters exercise their option to purchase additional common shares in full), after deducting the underwriting discount and prior to paying any offering expenses, based on an offering price of \$12.40 per share (the closing price for our common shares on the NYSE on October 19, 2022). We intend to use the net proceeds of this offering for general corporate purposes.

DIVIDEND POLICY

We do not expect to pay any cash dividends on our common shares in the foreseeable future. All decisions regarding the payment of dividends will be made by our Board from time to time in accordance with applicable law.

CAPITALIZATION

The following table sets forth the Biohaven Business cash and capitalization as of June 30, 2022

- on a historical basis;
- on a pro forma basis to give effect to the pro forma adjustments included in our unaudited pro forma combined financial information; and
- on a pro forma as adjusted basis, giving effect to the sale of the shares in this offering at the assumed price of \$12.40 per share, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us and excluding any exercise of the underwriters' option to purchase additional shares.

The information below is not necessarily indicative of what our capitalization would have been had the Spin-Off and Distribution been completed as of June 30, 2022. In addition, it is not indicative of our future capitalization. This table should be read in conjunction with "Unaudited Pro Forma Combined Financial Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Summary Historical and Unaudited Pro Forma Combined Financial Data" and the audited combined financial statements and corresponding notes included elsewhere in this prospectus.

(Amounts in thousands)	As of June 30, 2022		
	Historical	Pro Forma	Pro Forma as Adjusted
Cash	\$ 23,209	\$ 257,799	\$ 489,919
Debt:			
Current debt	—	—	—
Long-term debt	—	—	—
Equity:			
Net investment from Parent	24,998	—	—
Common shares, no par value; 200,000 shares authorized, 36,587 shares issued and outstanding on a pro forma basis; 59,376 shares issued and outstanding on a pro forma as adjusted basis	—	262,228	494,348
Additional paid-in capital	—	—	—
Total capitalization	\$ 24,998	\$ 262,228	\$ 494,348

DILUTION

If you invest in our common shares in this offering, your ownership interest will be diluted immediately to the extent of the difference between the public offering price per common share and the as adjusted net tangible book value per common share immediately after this offering.

Our pro forma net tangible book value as of June 30, 2022 was \$242.4 million, or \$6.16 per common share. Our pro forma net tangible book value is the amount of our total tangible assets less our total liabilities. Pro forma net tangible book value per share represents historical net tangible book value divided by the 39,375,944 common shares outstanding as of October 14, 2022.

After giving effect to the issuance and sale of 20,000,000 common shares in this offering at the public offering price of \$12.40 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2022 would have been \$474.6 million, or \$7.99 per common share. This represents an immediate increase in as adjusted net tangible book value of \$1.83 per share to existing shareholders and immediate dilution in as adjusted net tangible book value of \$4.41 per share to new investors purchasing common shares in this offering. The following table illustrates this per share dilution:

Public offering price per share	\$	12.40
Pro forma net tangible book value per share as of June 30, 2022	\$	6.16
Increase in as adjusted net tangible book value per share attributable to this offering		1.83
As adjusted net tangible book value per share after this offering		7.99
Dilution per share to new investors purchasing common shares in this offering	\$	4.41

If the underwriters exercise their option to purchase additional shares in this offering in full, the as adjusted net tangible book value per share after this offering would be \$8.17 per share and the dilution in as adjusted net tangible book value per share to new investors purchasing common shares in this offering would be \$4.23 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The table and discussion above do not include:

- 9,110,000 common shares issuable upon the exercise of stock options outstanding as of October 14, 2022, at an exercise price of \$7 per share;
- 80,000 common shares reserved for future issuance of awards under the 2022 Plan; and
- 393,769 common shares reserved for future issuance under our 2022 Employee Share Purchase Plan.

UNAUDITED PRO FORMA COMBINED FINANCIAL INFORMATION

The unaudited pro forma combined financial information of the Company gives effect to the Separation and related adjustments in accordance with Article 11 of the SEC's Regulation S-X. In May 2020, the SEC adopted Release No.33-10786 "Amendments to Financial Disclosures about Acquired and Disposed Businesses," or the Final Rule. The Final Rule was effective on January 1, 2021 and the unaudited pro forma combined financial information herein is presented in accordance therewith.

The unaudited pro forma combined financial information presented below have been derived from our historical combined financial statements included in this prospectus. While the historical combined financial statements reflect the historical financial results of the Biohaven Business, these pro forma statements give effect to the separation of the Biohaven Business into an independent, publicly traded company.

The unaudited pro forma combined balance sheet gives effect to the Separation and related transactions described below as if they had occurred on June 30, 2022. The unaudited pro forma adjustments to the combined statement of operations for the six months ended June 30, 2022 and year ended December 31, 2021 assume that the Separation and related transactions occurred as of January 1, 2021.

The unaudited pro forma combined statement of operations for the six months ended June 30, 2022 and year ended December 31, 2021 and the unaudited pro forma combined balance sheet as of June 30, 2022 have been prepared to reflect adjustments to the Company's historical combined financial information for the following transaction accounting and autonomous entity adjustments:

- the issuance of approximately 36,587,038 common shares of the Company as part of the spin-off;
- the effect of our anticipated post-separation capital structure, which includes an anticipated cash advancement to the Company from the Former Parent equal to the remainder of \$275 million of cash minus the sum of the amount of marketable securities and cash and cash equivalents held by the Company as of the close of business on the day prior to the effective time of the Distribution, subject to certain adjustments agreed to by the Former Parent and Pfizer;
- the impact of the Separation and Distribution Agreement, dated as of May 9, 2022 (the "Distribution Agreement"), by and between the Company and the Former Parent, the Transition Services Agreement, dated as of October 3, 2022 (the "Transition Services Agreement"), by and between the Company and the Former Parent, and other agreements between the Company and the Former Parent and the provisions contained therein;
- the one-time expenses associated with the separation of the Company; and
- the impact of the aforementioned adjustments on the Company's income tax expense.

The pro forma adjustments are based on available information and assumptions that management believes are reasonable given the information that is currently available. The unaudited pro forma combined financial statements are for informational purposes only and do not purport to represent what the Company's financial position and results of operations actually would have been had the Spin-Off and the Distribution occurred on the dates indicated, or to project the Company's financial performance for any future period. The historical audited combined annual and unaudited combined interim financial statements of the Biohaven Business have been derived from Former Parent's historical accounting records and reflect certain allocations of expenses. All of the allocations and estimates in such financial statements are based on assumptions that Former Parent's management believes are reasonable. The historical combined financial statements do not necessarily represent the financial position or results of operations of the Biohaven Business had it been operated as a standalone company during the periods or at the dates presented. As a result, autonomous entity adjustments have been reflected in the unaudited pro forma combined financial information.

The unaudited pro forma combined financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our historical audited combined

annual and unaudited combined interim financial statements and corresponding notes thereto included elsewhere in this prospectus.

BIOHAVEN LTD.
UNAUDITED PRO FORMA COMBINED BALANCE SHEET

(Amounts in thousands)

	As of June 30, 2022		
	Historical	Transaction Accounting Adjustments	Pro Forma
Assets			
Current assets:			
Cash	\$ 23,209	\$ 234,590 [A], [B], [C]	\$ 257,799
Prepaid expenses	14,469	—	14,469
Other current assets	9,073	—	9,073
Total current assets	46,751	234,590	281,341
Property and equipment, net	13,397	—	13,397
Intangible assets	18,400	—	18,400
Goodwill	1,390	—	1,390
Other non-current assets	18,282	—	18,282
Total assets	\$ 98,220	\$ 234,590	\$ 332,810
Liabilities and Equity			
Current liabilities:			
Accounts payable	\$ 6,377	\$ (2,640) [B]	\$ 3,737
Accrued expenses and other current liabilities	59,473	—	59,473
Total current liabilities	65,850	(2,640)	63,210
Other non-current liabilities	7,372	—	7,372
Total liabilities	73,222	(2,640)	70,582
Commitments and contingencies			
Equity:			
Common shares, no par value 200,000 shares authorized; 36,587 shares issued and outstanding on a pro forma basis	—	262,228 [D]	262,228
Net investment from Parent	24,998	(24,998) [A], [C], [D]	—
Total equity (deficit)	24,998	237,230	262,228
Total liabilities and equity (deficit)	\$ 98,220	\$ 234,590	\$ 332,810

BIOHAVEN LTD.

UNAUDITED PRO FORMA COMBINED STATEMENT OF OPERATIONS

(Amounts in thousands)

	Six Months Ended June 30, 2022		
	Historical	Autonomous Entity Adjustments	Pro Forma
Operating expenses:			
Research and development	\$ 247,183	\$ 2,701 [E]	\$ 249,884
General and administrative	39,700	9,822 [E]	49,522
Total operating expenses	286,883	12,523	299,406
Loss from operations	(286,883)	(12,523)	(299,406)
Other (expense) income:			
Other expense, net	(71)	—	(71)
Total other (expense) income, net	(71)	—	(71)
Loss before provision for income taxes	(286,954)	(12,523)	(299,477)
Provision for income taxes	13,365	1,480 [G]	14,845
Net loss	<u>\$ (300,319)</u>	<u>\$ (14,003)</u>	<u>\$ (314,322)</u>
Net loss per share - basic and diluted	N/A	[H], [I]	(8.59)
Weighted average common shares outstanding—basic and diluted	N/A	[H], [I]	36,587

BIOHAVEN LTD.

UNAUDITED PRO FORMA COMBINED STATEMENT OF OPERATIONS

(Amounts in thousands)

	Year Ended December 31, 2021			
	Historical	Transaction Accounting Adjustments	Autonomous Entity Adjustments	Pro Forma
Operating expenses:				
Research and development	\$ 181,486	—	\$ 5,775 [E] 5,911 [F] 14,046 [E]	\$ 193,172
General and administrative	37,414	2,550 [C]	213 [F]	54,223
Total operating expenses	218,900	2,550	25,945	247,395
Loss from operations	(218,900)	(2,550)	(25,945)	(247,395)
Other income (expense):				
Gain (loss) from equity method investment	5,261	—	—	5,261
Other income, net	1,209	—	17,683 [F]	18,892
Total other income (expense), net	6,470	—	17,683	24,153
(Loss) income before provision for income taxes	(212,430)	(2,550)	(8,262)	(223,242)
Provision for income taxes	1,366	— [G]	221 [G]	1,587
Net (loss) income	\$ (213,796)	\$ (2,550)	\$ (8,483)	\$ (224,829)
Net loss per share - basic and diluted	N/A		[H], [I]	\$ (6.60)
Weighted average common shares outstanding - basic and diluted	N/A		[H], [I]	34,077

Notes to Unaudited Pro Forma Combined Financial Data

- (A) Reflects the cash contribution from Former Parent to the Company for funding amount pursuant to the Distribution Agreement and subject to adjustments agreed to between Former Parent and Pfizer as described in more detail below.

Immediately prior to the effective time of the Distribution, Pfizer or an affiliate of Pfizer advanced to Former Parent \$275 million, minus the sum of the amount of marketable securities and cash and cash equivalents contained in any accounts held by the Company as of the close of business on the day prior to the date of the Distribution, and Former Parent contributed such funding to the Company. The Company's liabilities under the Distribution Agreement include payment of certain distribution related expenses (see Note (B) below for more information) of the Spin-Off and Merger, which amounts, estimated at approximately \$5.8 million, are deducted from the cash paid by Pfizer to Former Parent immediately prior to the effective time of the Distribution. Former Parent and Pfizer also entered into a side letter, which provided that the Company funding amount would also be reduced by approximately \$4 million in connection with the purchase by the Company of shares of capital stock of Artizan Biosciences Inc., and by approximately \$7.4 million of transaction expenses allocated to the Company.

Following the adjustments described above, we anticipate that the Company had approximately \$257.8 million in cash as of the Distribution date.

The following adjustment has been recorded to cash (in thousands):

	Amount
Biohaven Funding amount, prior to adjustments	\$ 275,000
Less:	
Biohaven cash as of June 30, 2022	(23,209)
Artizan funding amount	(4,000)
Other transaction expenses as agreed per the side letter	(7,429)
Distribution expenses - Amount incurred to date (of which \$2.6M is accrued as of June 30, 2022 (See Note (B) below))	(3,222)
Distribution expenses - Estimated remaining amount (See Note (C) below)	(2,550)
Transaction accounting adjustment to cash	\$ 234,590

- (B) Reflects the payment of \$2.6 million of certain expenses incurred and accrued by the Company as of June 30, 2022. In accordance with the terms of the Distribution Agreement, all costs and expenses incurred on or prior to the Distribution date (whether or not paid on or prior to the Distribution date) in connection with the preparation, execution, delivery, printing and implementation of the Distribution Agreement, the Transition Services Agreement and the Spin-Off registration statement, and the Distribution and the consummation of the transactions contemplated thereby, shall be charged to and paid by the Company, and shall be deemed to be the Company's liabilities.
- (C) Reflects the payment of the remaining \$2.6 million estimated Distribution expenses. The pro forma combined statement of operations for the year ended December 31, 2021 reflects the estimated Distribution related costs expected to be incurred by the Company subsequent to June 30, 2022. The Distribution expenses, except for \$1.5 million in recurring costs for audit fees, are nonrecurring.
- (D) Represents the reclassification of Former Parent's net investment in the Company, including other pro forma adjustments, into common shares, no par value, to reflect the number of our common shares expected to be outstanding at Distribution date. The assumed number of outstanding common shares is based on the Former Parent common shares outstanding as of June 30, 2022 and a pro-rata distribution ratio of one Biohaven common share for every two Former Parent common shares, plus incremental shares of 1,031,503 for the Company RSUs and performance share units ("PSUs") that fully vested upon the

Effective Time as stated in the Distribution Agreement and assumed to be issued by the Company on the Distribution date.

- (E) Reflects the incremental compensation costs for the difference in the amount of salary and bonus and stock-based compensation expenses allocated to the historical statements of operations for the Company and the amount of compensation costs that the Company expects to incur based on actual current employees that are expected to transfer to the Company and based on current employment agreements in place and historical compensation cost amounts.

The following adjustments have been recorded to research and development and general and administrative (in thousands):

	Six months ended June 30, 2022	Year ended December 31, 2021
Salary and bonus	\$ 2,701	\$ 5,775
Stock-based compensation	—	
Autonomous entity adjustment to research and development	\$ 2,701	\$ 5,775
Salary and bonus	\$ 5,362	\$ 9,960
Stock-based compensation	\$ 4,460	\$ 4,086
Autonomous entity adjustment to general and administrative	\$ 9,822	\$ 14,046

- (F) Reflects the effect of a Transition Services Agreement whereby the Company will provide certain transition services to Former Parent, and Former Parent will provide certain transition services to the Company, generally for up to one year with options to extend, as necessary. The other income, net adjustment of \$17.7 million reflects the Transition Services Agreement revenue that the Company would have recorded for services and resources related to commercialization and administration support provided to Former Parent under the Transition Services Agreement. Pricing under this agreement will reflect the Company's costs plus a nominal markup. The research and development adjustment of \$5.9 million and the general and administrative adjustment of \$0.2 million reflects the costs that the Company would have recorded for the services Former Parent will provide to the Company. The research and development and general and administrative adjustments reflect the historical services from Former Parent to the Company under the terms of the Transition Services Agreement. The parties enter into the Transition Services Agreement prior to the Separation.
- (G) Reflects the adjustment to provision for income taxes of \$1.5 million and \$0.2 million for the six months ended June 30, 2022 and year ended December 31, 2021, respectively. The adjustment was determined by applying the respective statutory tax rates to pre-tax pro forma adjustments and reflecting the impact of the valuation allowance recorded against deferred taxes, on a jurisdictional level. The Company's post-separation income taxes will be impacted by many factors, including the profitability in local jurisdictions and the legal entity structure subsequent to Separation, and may be materially different from the pro forma results.
- (H) The number of our common shares used to compute basic earnings per share for the six months ended June 30, 2022 and year ended December 31, 2021 is based on the number of our common shares assumed to be outstanding on those dates, assuming the distribution ratio of one share of Biohaven common share for every two Former Parent common shares outstanding, plus incremental shares of 1,031,503 and 610,253 for the six months ended June 30, 2022 and year ended December 31, 2021, respectively, for Biohaven RSUs and PSUs that will be fully vested upon the Effective Time as stated in the Distribution Agreement and assumed to be issued by the Company on the Distribution date.
- (I) The number of shares used to compute diluted loss per shares is the same as the basic Biohaven common shares as described in Note (H) above, due to a net loss reported in the unaudited pro forma combined

statements of operations for the six months ended June 30, 2022 and year ended December 31, 2021. The Company has not considered the effect of outstanding options and warrants expected to be issued by the Company as replacement awards to Former Parent employees transferring to the Company, since their inclusion would be anti-dilutive.

The Company's anti-dilutive pro forma options and warrants are as follows based on the Distribution Ratio, using an assumed Former Parent value equal to the Merger Consideration pursuant to the Merger Agreement and an assumed Biohaven value of the cash contribution per share from Former Parent to the Company for the funding amount pursuant to the Distribution Agreement and subject to adjustments agreed to between Former Parent and Pfizer (in thousands):

	Six months ended June 30, 2022	Year ended December 31, 2021
Options	2,696	2,609
Warrants	31	31
Total	<u>2,727</u>	<u>2,640</u>

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of the financial condition and results of operations of the Biohaven Business (as defined below) should be read in conjunction with "Unaudited Pro Forma Combined Financial Information" and the audited combined and the unaudited condensed combined financial statements and corresponding notes thereto included elsewhere in this prospectus. This discussion includes forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would" or the negative version of these words and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements include, but are not limited to, statements concerning the following:

- our plans to develop and commercialize our product candidates;
- disruption from the Separation making it more difficult to maintain business and operational relationships;
- unknown liabilities;
- the risk of litigation and/or regulatory actions related to the separation or our business;
- risks and costs related to the implementation of the Separation, including any changes to the configuration of the businesses included in the Separation, if implemented;
- future business combinations or disposals;
- risks related to diverting management's attention from the Company's ongoing business operation;
- 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;
- the clinical utility of our product candidates;
- 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.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. We cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Separation from Former Parent

On May 9, 2022, the Board of Directors of Former Parent approved and directed Former Parent’s management to effect the spin-off of the Kv7 ion channel activators, glutamate modulation and myostatin inhibition platforms, preclinical product candidates, and certain corporate infrastructure currently owned by Former Parent, or collectively the “Biohaven Business”. The Spin-Off was subsequently completed on October 3, 2022. To implement the Spin-Off, Former Parent transferred the related license agreements, intellectual property and Former Parent’s corporate infrastructure, including certain non-commercial employee agreements, share-based awards and other corporate agreements (the “Business”) to Biohaven Ltd, through the Separation. On October 3, 2022, each Former Parent shareholder received one of our common shares for every two Former Parent common shares held of record at the close of business on September 26, 2022, the record date for the Distribution. Registered shareholders received cash in lieu of any fractional common shares that they would have received as a result of the application of the Distribution ratio. Upon completion of the Distribution, we became a stand-alone, publicly traded company focused on the development of our Kv7 ion channel activators, glutamate modulation and myostatin inhibition platforms, which we believe have the potential to alter existing treatment approaches across a diverse set of neurological indications with high unmet need in both large markets and orphan indications.

The historical combined financial statements of the Biohaven Business have been prepared on a stand-alone basis and are derived from Former Parent’s consolidated financial statements and accounting records and are presented in conformity with U.S. GAAP.

The financial position, results of operations and cash flows of the Biohaven Business historically operated as part of Former Parent’s financial position, results of operations and cash flows prior to and until the distribution of our common shares to Former Parent’s shareholders. These historical combined financial statements may not be indicative of the future performance of the Biohaven Business and do not necessarily reflect what its combined results of operations, financial condition and cash flows would have been had it operated as a separate, publicly traded company during the periods presented.

Where we describe historical business activities in this prospectus, we do so as if these transfers had already occurred and Former Parent’s activities related to such assets and liabilities had been performed by the Company.

Refer to Note 1, Nature of the Business and Basis of Presentation, of the Notes to the Combined Financial Statements appearing elsewhere in this prospectus for further discussion of the underlying basis used to prepare the combined financial statements.

Transition from Former Parent and Costs to Operate as an Independent Company

The combined financial statements reflect the operating results and financial position of the Biohaven Business as it was operated by Former Parent prior to the Separation, rather than as an independent company. We have incurred and will continue to incur ongoing operating expenses to operate as an independent company. These costs include the cost of various corporate headquarters functions, information technology-related costs and costs to operate stand-alone accounting, legal and other administrative functions. We also incur non-recurring expenses and non-recurring capital expenditures. As an independent company, our information technology operating costs may be higher than the costs allocated in the historical combined financial statements. It is not practicable to estimate the costs that would have been incurred in each of the periods presented in the historical combined financial statements for the functions described above. Actual costs that would have been incurred if we operated as a stand-alone company during these periods would have depended on various factors, including organizational design, outsourcing and other strategic decisions related to corporate functions, information technology and back office infrastructure. We have entered into a transition services agreement with Former Parent, pursuant to which we provide Former Parent with, and also receive from Former Parent, certain services and resources related to corporate functions for a transitional period. During the transition from Former Parent, we may incur non-recurring expenses to expand our infrastructure.

Transactions with Related Parties

We have entered into a Distribution Agreement and various agreements relating to transition services, licenses and certain other matters with Former Parent. These agreements govern our relationship with Former Parent and include the allocation of employee benefits, taxes and certain other liabilities and obligations attributable to periods prior to, at and after the Distribution. We have agreed to provide Former Parent with indemnities with respect to liabilities arising out of our business, and Former Parent has agreed to provide us with indemnities with respect to liabilities arising out of the business retained by Former Parent. These agreements also include arrangements with respect to support services and a number of on-going commercial relationships. The terms of these agreements, including information on the business purpose of such agreements, transaction prices, related ongoing contractual commitments and any related special risks or contingencies are discussed in greater detail under “Certain Relationships and Related-Party Transactions” appearing elsewhere in this prospectus.

Overview

We are a clinical-stage biopharmaceutical company that combines a deep understanding of neuroscience, immunoscience, disease-related biology, advanced chemistry and expertise in global clinical trials to advance novel therapies for patients. Our experienced management team brings with it a proven track record of delivering new drug approvals for products for diseases such as migraine, depression, bipolar and schizophrenia, and our research programs, built on a deep understanding of disease-related biology and neuropharmacology, are advancing novel therapies with target indications, including epilepsy, mood disorders, OCD, SMA and pain disorders. Our neuroscience portfolio includes a broad pipeline of drug candidates modulating distinct nervous system targets, including Kv7, glutamate receptors, myostatin, and TRP channels.

We are advancing our broad and diverse pipeline with at least five clinical trials currently underway or expected to start by the end of 2022. We have built a highly experienced team of senior leaders and neuroscience drug developers who combine a nimble, results-driven biotech mindset with capabilities in drug discovery and development. In addition, we have several preclinical assets in our early discovery program, targeting neuroscience and immunology indications.

The following table summarizes our recent and expected clinical-stage milestones:

Drug Name	Indication	1H2021	2H2021	1H2022	2H2022	2023
BHV-7000 Kv7 channel modulator	Focal epilepsy	[Bar]			Start Phase 1	
Troiriluzole NCE prodrug of riluzole	Spinocerebellar ataxia	[Bar]		Topline		
	Obsessive-Compulsive Disorder (“OCD”)	[Bar]				Complete Enrollment
Taldefgrobep Alfa Anti-myostatin adnectin	Spinal Muscular Atrophy (“SMA”)	[Bar]			Start Phase 3	
BHV-1100 ARM combo	Multiple Myeloma		Start Phase 1			
Milestone Achieved						

Kv7 Platform

BHV-7000

In April 2022, we closed the acquisition from Knopp Biosciences LLC (“Knopp”) of Channel Biosciences, LLC (“Channel”), a wholly owned subsidiary of Knopp owning the assets of Knopp’s Kv7 channel targeting platform, pursuant to a Membership Interest Purchase Agreement, dated February 24, 2022. The acquisition of the Kv7 channel targeting platform adds 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 potassium channel activator with a preclinical profile suggestive of a wide therapeutic index, high selectivity, and significantly reduced GABA-ergic activity. In the second quarter of 2022, our Clinical Trial Application for BHV-7000 was approved by Health Canada, and we subsequently began clinical development. The Company is evaluating and has not yet finalized potential clinical trial designs, including trial size and primary and secondary endpoints.

In consideration for the transaction, on April 4, 2022, the Company made an upfront payment comprised of \$35 million in cash and 493,254 common shares of Former Parent, valued at approximately \$58.8 million, 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 million for commercial sales-based milestones of BHV-7000. 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 tens for the pipeline programs.

Glutamate Platform

The most advanced product candidate from our glutamate receptor antagonist platform is troiriluzole (previously referred to as trigiriluzole 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 and its oral prodrug BHV-5000.

Troiriluzole

Spinocerebellar Ataxia

In May 2022, the Company announced top-line results from the Phase 3 clinical trial evaluating the efficacy and safety of its investigational therapy, troiriluzole, in adult patients with SCA. The primary endpoint, change from baseline to week 48 on the modified functional Scale for the Assessment and Rating of Ataxia (f-SARA), did not reach statistical significance in the overall SCA population as there was less than expected disease progression over

the course of the study. In the overall study population (N=213), the troriluzole and placebo groups each had mean baseline scores of 4.9 on the f-SARA and the two groups showed minimal change at the 48-week endpoint with f-SARA scores of 5.0 and 5.1, respectively (p=0.76). Troriluzole was well tolerated with an adverse event profile similar to placebo. The frequency of subjects with any TEAE was 80.6% for troriluzole vs. 84.4% for placebo and the frequency of subjects with serious TEAEs was 5.6% for troriluzole vs. 7.3% for placebo.

Post-hoc analysis of efficacy measures by genotype suggests a treatment effect in patients with the SCA Type 3 (“SCA3”) genotype, which represents the most common form of SCA and accounted for 41% of the study population. In the SCA3 subgroup, troriluzole showed a numerical treatment benefit on the change in f-SARA score from baseline to Week 48 compared to placebo (least squares (“LS”) mean change difference -0.55, nominal p-value = 0.053, 95% CI: -1.12, 0.01). SCA patients treated with troriluzole showed minimal disease progression over the study period. Further, in patients in the SCA3 subgroup who were able to walk without assistance at baseline (*i.e.*, f-SARA Gait Item score = 1), troriluzole demonstrated a greater numerical treatment benefit on the change in f-SARA score from baseline to Week 48 compared to placebo (LS mean change difference -0.71, nominal p-value = 0.031, 95% CI: -1.36, -0.07). Notably, the f-SARA is a novel, 16-point scale developed based on feedback from the FDA as the primary outcome measure for this trial; the scale was designed to assess clinically meaningful changes in function.

Across all SCA genotypes, and SCA3 specifically, patient reported falls, as measured by adverse events, reveal reduction of fall risk in the troriluzole group compared to placebo.

The risk reduction of falls in the troriluzole group combined with the progression of f-SARA scores in the untreated SCA3 group compared to SCA3 patients on troriluzole demonstrates that SCA3 patients are experiencing a clinically meaningful improvement in ataxia symptoms on troriluzole treatment.

Obsessive Compulsive Disorder

We commenced a Phase 2/3 double-blind, randomized, controlled trial to assess the efficacy of troriluzole in adults with OCD 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. Troriluzole treated subjects (n = 111) had a mean Y-BOCS improvement of -3.4 points from baseline versus -2.9 for placebo-treated (n = 115) subjects [difference -0.5 and p-value = 0.451] at week 4, -5.1 points (n = 96) versus -3.6 for placebo-treated (n = 108) subjects [difference -1.5 and p-value = 0.041] at week 8, and -5.9 points (n = 99) versus -4.9 for placebo-treated (n = 102) subjects [difference -1.0 and p-value = 0.220] at week 12. Troriluzole’s safety profile was generally consistent with past clinical trial experience with its active metabolite, riluzole. Treatment emergent adverse events (“TEAE”s) were mostly reported to be mild in intensity. TEAEs that occurred in at least 5% of patients in the troriluzole group, and more frequently in the troriluzole group than in the placebo group, were headache, dizziness, fatigue, somnolence, nausea and nasopharyngitis.

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 a Phase 3 program. The Phase 3 program will have an estimated total enrollment of 1,300 participants with a primary endpoint of change from baseline on the Y-BOCS total score at week 4, 8 and 10. The two Phase 3 randomized, double-blind, placebo-controlled trials that make-up our Phase 3 program for OCD are currently ongoing with enrollment expected to be completed in 2023.

Glioblastoma

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, which we believe was based on the existence of 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. In July 2022, the Company and GCAR announced that enrollment has commenced in GBM AGILE for the evaluation of troriluzole.

BHV-5500

We are developing BHV-5500 (lanicemine), 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 neuropathy. Former Parent acquired worldwide rights to BHV-5500 and its oral prodrug BHV-5000 under an exclusive license agreement with AstraZeneca AB in October 2016. Current work is focused on formulation development.

Myostatin Platform

Taldefgrobep Alfa

In February 2022, 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.

In July 2022, we commenced enrollment in a Phase 3 clinical trial assessing the efficacy and safety of taldefgrobep alfa in Spinal Muscle Atrophy (“SMA”). 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 Phase 3 placebo-controlled, double-blind trial is designed to evaluate the efficacy and safety of taldefgrobep as an adjunctive therapy for participants who are already taking a stable dose of nusinersen or risdiplam or have a history of treatment with onasemnogene abeparvovec-xioi, compared to placebo. The study is not restricted nor limited to patients based on ambulatory status or classification of SMA. We expect to enroll approximately 180 patients in this randomized, double-blind, placebo-controlled global trial.

Early Discovery Programs

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 to serve as the integrated chemistry and discovery research arm of the Company. We are continuing 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 one with PeptiDream for the development of immuno-oncology therapeutics.

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, Former Parent and FCCDC have established a TDP-43 Research Plan that provides for certain milestones to be achieved by FCCDC, and milestone payments to be made by the Company. The Company is evaluating and has not yet finalized potential clinical trial designs, including size and primary and secondary endpoints.

University of Connecticut License Option

In October 2018, we entered into 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. 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. The Company is evaluating and has not yet finalized potential clinical trial designs, including size and primary and secondary endpoints.

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 early 2023, as well as to explore additional disease targets. 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. In June 2022, we and Artizan executed a non-binding indication of interest which describes terms under which we and Artizan would amend the 2020 Artizan Agreement to eliminate certain milestone payments required by us in exchange for limiting our option to the selection of the first (ARZC-001) licensed product. The Company is evaluating and has not yet finalized potential clinical trial designs, including size and primary and secondary endpoints.

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 treatment of other diseases and conditions. The Company is evaluating and has not yet finalized potential clinical trial designs, including size and primary and secondary endpoints. 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.

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 open-label single center Phase 1a/1b study 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 or second remission prior to autologous stem cell transplant (“ASCT”). We expect to enroll 30 newly diagnosed multiple myeloma patients. The primary outcome measures are dose limiting toxicities following combination product administration (time frame: 90 to 100 days post-combination product administration) and incidence and severity of side effects related to the combination product.

TRPM3 Antagonists

In January 2022, we entered into an Exclusive License and Research Collaboration Agreement with Katholieke Universiteit Leuven (“KU Leuven”) to develop and commercialize TRPM3 antagonists to address the growing proportion of people worldwide living with chronic pain disorders (the “KU Leuven Agreement”). 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, 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 is being evaluated 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. The Company is evaluating and has not yet finalized potential clinical trial designs, including size and primary and secondary endpoints.

Components of the Results of Operations of the Biohaven Business

Revenue

To date, the Biohaven Business has not generated any revenue from product sales and we do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval or additional license agreements with third parties, then Biohaven Business may generate revenue in the future from product sales.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. The Biohaven Business expenses 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; and
- payments made in cash, equity securities or other forms of consideration under third-party licensing agreements prior to regulatory approval of the product candidate.

The Biohaven Business recognizes 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

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, CMOs, 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 the Biohaven Business does 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 late-stage clinical trials, and prepare regulatory filings for our product candidates. We also expect to incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into license agreements to acquire the rights to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishment of an appropriate safety profile with IND-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- establishment of commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- acquisition, maintenance, defense and enforcement of patent claims and other intellectual property rights;
- significant and changing government regulation;
- initiation of commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintenance of a continued acceptable safety profile of the product candidates following approval.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including salaries, benefits and travel expenses for our executive, finance, business, corporate development and other administrative functions; and non-cash share-based compensation expense. General and administrative expenses also include facilities and other related expenses, including rent, depreciation, maintenance of facilities, insurance and supplies; and for public relations, audit, tax and legal services, including legal expenses to pursue patent protection of our intellectual property.

We anticipate that our general and administrative expenses, including payroll and related expenses, will remain significant in the future as we continue to support our research and development activities 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, office-related costs, such as information technology costs, and certain costs to establish ourselves as a standalone public company, as well as ongoing additional costs associated with operating as an independent, publicly traded company.

Other Income (Expense)

Gain (Loss) from Equity Method Investment

Prior to the Company's acquisition of Kleo in January 2021, the Company owned approximately 41.9% of the outstanding shares as of December 31, 2020, and accounted for the Company's investment in Kleo under the equity method of accounting. As a result, the Company's proportionate share of Kleo's net income or loss each reporting period was included in other income (expense), net, in the combined statements of operations and comprehensive loss and results in a corresponding adjustment to the carrying value of the equity method investment on the combined balance sheet.

On January 4, 2021, the Company acquired the remaining shares of Kleo it did not previously own.

Other Income, Net

Other income, net primarily consists of a gain recognized upon the Company's determination that the value of the contingent value right related to our Kleo acquisition was immaterial as of December 31, 2021. The consideration transferred for the Kleo acquisition included 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 \$17.3 million. At December 31, 2021, the Company determined the value of the contingent value right to be immaterial and recognized a gain of \$1.5 million related to the contingent value right in other income, net.

Provision for Income Taxes

The income tax amounts in the combined financial statements have been calculated on a separate return method and are presented as if the Company's operations were separate taxpayers in the respective jurisdiction. Therefore, tax expense, cash tax payments, and items of current and deferred taxes may not be reflective of our actual tax balances prior to or subsequent to the Distribution.

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, the Company and all dividends, interest, rents, royalties, compensation and other amounts paid by the Company to persons who are not resident in the BVI and any capital gains realized with respect to any shares, debt obligations, or other securities of the Company by persons who are not resident in the BVI are exempt from all provisions of the Income Tax Ordinance in the BVI.

BVI has historically outsourced all of the research and clinical development for its programs under a master services agreement with BPI. As a result of providing services under this agreement, BPI was profitable during the years ended December 31, 2021 and 2020, and BPI is subject to taxation in the United States. As such, in each reporting period, the Biohaven Business tax provision includes the effects of consolidating the results of operations of BPI.

At December 31, 2021 and 2020, we continued to maintain a full valuation allowance against our net deferred tax assets, which are comprised primarily of research and development credit carryforwards and future stock based compensation deductions based on management's assessment that it is more likely than not that the deferred tax assets will not be realized. The Biohaven Business recorded an income tax provision during the years ended December 31, 2021 and 2020 of \$1.4 million and \$0.0 million, respectively, which primarily represents U.S. Federal tax and state taxes related to BPI's profitable operations in the United States.

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.

Results of Operations

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table summarizes the results of operations of the Biohaven Business for the six months ended June 30, 2022 and 2021:

(in thousands)	Six Months Ended June 30,		Change
	2022	2021	
Operating expenses:			
Research and development	247,183	92,695	154,488
General and administrative	39,700	19,830	19,870
Total operating expenses	286,883	112,525	174,358
Loss from operations	(286,883)	(112,525)	(174,358)
Other income (expense):			
Gain from equity method investment	—	5,261	(5,261)
Other expense, net	(71)	(240)	169
Total other income (expense), net	(71)	5,021	(5,092)
Loss before provision for income taxes	(286,954)	(107,504)	(179,450)
Provision for income taxes	13,365	41	13,324
Net loss and comprehensive loss	(300,319)	(107,545)	(192,774)

Research and Development Expenses

(in thousands)	Six Months Ended June 30,		Change
	2022	2021	
Direct research and development expenses by program:			
BHV-7000	\$ 119,438	\$ —	\$ 119,438
Troriluzole	\$ 26,642	\$ 29,683	\$ 3,041
Verdiperstat	8,121	13,482	5,361
BHV-1100	499	770	(271)
BHV-1200 (COVID 19)	4,973	602	4,371
BHV-2000	6,996	—	6,996
Other programs	215	(144)	359
Unallocated research and development costs:			
Personnel related (including share-based compensation)	55,240	32,464	22,776
Preclinical research programs	18,224	12,904	5,320
Other	6,835	2,934	3,901
Total research and development expenses	\$ 247,183	\$ 92,695	\$ 154,488

Research and development expenses were \$247.2 million for the six months ended June 30, 2022, compared to \$92.7 million for the six months ended June 30, 2021. The increase of \$154.5 million was primarily due to increases of \$119.4 million in expenses related to BHV-7000, \$4.4 million related to BHV-1200, \$7.0 million related to BHV-2000, \$5.3 million in costs related to our preclinical research programs, and \$22.8 million in personnel related costs. The \$119.4 million increase in expense for BHV-7000 was primarily due to the Kv7 Platform Acquisition, which resulted in \$93.7 million of expense recorded to R&D during the six months ended June 30, 2022, and a \$25.0

million milestone payment accrued during the second quarter of 2022 which became payable in June 2022. These increases were partially offset by decreases of \$5.4 million in direct costs for the Verdiperstat program and \$3.0 million in direct costs for the Troriluzole program. Personnel-related costs for the six months ended June 30, 2022 and 2021 included share-based compensation expense of \$37.3 million and \$21.9 million, respectively.

General and Administrative Expenses

General and administrative expenses were \$39.7 million for the six months ended June 30, 2022, compared to \$19.8 million for the six months ended June 30, 2021. The increase of \$19.9 million was primarily due to increases in personnel-related costs, including share-based compensation, as well as increased expenses related to accounting, legal and other professional fees. Personnel-related costs for the six months ended June 30, 2022 and 2021 included share-based compensation expense of \$23.7 million and \$15.4 million, respectively.

Other Income (Expense), Net

Other income (expense), net was a net expense of \$0.1 million for the six months ended June 30, 2022, compared to net income of \$5.0 million for the six months ended June 30, 2021. The decrease of \$5.1 million in net income was primarily due to the acquisition of Kleo Pharmaceuticals, Inc. in January 2021, which resulted in a gain of \$5.3 million being recognized during the six months ended June 30, 2021 upon our remeasurement to fair value of the existing equity interest in Kleo.

Provision for Income Taxes

We recorded a provision for income taxes of \$13.4 million for the six months ended June 30, 2022 and an insignificant provision for the six months ended June 30, 2021. The increase in income tax expense was primarily attributable to the mandatory capitalization of R&D expenses effective January 1, 2022 under the Tax Cuts and Jobs Act, offset by an increased benefit to the Company's foreign derived intangible income deduction.

Comparison of the Years Ended December 31, 2021 and 2020

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

(in thousands)	Year Ended December 31,		Change
	2021	2020	
Operating expenses:			
Research and development	\$ 181,486	\$ 98,460	\$ 83,026
General and administrative	37,414	16,046	21,368
Total operating expenses	218,900	114,506	104,394
Loss from operations	(218,900)	(114,506)	(104,394)
Other income (expense):			
Gain (loss) from equity method investment	5,261	(4,162)	9,423
Other income, net	1,209	—	1,209
Total other income (expense), net	6,470	(4,162)	10,632
Loss before provision for income taxes	(212,430)	(118,668)	(93,762)
Provision for income taxes	1,366	—	1,366
Net loss and comprehensive loss	\$ (213,796)	\$ (118,668)	\$ (95,128)

Research and Development Expenses

(in thousands)	Year Ended December 31,		Change
	2021	2020	
Direct research and development expenses by program:			
Troriluzole	\$ 50,637	\$ 42,101	\$ 8,536
Verdiperstat	30,664	21,036	9,628
BHV-1100	1,476	—	1,476
BHV-1200 (COVID 19)	3,023	—	3,023
Other programs	1,108	390	718
Unallocated research and development costs:			
Personnel related (including share-based compensation)	64,308	31,060	33,248
Preclinical research programs	22,592	1,434	21,158
Other	7,678	2,439	5,239
Total research and development expenses	\$ 181,486	\$ 98,460	\$ 83,026

Research and development expenses were \$181.5 million for the year ended December 31, 2021, compared to \$98.5 million for the year ended December 31, 2020. The increase of \$83.0 million was primarily due to increases of \$8.5 million in direct costs for the troriluzole program, \$9.6 million in direct costs for the verdiperstat program, \$33.2 million in personnel related costs, and \$21.2 million in costs related to our preclinical research programs.

The increase in personnel costs of \$33.2 million was primarily a result of hiring additional personnel to support the expanding number of clinical trials and preclinical programs. Personnel-related costs for the years ended December 31, 2021 and 2020 included share-based compensation expense of \$39.4 million and \$18.5 million, respectively.

The \$21.2 million increase in preclinical research costs was primarily due to the following: an upfront payment of \$2.0 million to Yale University in connection with the Yale MoDE Agreement; an upfront payment of \$5.9 million to Moda Pharmaceuticals LLC in connection with a consulting agreement to further the scientific advancement of technology, drug discovery platforms (including the technology licensed under the Yale MoDE Agreement), product candidates and related intellectual property owned or controlled by the Company; and a \$3.8 million upfront payment to Reliant Glycosciences, LLC in connection with a development and license agreement to develop and commercialize conjugated antibodies for therapeutic uses relating to IgA nephropathy and treatment of other diseases and conditions. The remainder of the increase primarily related to the rise in the number of ongoing preclinical research programs, including increased costs for outsourced chemistry and research arrangements.

General and Administrative Expenses

General and administrative expenses were \$37.4 million for the year ended December 31, 2021, compared to \$16.0 million for the year ended December 31, 2020. The increase of \$21.4 million was primarily due to increased personnel-related expenses of \$16.4 million, including share-based compensation expense, and a \$2.0 million increase in expenses related to accounting, legal and other professional fees. Share-based compensation expense included in personnel-related costs increased \$15.2 million, from \$11.0 million for the year ended December 31, 2020 to \$26.3 million for the year ended December 31, 2021, primarily due to annual equity incentive awards that were granted by Former Parent in the first quarter of 2021.

Other Income (Expense), Net

Other income (expense), net was a net income of \$6.5 million for the year ended December 31, 2021, compared to net expense of \$4.2 million for the year ended December 31, 2020. The decrease of \$10.6 million in net expense was primarily due to a \$9.4 million change in gain (loss) on equity investment, primarily due to the acquisition of

Kleo Pharmaceuticals, Inc. in January 2021, which resulted in a gain of \$5.3 million being recognized during 2021 upon our remeasurement to fair value of the existing equity interest in Kleo. The decrease was also due to a \$1.2 million increase in other income, net, which was primarily due to a \$1.5 million gain recognized in 2021 upon the Company's determination that the fair value of a contingent value right recorded relating to the acquisition of Kleo Pharmaceuticals was immaterial as of December 31, 2021.

Provision for Income Taxes

We recorded a provision for income taxes of \$1.4 million for the year ended December 31, 2021 and \$0.0 million for December 31, 2020. We recorded a tax provision for the year ended December 31, 2021 for the U.S. Federal and state income taxes related to BPI's profitable operations in the United States.

Liquidity and Capital Resources

Since inception as a business of Former Parent, we have not generated any revenue and have incurred significant operating losses and negative cash flows from operations. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. We expect to continue to incur significant expenses for at least the next several years as we advance our product candidates from discovery through preclinical development and clinical trials and seek regulatory approval and pursue commercialization of any approved product candidate. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional product candidates.

Historically, we have funded our operations primarily with proceeds allocated to our business from financing arrangements entered into by Former Parent and through the one-time issuance of contingently redeemable non-controlling interests. Prior to the Distribution, transfers of cash for general operating, investing, and financing activities and net cost allocation from Former Parent were reflected in net investment from Parent in our combined balance sheets. The cash reported on our combined balance sheet represents cash held by Biohaven entities at the end of the period presented.

As of June 30, 2022, we had cash of \$23.2 million, excluding restricted cash of \$0.8 million relating to collateral held by a bank for a letter of credit ("LOC") issued in connection with leased office space in Yardley, Pennsylvania. We continuously assess our working capital needs, capital expenditure requirements, and future investments or acquisitions.

Cash Flows

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

(Amounts in thousands)	June 30,		December 31,	
	2022	2021	2021	2020
Net cash used in operating activities	\$ (126,722)	\$ (69,053)	\$ (145,840)	\$ (75,957)
Net cash (used in) provided by investing activities	(36,250)	1,176	944	(2,697)
Net cash provided by financing activities	109,874	75,791	138,447	152,242
Net (decrease) increase in cash and restricted cash	\$ (53,098)	\$ 7,914	\$ (6,449)	\$ 73,588

Operating Activities

Net cash used in operating activities was \$126.7 million for the six months ended June 30, 2022 and primarily consisted of a net loss of \$300.3 million adjusted for non-cash items, including share-based compensation of \$60.9 million, acquisition of IPR&D asset of \$93.7 million (of which 35.0 million was paid in cash and classified as an investing activity and \$58.7 million was paid in Parent common shares), depreciation and amortization of \$0.7 million, issuance of Parent common shares as payment for license and consulting agreements of \$1.8 million, and other non-cash items of \$— million, as well as the change in our net working capital.

Net cash used in operating activities was \$69.1 million for the six months ended June 30, 2021 and primarily consisted of a net loss of \$107.5 million adjusted for non-cash items, including share-based compensation of \$37.3 million, depreciation and amortization of \$0.5 million, issuance of Parent common shares as payment for license and consulting agreements of \$4.2 million, gain from equity method investment of \$5.3 million, and other non-cash items of \$2.0 million, as well as the change in our net working capital. The year-over-year increase in cash usage of \$57.7 million was primarily due an increase in R&D development spending.

Net cash used in operating activities was \$145.8 million for the year ended December 31, 2021 and primarily consisted of a net loss of \$213.8 million adjusted for non-cash items, including share-based compensation of \$65.6 million, depreciation and amortization of \$1.4 million, issuance of Parent common shares as payment for license and consulting agreements of \$7.9 million, gain from equity method investment of \$5.3 million, and other non-cash items of \$3.4 million, as well as the change in our net working capital. The year-over-year increase in cash usage of \$69.9 million was primarily due an increase in R&D development spending.

Net cash used in operating activities was \$76.0 million for the year ended December 31, 2020 and primarily consisted of a net loss of \$118.7 million adjusted for non-cash items, including share-based compensation of \$29.5 million, depreciation and amortization of \$0.1 million, and loss from equity method investment of \$4.2 million, as well as the change in our net working capital.

Investing Activities

Net cash used in investing activities was \$36.3 million for the six months ended June 30, 2022 and was primarily due to our acquisition of Channel Biosciences LLC for \$93.7 million of which \$35.0 million was paid in cash and classified as a payment for IPR&D asset acquisition under investing activities and \$58.7 million was paid in Parent common shares.

Net cash provided by investing activities was \$1.2 million for the six months ended June 30, 2021 and was due to \$1.9 million in cash acquired from the business acquisition of Kleo partially offset by \$0.7 million in purchases of lab equipment to support Biohaven Labs.

Net cash provided by investing activities was \$0.9 million for the year ended December 31, 2021 and was due to \$1.9 million in cash acquired from the business acquisition of Kleo partially offset by \$0.9 million in purchases of lab equipment to support Biohaven Labs.

Net cash used in investing activities was \$2.7 million for the year ended December 31, 2020 and was due to \$1.1 million in purchases of office and lab equipment and \$1.6 million in payments for leasehold improvements related to our Yardley office lease.

Financing Activities

Net cash provided by financing activities was \$109.9 million for the six months ended June 30, 2022 and was due to \$109.9 million in net transfer from Parent for our general operating, investing, and financing activities and net cost allocations from Parent, excluding share-based compensation.

Net cash provided by financing activities was \$75.8 million for the six months ended June 30, 2021 and was primarily due to \$75.4 million in net transfer from Parent for our general operating, investing, and financing activities and net cost allocations from Parent, excluding share-based compensation.

Net cash provided by financing activities was \$138.4 million for the year ended December 31, 2021 and was primarily due to \$138.1 million in net transfer from Parent for our general operating, investing, and financing activities and net cost allocations from Parent, excluding share-based compensation.

Net cash provided by financing activities was \$152.2 million for the year ended December 31, 2020 and was due to \$92.2 million in net transfer from Parent for general operating and investing activities and net cost allocations from Parent, excluding share-based compensation, and \$60.0 million from the sale of contingently redeemable non-controlling interest by BioShin Limited.

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 potential commercialization of our product candidates. Our costs will also increase as we:

- continue the development of our clinical-stage neurology assets, including the initiation of a Phase 1 clinical trial for BHV-7000 for the treatment of focal epilepsy and a Phase 3 clinical trial for taldefgrobep alfa for the treatment of SMA;
- continue the development of our glutamate modulation product candidate;
- 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;
- 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.

We expect that our cash, as of the date of this prospectus, will be sufficient to fund our current forecast for operating expenses, financial commitments and other cash requirements for more than one year. Thereafter, we expect we will 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 commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize or whether we commercialize jointly or on our own.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;

- the effect of COVID-19 pandemic on our business operations and funding needs;
- 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; and
- the extent to which we acquire or in-license other product candidates and technologies

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 its 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.

Critical Accounting Policies and Significant Judgments and Estimates of the Biohaven Business

Our financial results are affected by the selection and application of accounting policies and methods. Significant accounting policies which require management’s judgment are discussed below.

Valuation and Impairment of Intangible Assets

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. If successfully completed, the Company would make a determination with respect to each project 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 fair value of acquired intangible assets is primarily determined using an income-based approach referred to as the multi-period excess earnings method utilizing Level 3 fair value inputs. The market participant valuation assumes a global view considering all potential jurisdictions and indications based on discounted after-tax cash flow projections, risk adjusted for estimated probability of technical and regulatory success.

The Company evaluates IPR&D for impairment at least annually in the fourth quarter and 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.

Accrued Research and Development Expenses

As part of the process of preparing the combined financial statements of the Biohaven Business, the Biohaven Business is required to estimate its accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on its behalf and estimating the level of service performed and the associated cost incurred for the service when it has not yet been invoiced or otherwise notified of actual costs. The majority of its service providers invoice the Biohaven Business in arrears for services performed, on a pre-determined schedule or when contractual milestones

are met; however, some require advance payments. The Biohaven Business makes estimates of its accrued expenses as of each balance sheet date in the combined financial statements based on facts and circumstances known to the Biohaven Business at that time. It periodically confirms the accuracy of these estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors, including central laboratories, in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical and clinical studies; and
- CMOs in connection with drug substance and drug product formulation of preclinical and clinical trial materials.

The Biohaven Business bases its expenses related to preclinical studies and clinical trials on its estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, the Biohaven Business estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Biohaven Business adjusts the accrual or the amount of prepaid expenses accordingly. Although it does not expect its estimates to be materially different from amounts actually incurred, the Biohaven Business' understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses of the Biohaven Business.

Cost Allocations

The Biohaven Business has historically operated as part of Former Parent and not as a separate, publicly traded company. Accordingly, certain shared costs and share-based compensation expenses have been allocated to us and are reflected as expenses in the accompanying combined statements of operations and comprehensive loss. Management considers the expense methodology and resulting allocation to be reasonable for all periods presented; however, the allocations may not be indicative of actual expenses that would have been incurred had we operated as an independent, publicly traded company for the periods presented. Actual costs that we may have incurred had we been a stand-alone company would depend on a number of factors, including the organizational structure, what corporate functions the Company might have performed directly or outsourced and strategic decisions the Company might have made in areas such as executive management, legal and other professional services, and certain corporate overhead functions.

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 combined financial statements appearing at the end of this prospectus.

Emerging Growth Company

We are an "emerging growth company," as defined in the JOBS Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies, including, but not limited to, presenting only two years of audited financial statements, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation, and an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or golden parachute arrangements.

In addition, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this provision of the JOBS Act. As a result, we will not be subject to new or revised accounting standards at the same time as other public companies that are not emerging growth companies. Therefore, our consolidated financial statements may not be comparable to those of companies that comply with new or revised accounting pronouncements as of public company effective dates.

BUSINESS

We were incorporated on May 2, 2022 as a direct, wholly owned subsidiary of Biohaven Pharmaceutical Holding Company Ltd. On May 9, 2022, we and Former Parent entered into the Distribution Agreement. On October 3, 2022, Former Parent completed the Distribution to holders of its common shares of all of the outstanding common shares of Biohaven and the Spin-Off of Biohaven from Former Parent. Unless expressly indicated or the context requires otherwise, the terms “Biohaven,” “Company,” “we,” “us,” and “our” in this prospectus refer to Biohaven Ltd. and its subsidiaries, including as a business of the Former Parent, to the extent the context requires.

Following the Distribution, we now own clinical stage assets, including the Kv7 ion channel activators, glutamate modulation and myostatin inhibition platforms, preclinical product candidates, and certain corporate infrastructure previously owned by Former Parent and have proprietary rights to a number of trademarks used in this prospectus which are important to our business, including the Biohaven logo. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and TM symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

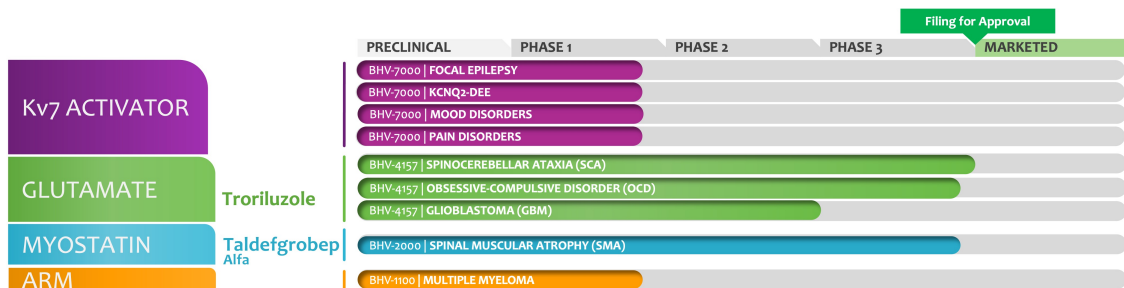
Overview

We are a clinical-stage biopharmaceutical company that combines a deep understanding of neuroscience, immunology, disease-related biology, advanced chemistry and expertise in global clinical trials to advance novel therapies for patients. Our experienced management team brings with it a proven track record of delivering new drug approvals for products for diseases such as migraine, depression, bipolar and schizophrenia, and our research programs, built on a deep understanding of disease-related biology and neuropharmacology, are advancing novel therapies with target indications, including epilepsy, mood disorders, OCD, SCA, SMA and pain disorders. Our neuroscience portfolio includes a broad pipeline of drug candidates modulating distinct nervous system targets, including Kv7, glutamate receptors, myostatin, and TRP channels.

We are advancing our broad and diverse pipeline with at least five clinical trials currently underway or expected to start by the end of 2022. We have built a highly experienced team of senior leaders and neuroscience drug developers who combine a nimble, results-driven biotech mindset with capabilities in drug discovery and development. In addition, we have several preclinical assets in our early discovery program, targeting neuroscience and immunology indications.

Product Candidates

The following table summarizes some of our key clinical programs in addition to upcoming potential clinical development milestones for our product candidates. We hold the worldwide rights to all of our product candidates.



Our Kv7 Platform

Kv7 Platform Acquisition

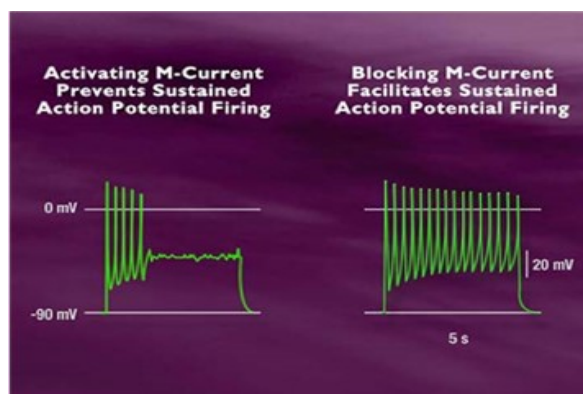
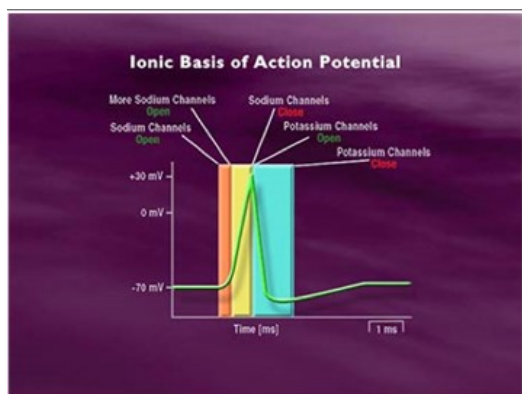
In February 2022, we announced that we entered into a definitive agreement with Channel Biosciences, LLC, a subsidiary of Knopp Biosciences, LLC, to acquire a drug discovery platform targeting Kv7 ion channels, adding the latest advances in ion channel modulation to our growing neuroscience portfolio. BHV-7000 (formerly known as KB-3061), the lead asset from the Kv7 platform is an activator of Kv7.2/Kv7.3, a key ion channel involved in neuronal signaling and in regulating the hyperexcitable state in epilepsy. In the second quarter of 2022, our Clinical Trial Application for BHV-7000 was approved by Health Canada, and we subsequently began clinical development. The Company is evaluating and has not yet finalized potential clinical trial designs, including trial size, and primary and secondary endpoints.

Kv7's Role in Epilepsy and Other Central Nervous System Disorders

Epilepsy

Because of their fundamental role in health and their aberrant role in disease, ion channels in cell membranes represent a broad and important class of drug targets. Sodium channels and potassium channels form the ionic basis of the action potential in electrically charged cells throughout the body (see figures below). The Kv7 protein in particular forms a channel that regulates the flow of charged potassium ions (K⁺) across cell membranes, repolarizing nerve cells and resetting them for normal action potential firing. Kv7 channels include a family of channel subtypes, designated as Kv7.1 through Kv7.5, and they are formed by tetramers of identical or compatible subunits. Some of these channel subtypes localize in nerve cells (neurons) while others can be found in cardiac muscle, smooth muscle, and other tissue types.

The Kv7 subunits, Kv7.2 and Kv7.3, are widely expressed in the brain, notably in the cortex and hippocampus, and together they form Kv7.2/7.3 heteromeric channels that produce the M-current (I_{KM}), a critical regulator of neuronal excitability (see figures below). Kv7.2/7.3 channels normally perform a natural “braking” function by regulating the electrical excitability and hyperexcitability of brain cells. Dysfunction of these channels, due to genetic mutations or other factors, increases seizure risk, while augmenting the ‘open’ activity of these channels has been demonstrated to reduce neuronal hyperexcitability and seizure frequency in electrophysiology laboratories, in animal models, and, most importantly, in patients.



White, Role of Potassium Channel Ions in Epilepsy, Medscape.org

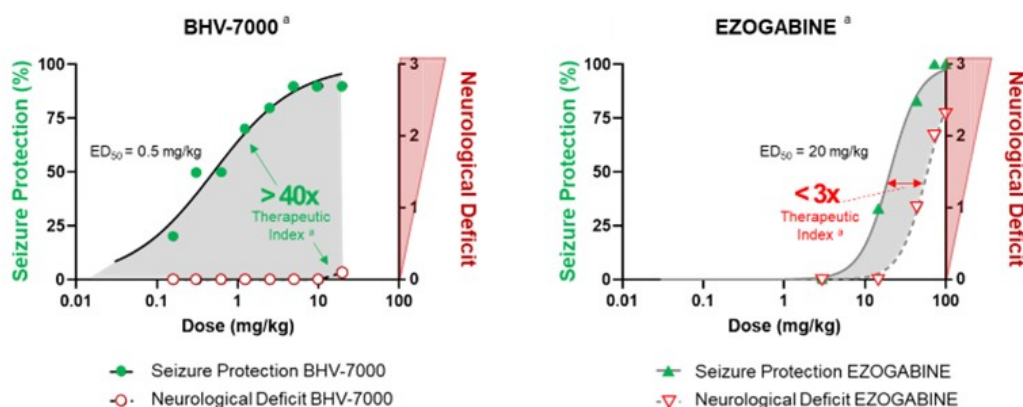
We are synthesizing novel Kv7.2/7.3 activators as we seek to improve on the selectivity, potency, and other characteristics of ezogabine (Potiga in the U.S. and Trobalt (retigabine) in Europe), a drug approved in 2011 for the treatment of refractory epilepsy and voluntarily withdrawn from the market in 2017 because of poor tolerability and structure-related toxicities that limited its use, and ezogabine-like compounds while averting its negative attributes,

including off-target activity at a different brain ion channel, gamma-aminobutyric acid (“GABA”)A receptor (“GABAA-R”).

Using a structure-based approach, supplemented by in silico modeling, we have identified structural features of our molecules critical to Kv7 activation. We have applied these analyses to the generation of proprietary chemical leads structurally distinct from known Kv7 activators, including ezogabine and flupirtine, the only other approved Kv7 modulator, approved in Europe for the treatment of acute pain. Our team has synthesized a large library of Kv7-activating molecules and are advancing them according to stringent criteria requiring improvements over ezogabine, including chemical stability, synthetic tractability, the avoidance of structural motifs associated with the generation of reactive metabolites and other unwanted, off-target activity, including GABAA-R activation.

Epilepsy is the initial disease we are targeting with activators from our Kv7 platform. Epilepsy affects approximately 3.5 million Americans, or more than 1.2% of adults and 0.6% of children in the U.S., and more than 50 million patients worldwide, according to the World Health Organization (“WHO”). It is the fourth most common neurological disorder, and many patients struggle to achieve freedom from seizures, with more than one third of patients requiring two or more medications to manage their epilepsy. While the use of anti-seizure medications is often accompanied by dose-limiting side effects, our clinical candidate BHV-7000 is specifically designed to target subtypes of Kv7 potassium channels without engagement of GABA_A receptors. The lack of GABAA-R activity potentially gives BHV-7000 a wide therapeutic window and is expected to result in an improved side effect profile, limiting the somnolence and fatigue often seen in patients receiving anti-seizure medications. By adding BHV-7000 to our pipeline, we aim to bring this potassium channel modulator as a potential solution to patients with epilepsy who remain uncontrolled on their current regimens.

BHV-7000 is a Kv7.2/7.3 channel activator from a novel, bicyclic imidazole class with significant in vivo anticonvulsant activity and a wide therapeutic index. In the most widely used and highly-validated preclinical model of epilepsy, the maximal electroshock (“MES”) model, data for BHV-7000 and ezogabine were collected in independent experiments (see figures below), measuring the activity of both compounds in preventing seizures (ED₅₀) and recording the neurologic deficit 5 to 15 minutes prior to the MES test to calculate the tolerability index (“TI”). The neurologic deficit is a behavioral index ranging from normal activity (score of 0) to a loss of righting reflex (score of 3). As shown below, BHV-7000 was demonstrated to have a calculated ED₅₀ = 0.5 mg/kg with limited impact on behavior producing a TI > 40x. In contrast, ezogabine was 40x less potent (a calculated ED₅₀ = 20 mg/kg) in the MES model with a narrow TI < 3x. The narrow preclinical TI for ezogabine is consistent with the clinical experience with the drug where side effects such as somnolence and dizziness limited its use at doses that prevented seizures in patients.



KCNQ2 Epileptic Encephalopathy

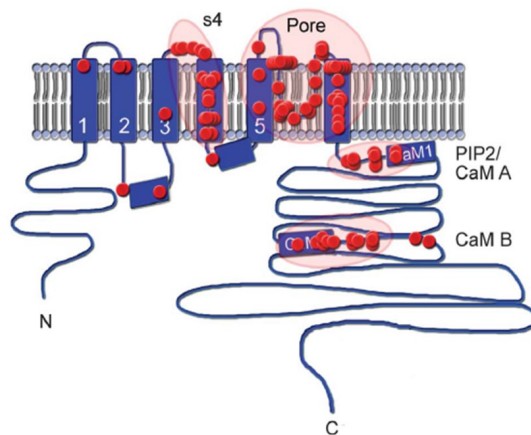
KCNQ2 epileptic encephalopathy (“KCNQ2-EE”) is a rare pediatric epileptic encephalopathy first described in 2012 resulting from dominant-negative mutations in the KCNQ2 gene. Epileptic encephalopathies (“EE”) comprise a

group of epilepsy syndromes in which onset of recurrent and medically refractory seizures are associated with cognitive and broader developmental delay or regression. Early infantile epileptic encephalopathy, also called Ohtahara syndrome, and early myoclonic encephalopathy are the earliest-presenting of these age-dependent syndromes, clinically defined by onset within the first three months after birth. Although only recently described, heterozygous de novo variants in KCNQ2 are a highly validated cause of early onset epileptic encephalopathy, and KCNQ2-EE has emerged as a well-defined clinical entity with a characteristic neonatal presentation, including hypotonia, treatment-resistant tonic seizures, a profoundly abnormal interictal electroencephalogram (“EEG”) with prominent burst-suppression, and most often with moderate-to-profound global developmental delay, resulting from a defined subset of missense variants in the gene. KCNQ2-EE is thus both a seizure disorder and a developmental disorder caused by pathogenic, dominant-negative KCNQ2 mutations.

Identification of genetic etiologies has created the opportunity to treat not just the symptoms of KCNQ2-EE, including seizures, but also the underlying causes, including attenuating or reversing the effects of the dominant-negative variants responsible for KCNQ2-EE. Developmental delay is an intractable feature of KCNQ2-EE even though seizure frequency tends to diminish after infancy and EEG organization tends to improve. Importantly, limited clinical evidence, including a case series of four infants with KCNQ2-EE, suggests that pharmacological augmentation of reduced Kv7.2 channel current with ezogabine reduces seizures and may improve developmental milestone attainment.

Severe pathogenic KCNQ2 mutations disrupt the function of the KCNQ2 gene product, Kv7.2, a voltage-gated potassium channel subunit which, in addition to being a critical regulator of neuronal excitability, plays a fundamental role in early brain development. Kv7.2 polypeptides are co-assembled in either homotetrameric channels, or, in combination with Kv7.3 subunits, to form heterotetrameric channels. Both subunit configurations contribute to IKM. Significant reduction of Kv7.2/7.2 activity or Kv7.2/7.3 activity with loss of 50% or more of current density through these channels abrogate these functions, leading to neuronal hyperexcitability and impaired brain development.

In addition to its activity in the MES model, we explored the ability of BHV-7000 to reverse the reduced current density associated with KCNQ2-EE and support its use as potential treatment for the disease. Most encephalopathy-associated pathogenic KCNQ2 variants identified to date disrupt channel function in any of four distinct “hot spots” of the protein, including the S4 voltage sensor, the ion channel pore, and the proximal and distal regions of the C-terminal domain (see figure below).

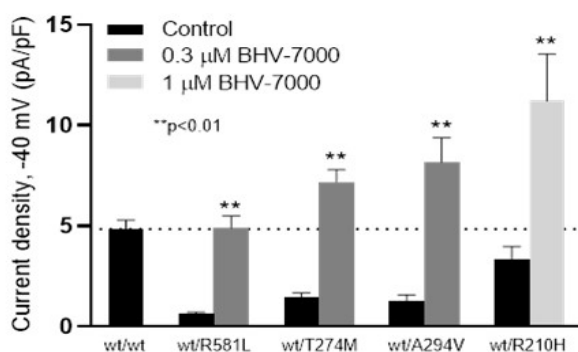


Millichap, Neurol Genet (2016)

To determine the effects of BHV-7000 on the function of Kv7.2 and Kv7.2/7.3 channels poisoned by dominant-negative KCNQ2 mutations, four highly recurrent human missense variants representative of the “hot spot” domains

were introduced into KCNQ2 cDNA by site-directed mutagenesis. Using lipid-mediated transfection, plasmids including the pathogenic variants were co-expressed with wild-type (“wt”) KCNQ2 subunits or wt KCNQ2 and wt KCNQ3 subunits in Chinese hamster ovary (“CHO”) cells.

The figure below shows the effects of BHV-7000 on current density of wt/wt Kv7.2 channels and those formed by 1:1 coexpression of wt KCNQ2 genes with either of two KCNQ2 pore domain variants (T274M, A294V), a C-terminal variant (R581L), or a voltage-sensing variant (R210H). In the control condition, all pathogenic variants produced a marked reduction in current density to below wt/wt levels. BHV-7000 at 0.3 μM restored current density in mutated pore and C-terminal channels to or beyond wt control current density (**<0.01). Similarly, application of BHV-7000 at 1 μM restores function to mutated channels expressing the R210H KCNQ2 S4 voltage sensor domain pathogenic variant in the heterotetrameric (wt/R210H) configuration, to above wt/wt levels of activation.



BHV-7000 has been granted Rare Pediatric Disease Designation by the FDA for the treatment of KCNQ2-EE.

Neuropathic Pain

Neuropathic pain, as defined by the International Association for the Study of Pain, is pain caused by a lesion or disease of the somatosensory nervous system and includes a collection of heterogeneous conditions that are often chronic and debilitating and for which long term therapy is difficult. In the United States, over 20 million adults are estimated to be living with neuropathic pain. Pharmacological treatments for neuropathic pain vary according to patient needs, although recommendations such as the WHO analgesic ladder, United States Centers for Disease Control (“CDC”), and FDA guidelines are in use. Initial or first line treatment for neuropathic pain includes non-opioid analgesics, in particular, antidepressants, anticonvulsants, steroids, and anxiolytics. Second line treatment of persistent, severe pain may require escalation to opiates, often less potent ones at first, followed by more potent opiates for intense refractory pain.

Thus, an urgent need exists for effective, non-addictive pain therapies. Flupirtine, a non-selective Kv7 activator, was previously approved in several European countries and indicated for the treatment of pain. However, the European Medicines Agency recommended withdrawal of its marketing authorization in 2018 because of the risk of serious liver injury. Selective Kv7 potassium channel activators represent a new approach in the development of non-opioid therapeutic options for neuropathic pain. In addition to leveraging reduced abuse and addiction risk potential of potassium channel activators, our Kv7 potassium channel platform addresses the complexities of channel subtype physiology through targeted pharmacology to overcome the limitations inherent in unbiased Kv7 activators and is intended to deliver a well-tolerated, highly effective, non-opioid treatment for neuropathic pain.

Our Kv7 program research was supported in part with funding from the National Institutes of Health (“NIH”) to advance the development of novel Kv7 non-opioid therapies for the treatment of chronic pain. The NIH funding is by the NIH Helping to End Addiction Long-term Initiative (“NIH HEAL Initiative”), which aims to improve treatments for chronic pain, curb the rates of opioid use disorder and overdose, and achieve long-term recovery from opioid addiction. The goal of our Kv7 program is to discover a small-molecule activator of the Kv7.2/7.3 voltage-

gated potassium channel to treat neuropathic pain. Similar to our epilepsy program, we are targeting compounds with these characteristics:

- Biased for Kv7.2/3 activation vs. Kv7.4 activation to minimize potential adverse smooth muscle effects
- Selective against GABA_A receptors to minimize potential tolerability issues
- Selective against Kv7.1/KCNE1 (IKs) and hERG (IKr) to minimize cardiac side-effects
- Potent and effective across animal models of neuropathic pain

A fundamental program hypothesis is that creating Kv7.2/3 activators with minimal activation of Kv7.4 and GABA_A receptors will greatly improve the tolerability profile of a successful candidate compound. Ezogabine has known effects on the GABA system, both directly as a GABA_A positive allosteric modulator, and indirectly by affecting GABA synthesis or metabolism, a pharmacology consistent with the dose-related increases in somnolence and dizziness reported in ezogabine clinical trials. Our program is directed to reducing this potential source of poor tolerability by selecting compounds with no or minimal activity for the GABA_A receptor.

Axonal excitability and neurotransmitter release are altered in neuropathic pain due to sodium channel plasticity, increased voltage-gated calcium channels in the spinal cord, and diminished potassium channel activity in dorsal root ganglion (“DRG”) neurons. These changes in ion channel number, distribution, and function are common to many neuropathic pain subtypes. The functional density of Kv7.2/3 channels is a key variable governing sensory DRG control of intrinsic excitability. There are some reports that demonstrate downregulation of Kv7 potassium channel mRNA, protein and function in experimental neuropathic pain models.

Using human induced pluripotent stem cell (“iPSC”)-derived sensory neurons, we have assessed the physiological activity of these neurons by modulating Kv7 channels across three electrophysiologic parameters: resting membrane potential (V_m), change of rheobase = the current required to stimulate an action potential (“AP”), and the number of APs elicited by a suprathreshold stimulus (3x rheobase). We are currently evaluating the activity of various compounds from our proprietary series of selective Kv7.2/7.3 activators in multiple preclinical models of neuropathic pain.

Mood disorders

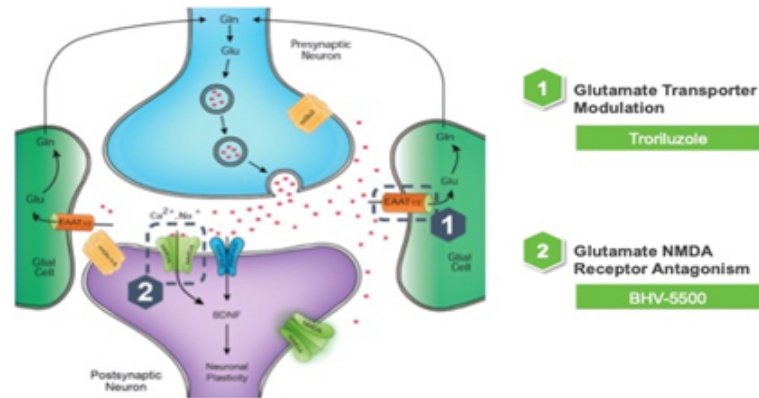
Approximately 1 in 5 adults in the U.S. are living with neuropsychiatric illnesses that are, in turn, associated with inadequate treatment, poor quality of life, disability, and considerable direct and indirect costs. There is significant unmet need for novel and effective therapeutic options that are not limited by long latency periods to clinical effects, low response rates, and significant risks and side effects. Increasing evidence from animal models and clinical trials now suggests that Kv7.2/7.3 targeting drugs offer the potential to treat a spectrum of these neuropsychiatric diseases including, but not limited to, mood disorders such as major depressive disorder, bipolar disorder and anxiety.

Our Glutamate Platform

The most advanced product candidate from our glutamate receptor antagonist platform is tririluzole (previously referred to as trigriluzole and BHV-4157), which is in two Phase 3 trials in OCD. Other product candidates include BHV-5500, which is an antagonist of the glutamate N-methyl-D-aspartate (“NMDA”) receptor and its oral prodrug BHV-5000.

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

The mechanism of action of our glutamate platform is depicted below. Glutamate must be tightly regulated once released from a pre-synaptic neuron and acts as a signaling neurotransmitter to stimulate the post-synaptic neuron via glutamate receptors (e.g., N-methyl-D-aspartate (“NMDA”), alpha-amino-3-hydroxy-5-methyl-4-isoxazole-propionic acid (“AMPA”) or Kainate receptors). Glial cells surrounding the synaptic junction are predominantly responsible for clearing glutamate through transporters, the EAATs. There are five distinct types of glutamate transporters. The figure below depicts the areas of modulation that are affected by our product candidates. (1) As depicted in the glial cell to the right in the figure below, troriluzole increases the activity and expression of the EAATs to increase the clearance of glutamate released from the pre-synaptic neuron. Troriluzole also is designed to inhibit presynaptic ion channels that may inhibit the release of glutamate from presynaptic neurons. (2) As depicted in the postsynaptic neuron to the bottom of the figure below, BHV-5500 blocks glutamate signaling that is mediated by post-synaptic NMDA receptors. Modulating glutamate also has the potential to be neuroprotective and increase the release of neurotrophic factors, including brain derived neurotrophic factor (“BDNF”) which are endogenous molecules that help to support the survival of existing neurons, and encourage the growth and differentiation of new neurons and synapses.



Adapted from Glutamate abnormalities in obsessive compulsive disorder: Neurobiology, pathophysiology, and treatment, C. Pittenger, M. Bloch, and K. Williams

Glutamate Transporter Modulation

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

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. Initial development has focused on its use in treating SCA, an orphan neurological indication that currently has no approved drug therapies and for which the active metabolite, riluzole, has demonstrated preliminary efficacy in two prior randomized controlled trials conducted by third parties.

Ristori et al. reported a randomized, double-blind, placebo-controlled trial of 40 patients presenting with cerebellar ataxias of diverse etiologies, including SCA. Subjects were randomized to receive 8 weeks treatment with either placebo or riluzole (50 mg Riluzole tablets, twice daily). Statistically significant improvement in the riluzole

treated group was demonstrated on the International Cooperative Ataxia Rating Scale (“ICARS”). The number of patients with a 5-point ICARS drop was higher in the riluzole group than in the placebo group after 4 weeks (9/19 vs 1/19; odds ratio [“OR”] =16.2; 95% confidence interval [“CI”] 1.8–147.1) and 8 weeks (13/19 vs 1/19; OR = 39.0; 95% CI 4.2– 364.2). The mean change in the riluzole group ICARS after treatment revealed a decrease ($p < 0.001$) in the total score (-7.05 [4.96] vs 0.16 [2.65]).

Romano et al. described results of a second randomized, placebo-controlled trial subjects diagnosed with a hereditary ataxia (including SCAs) randomized to receive 12 months of treatment with either placebo or riluzole (50 mg, twice daily). 60 patients were randomized. Statistically significant improvement in the riluzole treated group was demonstrated on the Scale for the Assessment of Ataxia (“SARA”). The proportion with decreased SARA score was 14 (50%) of 28 patients in the riluzole group versus three (11%) of 27 in the placebo group (OR 8.00, 95% CI 1.95– 32.83; $p=0.002$).

We acquired troriluzole from ALS Biopharma, LLC (“ALS Biopharma”) and Fox Chase Chemical Diversity Center, Inc. (“FCCDC”), along with an estate of over 300 prodrugs. A prodrug is a compound that, after administration, is metabolized in the body into an active drug. Troriluzole is actively transported by virtue of recognition of its tripeptide moiety by the PepT1 transporter in the gut and is responsible for the increased bioavailability of the drug. Once inside the body, the prodrug, troriluzole is cleaved by enzymes in the blood to the parent, riluzole. To mitigate the limitations of riluzole, several classes of prodrugs were designed, synthesized, and evaluated in multiple in vitro stability assays that predict in vivo drug levels. Troriluzole is a third generation of prodrug development and the product of six years of intensive chemistry efforts.

Riluzole is currently only indicated for ALS and has a number of non-desirable attributes that have limited its clinical use. Key limitations of riluzole include poor oral bioavailability, difficulty swallowing due to tablet formulation, food reducing efficacy, liver toxicity, pharmacokinetic variability, and oral numbness.

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

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

Our Clinical Program for Troriluzole

Phase 1 Studies with Troriluzole

In July 2016, we began a Phase 1 randomized, double-blind, placebo-controlled study to evaluate the safety, tolerability and pharmacokinetics (“PK”) of single and multiple ascending doses of troriluzole in normal healthy volunteers. 58 healthy volunteers were dosed with troriluzole and 20 were dosed with placebo. Both single and multiple doses up to 200 mg were well tolerated without evidence of novel, clinically significant safety signals or lab abnormalities. There was no apparent dose response regarding the frequency or severity of adverse events (“AEs”). In the blinded group, including subjects treated with both placebo and troriluzole, the most common AEs were headache (five subjects, two with moderate severity and three with mild severity) and constipation (two subjects). No pattern of AEs or lab abnormalities were apparent to provide specific cautions or to suggest cautions beyond what is appropriate for the active metabolite, riluzole. Commencing in December 2017, an additional single

and multiple dose study was conducted to assess the safety, tolerability and PK of a 280 mg dose in 10 healthy young and elderly volunteers (eight active; two placebo). The results supported adequate safety and tolerability and yielded mean exposures comparable to what would be expected from a 200 mg dose, a dose that has been safely used in clinic populations and associated with efficacy in a range of disorders in randomized controlled trials (Huntington Study Group Neurology 2003; Lacomblez Neurology 1996). In addition, a bioequivalence study was conducted to bridge a commercial formulation with a Phase 2/3 formulation in 32 healthy volunteers. The commercial formulation was well-tolerated and provided bioequivalent exposure with the Phase 2/3 formulation.

Troriluzole for OCD

OCD is a chronic neuropsychiatric disorder characterized by symptoms of obsessions (intrusive thoughts) and compulsions (repetitive behaviors) that can interfere with patients' functional abilities. According to the National Institute of Mental Health, the 12-month prevalence of OCD is 1% of the U.S. adult population, and approximately half of these cases are characterized as severe. First-line treatment for OCD includes cognitive behavioral therapy, selective serotonin reuptake inhibitors ("SSRIs") and adjunctive use of atypical antipsychotics. Nonetheless, up to 60% of patients have an inadequate response to conventional intervention strategies and some seek invasive neurosurgical procedures to ameliorate symptoms.

We are also currently developing troriluzole as a potential treatment option for patients suffering from OCD. Despite the significant public health burden, no novel mechanisms of action have been approved by the FDA for OCD in over two decades. The rationale for use of troriluzole in OCD is supported by clinical data with its active metabolite, riluzole, in populations with OCD in open-label and placebo-controlled clinical trials as well as in preclinical, genetic and neuroimaging studies implicating the glutamatergic hyperactivity in the pathogenesis of OCD.

In multiple case studies, the use of riluzole in patients with refractory OCD has commonly been associated with meaningful improvement of symptoms. A small-scale randomized controlled trial in adults with OCD conducted by a third party showed favorable trends for the use of riluzole in an outpatient setting. Another randomized controlled third-party study demonstrated statistically significant therapeutic effects with the adjunctive use of riluzole as compared to adjunctive placebo in 50 adults with refractory OCD. These clinical effects are consistent with findings such as genetic associations of glutamate transporter genes with OCD and increased glutamate concentrations in brain and cerebrospinal fluid of patients with OCD. Taken together, we believed there was a clear rationale for advancement of troriluzole, a prodrug of riluzole, into a Phase 2 proof-of-concept trial in OCD.

We commenced a Phase 2/3 double-blind, randomized controlled trial on the use of troriluzole in adults with OCD in late 2017. Results from the Phase 2/3 trial 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 endpoint at week 12. Troriluzole treated subjects (n = 111) had a mean Y-BOCS improvement of -3.4 points from baseline versus -2.9 for placebo-treated (n = 115) subjects [difference -0.5 and p-value = 0.451] at week 4, -5.1 points (n = 96) versus -3.6 for placebo-treated (n = 108) subjects [difference -1.5 and p-value = 0.041] at week 8, and -5.9 points (n = 99) versus -4.9 for placebo-treated (n = 102) subjects [difference -1.0 and p-value = 0.220] at week 12. Troriluzole's safety profile was generally consistent with past clinical trial experience with its active metabolite, riluzole. Treatment emergent adverse events ("TEAE"s) were mostly reported to be mild in intensity. TEAEs that occurred in at least 5% of patients in the troriluzole group, and more frequently in the troriluzole group than in the placebo group, were headache, dizziness, fatigue, somnolence, nausea and nasopharyngitis.

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 a Phase 3 program. The Phase 3 program will have an estimated total enrollment of 1,300 participants with a primary endpoint of change from baseline on the Y-BOCS total score at week 4, 8 and 10. The two Phase 3 randomized, double-blind, placebo-controlled trials that make-up our Phase 3 program for OCD are currently ongoing with enrollment expected to be completed in 2023.

Troriluzole for GBM

Preclinical and small-scale pilot studies are underway to explore troriluzole's use in the treatment of a pipeline of other indications such as some cancers whose spread is thought mediated by glutamate transmission, such as melanoma and glioblastoma.

In collaboration with Johns Hopkins University, we explored the potential applicability of troriluzole for glioblastoma. The oncology collaboration Johns Hopkins was based upon the mechanistic rationale that some tumors over express 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"), the most fatal form of brain cancer. Troriluzole will be evaluated in all patient subgroups of the trial which include newly-diagnosed methylated O6-methylguanine DNA methyltransferase ("MGMT"), newly-diagnosed unmethylated MGMT, and recurrent GBM. Troriluzole was selected for inclusion in GBM AGILE, which we believe was based on the existence of 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. For example, Medikonda et al. showed a survival benefit with troriluzole, alone and in combination with anti-programmed cell death protein-1 ("PD-1") immunotherapy, utilizing a frequently used murine brain tumor model. C57BL/6J mice were intracranially implanted with luciferase-tagged GL261 glioma cells. Mice were randomly assigned to the control, anti-PD-1, troriluzole or combination anti-PD-1 plus troriluzole treatment arms, and median overall survival was assessed. The troriluzole treatment arm demonstrated improved survival compared with the control arm (median survival of 36% vs. 0%; $p < 0.0001$), as did the combination anti-PD-1 plus troriluzole treatment arm (overall survival of 80% vs. 0; $p = 0.0007$).

In July 2022, the Company and GCAR announced that enrollment has commenced in GBM AGILE for the evaluation of troriluzole. GBM AGILE is a multi-arm, platform trial. The evaluation of each therapy in GBM AGILE proceeds in 2 possible stages. A therapy's Stage 1 is an adaptively randomized Screening stage for evaluating the therapy within patient signatures compared against a common control. A therapy in Stage 1 will stop accruing patients if it reaches its maximal sample size, drops for futility, or evinces inadequate safety. If a therapy reaches an efficacy threshold for graduation from Stage 1, it will move into Stage 2 within one of the prospectively defined signatures. The maximum sample size in Stage 1 is 150 patients. For a therapy graduating to Stage 2 there is a fixed randomization, expansion cohort. The maximum sample size in Stage 2 is 50 experimental patients in the graduating signature. The primary analysis of a regimen's effect on overall survival ("OS") uses all patients in both its stages and all control patients in the trial in the graduating signature, suitably adjusted for any possible time trends.

Troriluzole for SCA

Based on the results of our Phase 1 trial with troriluzole and two third-party academic trials that have shown preliminary efficacy of riluzole in cerebellar ataxias, we advanced troriluzole into a Phase 2/3 clinical trial for 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 once daily ("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. After eight weeks of treatment, troriluzole treated subjects ($n = 63$) demonstrated an improvement of -0.81 points [95% CI: -1.4 to -0.2] on the SARA versus -1.05 points [95% CI: -1.6 to -0.4] improvement in placebo-treated ($n = 68$), p -value = 0.52. In this trial, we observed a generally favorable safety and tolerability profile of troriluzole, with low discontinuation rates due to AEs. 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. As of June 28, 2022, in either the randomization phase or the open-label extension phase, two subjects had a

drug-related serious adverse event considered by the investigator to be related to troriluzole. Based on our learnings from the Phase 2b/3 study, including analyses from the open-label extension phase, we advanced troriluzole into 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 (“f-SARA”), and increased the dose of troriluzole to 200 mg QD. Notably, the f-SARA is a novel, 16-point scale based on feedback received from the FDA as the primary outcome measure for this trial; the scale was designed to assess clinically meaningful changes in function.

In May 2022, the Company announced top-line results from the Phase 3 clinical trial evaluating the efficacy and safety of its investigational therapy, troriluzole, in adult patients with SCA. The primary endpoint, change from baseline to week 48 on the f-SARA, did not reach statistical significance in the overall SCA population as there was less than expected disease progression over the course of the study. In the overall study population (n = 213), the troriluzole and placebo groups each had mean baseline scores of 4.9 on the f-SARA and the two groups showed minimal change at the 48-week endpoint with f-SARA scores of 5.0 and 5.1, respectively (p=0.76). Troriluzole was well tolerated with an adverse event profile similar to placebo. The frequency of subjects with any TEAE was 80.6% for troriluzole vs. 84.4% for placebo and the frequency of subjects with serious TEAEs was 5.6% for troriluzole vs. 7.3% for placebo.

Post-hoc analysis of efficacy measures by genotype suggests a treatment effect in patients with the SCA Type 3 (“SCA3”) genotype, which represents the most common form of SCA and accounted for 41% of the study population. In the SCA3 subgroup, troriluzole showed a numerical treatment benefit on the change in f-SARA score from baseline to week 48 compared to placebo (least squares (“LS”) mean change difference -0.55, nominal p-value = 0.053, 95% CI: -1.12, 0.01). SCA patients treated with troriluzole showed minimal disease progression over the study period. Further, in patients in the SCA3 subgroup who were able to walk without assistance at baseline (i.e., f-SARA Gait Item score = 1), troriluzole demonstrated a greater numerical treatment benefit on the change in f-SARA score from baseline to week 48 compared to placebo (LS mean change difference -0.71, nominal p-value = 0.031, 95% CI: -1.36, -0.07). Notably, the f-SARA is a novel, 16-point scale developed based on feedback from FDA as the primary outcome measure for this trial; the scale was designed to assess clinically meaningful changes in function.

Across all SCA genotypes, and SCA3 specifically, patient reported falls, as measured by adverse events, reveal reduction of fall risk in the troriluzole group compared to placebo.

The risk reduction of falls in the troriluzole group combined with the progression of f-SARA scores in the untreated SCA3 group compared to SCA3 patients on troriluzole demonstrates that SCA3 patients are experiencing a clinically meaningful improvement in ataxia symptoms on troriluzole treatment. Given these findings and the debilitating nature of SCA, we intend to interact with the FDA and/or EMA regarding the SCA3 genotype data in the first half of 2023. We have not yet decided on the format of such a regulatory interaction but we could seek advice through various formal or informal interactions with regulatory agencies or we could choose to submit an NDA if we believe that is warranted from the results of our ongoing post-hoc analyses. There are currently no FDA-approved medications for the treatment of SCA or any other cerebellar ataxia, and treatment is supportive. In general, multidisciplinary care provides supportive measures and the goal of this treatment is to improve quality of life and survival.

Glutamate NMDA Receptor Antagonism and BHV-5500 for Neuropathic Pain

An NMDA receptor antagonist is a type of glutamate antagonist that works to inhibit the action of NMDA receptors which may play a role in degenerative diseases that affect the brain. BHV-5500 (lanicemine) was in-licensed from AstraZeneca and is a low-trapping, NMDA receptor antagonist with differentiating pharmacologic properties from other agents in development targeting this receptor. The unique property of low-trapping antagonists is their ability to uncouple from the NMDA receptor more freely than other agents, a property that is thought to contribute to their mitigated risk of dissociative effects as has been observed in the clinic. Lanicemine, binds within the NMDA channel pore and functionally blocks the flow of charged ions through the NMDA receptor complex.

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-5500, that are not associated with the psychotomimetic effects and abuse potential could lead to better management of neuropathic pain without causing serious side effects.

Our Myostatin Platform

Taldefgrobep Alfa

In February 2022, we announced a worldwide license agreement with BMS for the development and commercialization rights to taldefgrobep alfa (also known as BMS-986089), a novel Phase 3 asset. Myostatin, a negative regulator of muscle growth, is a key member of the TGF (symbol Beta) family. Taldefgrobep novelty in a field of myostatin inhibitors is based on the mechanism where it binds to myostatin to both lower overall myostatin levels, but also to function as a receptor antagonist to block myostatin signaling in skeletal muscles. Blocking myostatin activity and signaling has shown to improve muscle function and strength in a number of disease models for neuromuscular wasting. Clinical studies have confirmed that taldefgrobep improved lean body mass directly through increase on contractile muscle and loss of adipose tissue as demonstrated in both normal healthy volunteers and in patients with Duchenne muscular dystrophy (“DMD”). The mechanism of improving overall muscle size and function opens the opportunity for taldefgrobep as monotherapy or combination therapy in a number of muscle-targeted neuromuscular diseases.

Our Clinical Trial for Taldefgrobep Alfa in SMA

In July 2022, we commenced enrollment in a Phase 3 clinical trial assessing the efficacy and safety of taldefgrobep alfa in SMA. 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 Phase 3 placebo-controlled, double-blind trial is designed to evaluate the efficacy and safety of taldefgrobep as an adjunctive therapy for participants who are already taking a stable dose of nusinersen or risdiplam or have a history of treatment with onasemnogene abeparvovec-xioi, compared to placebo. The primary outcome measures of the study will be efficacy of taldefgrobep alfa compared to placebo in the change in the 32 item Motor Function Measure (“MFM-32”) total score from baseline to Week 48. Scores range from 0-3 on each item, with higher scores indicating higher functioning. The study is neither restricted nor limited to patients based on ambulatory status or classification of SMA. We expect to randomize approximately 180 patients in this randomized, double-blind, placebo-controlled global trial.

About Spinal Muscular Atrophy

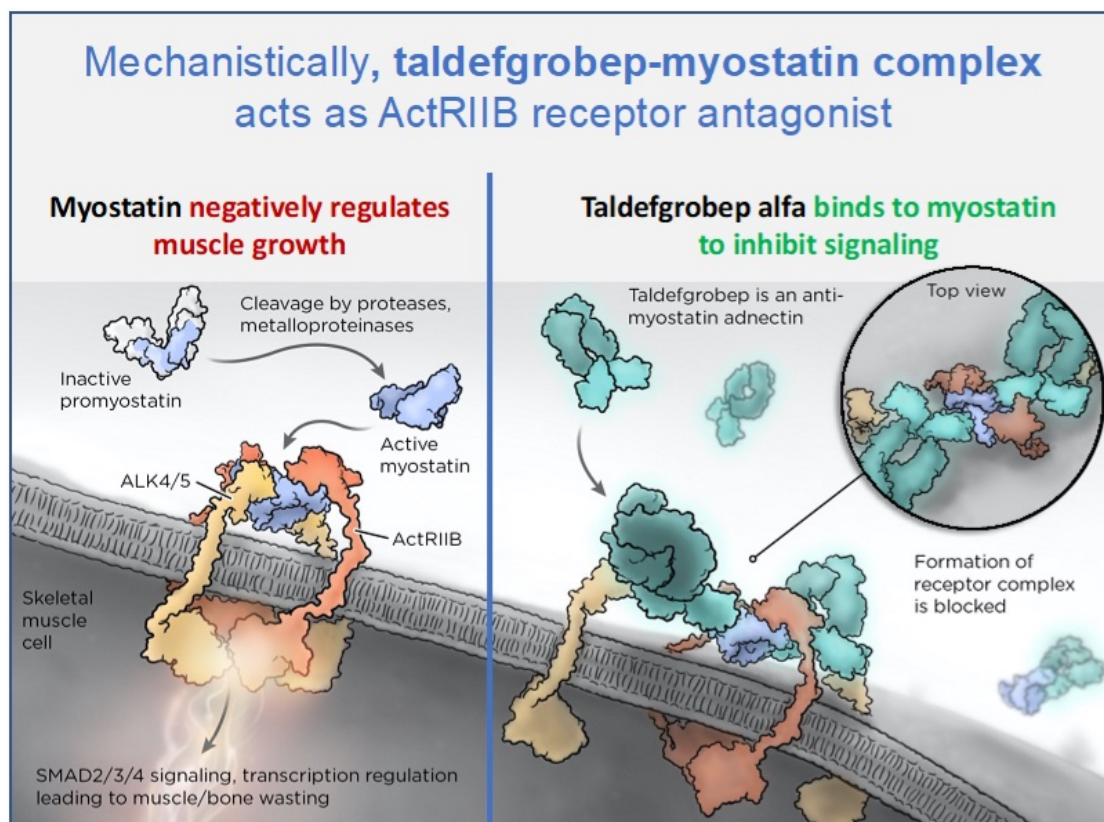
SMA is a rare genetic neurodegenerative disorder characterized by the loss of motor neurons, atrophy of the voluntary muscles of the limbs and trunk and progressive muscle weakness that is often fatal and typically diagnosed in young children. The underlying pathology of SMA is caused by insufficient production of the survival of motor neuron (“SMN”) protein, essential for the survival of motor neurons, and is encoded by two genes, SMN1 and SMN2. In the U.S., SMA affects approximately 1 in 11,000 births, and about 1 in every 50 Americans is a genetic carrier. Newborn screening is now available in 48 U.S. states and covers over 97% of all births.

Taldefgrobep Alfa’s Role in Spinal Muscular Atrophy

In the past three years, significant advancements were made to address the underlying cause of disease in SMA with the up-regulation of SMN1 and SMN2 expression which positions taldefgrobep as a potential combination

therapy to enhance muscle performance. Data from both an SMA animal model study that shows advantages of combination SMN therapy with taldefgrobep and the extensive clinical data in DMD support the advancement of taldefgrobep into a SMA Phase 3 study. Other indications in muscle wasting diseases will be a fast follow-on for taldefgrobep along with other life-cycle opportunities.

Our acquisition of taldefgrobep alfa expands our neuroscience pipeline. The advanced taldefgrobep alfa anti-myostatin development program offers extensive human safety data, especially in the pediatric population, which we plan to leverage and build upon in our future development efforts.



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, along with the Pittsburgh-based Kv7 platform, as our integrated chemistry and discovery research arm. Biohaven Labs will continue to augment its discovery efforts through research partnerships, including research agreements such as with KU Leuven and the Fox Chase Chemical Diversity Center Inc. and research grants such as from the Bill and Melinda Gates Foundation and the NIH HEAL Initiative.

TRPM3 Antagonists

KU Leuven Agreement

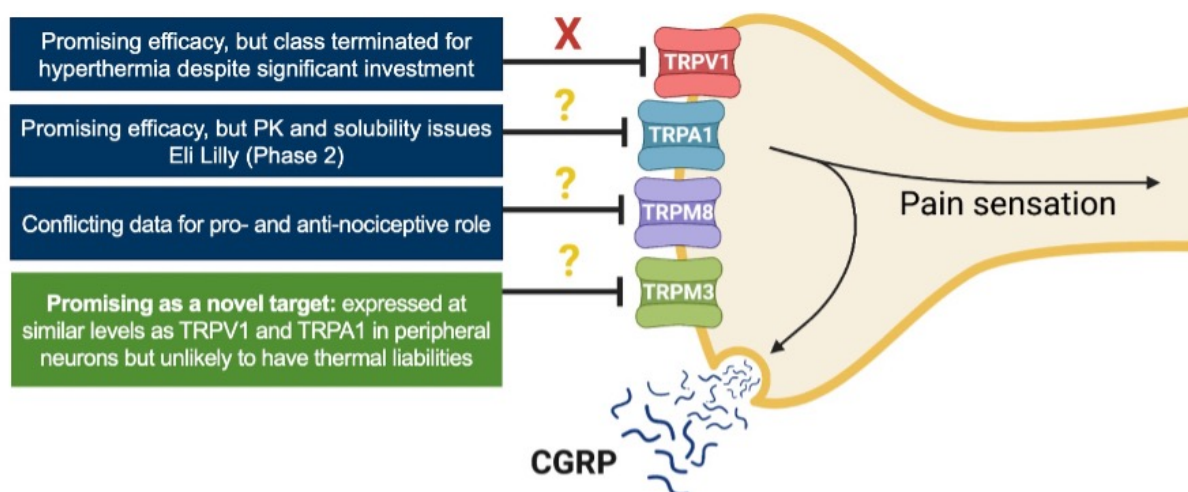
In January 2022, we entered into the KU Leuven Agreement to develop and commercialize TRPM3 antagonists to address the growing proportion of people worldwide living with chronic pain disorders (the “KU Leuven

Agreement”). 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, BHV-2100, which we are evaluating in several preclinical pain models and advancing towards the clinic in 2023. We are continuing to support further basic and translational research on the role of TRPM3 in pain and other disorders through our collaboration with Professors Joris Vriens and Thomas Voets, world leaders in TRP biology at KU Leuven.

Efforts to target TRP Channels for pain

Since the Nobel Prize-winning discovery of the capsaicin receptor TRPV1 in 1997, members of the Transient Receptor Potential (“TRP”) cation channel family have been elusive drug targets for the treatment of pain. Initially, there was much excitement and investment in TRPV1 antagonists due to promising preclinical efficacy and some evidence of clinical pain reduction. However, trials of most TRPV1 antagonists were terminated after the class consistently caused clinically-significant hyperthermia in study participants. Several companies then made efforts to progress antagonists of TRPA1, the receptor for mustard oil. Though Glenmark’s GRC 17536 showed encouraging results in a subset of diabetic peripheral neuropathic pain subjects in a Phase IIa study, it suffers from poor physiochemical properties and pharmacokinetics like many other TRPA1 antagonists. Due to the challenges with drugging TRPA1, only Eli Lilly’s LY3526318 remains in active clinical development.

TRPM3 is a novel target in the TRP family. Like TRPV1 and TRPA1, preclinical data and human genetic validation support TRPM3’s role in neuropathic pain. Unlike TRPV1 antagonists, TRPM3 antagonists are unlikely to possess significant thermal liabilities, and unlike TRPA1 antagonists, Biohaven’s TRPM3 antagonists have desirable physiochemical properties and good pharmacokinetic profiles. The figure below illustrates TRPM3 as a differentiated target for the treatment of pain in the TRP family.

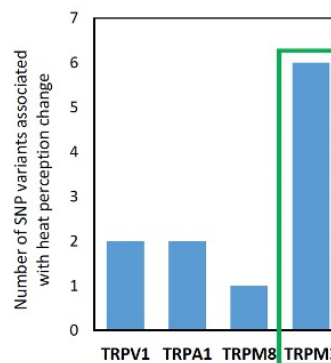
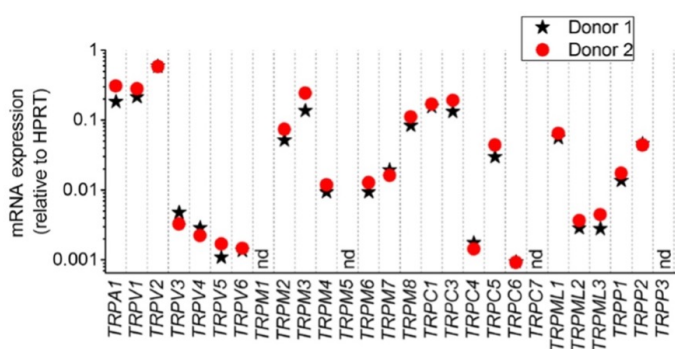


Adapted from Efforts to target TRP channels for pain, Kovivisto et al. 2022

About TRPM3

Transient Receptor Potential Melastatin 3 (“TRPM3”) is a novel druggable target in the TRP cation channel family. TRPM3 is functionally expressed in the human dorsal root ganglion, and several SNPs in TRPM3 are associated with altered pain sensation in response to UVB (see figure below). Additionally, people with TRPM3 gain-of-function mutations experience altered pain sensation (de Sainte Agathe 2020, Dymont 2019, Van Hoeymissen 2020). Knocking out or antagonizing TRPM3 in animal models attenuates the development of various pain states, including those associated with nerve injury, chemotherapy, and diabetic peripheral neuropathy, further indicating that TRPM3 is a promising target for neuropathic pain. Lastly, preclinical evidence suggests that

antagonizing TRPM3 may avoid the on-target body temperature effects and dangerous lack of noxious heat detection that afflicted TRPV1 antagonists.



Vangeel et al, 2020

Lotsch et al, 2020

Our Development of BHV-2100 for the Treatment of Neuropathic Pain

BHV-2100 is an orally-bioavailable small molecule antagonist of TRPM3. TRPM3 is expressed in the relevant human tissue types for neuropathic pain, and both preclinical models and human genetics implicate TRPM3 in pain signaling. BHV-2100 is our lead orally-bioavailable small molecule TRPM3 antagonist which we are developing as a potential non-opioid treatment for neuropathic pain. We are evaluating the ability of BHV-2100 to reduce pain behaviors across several preclinical models of neuropathic pain, including chemotherapy induced neuropathy, diabetic neuropathy, and nerve injury. First-in-human studies of BHV-2100 are anticipated to begin in 2023, complementing our efforts with our Kv7 platform. The Company is evaluating and has not yet finalized potential clinical trial designs, including trial size, and primary and secondary endpoints.

Additional research on TRPM3-mediated disorders

Under the KU Leuven agreement, Biohaven is supporting further basic and translational research at KU Leuven on the role of TRPM3 in pain and other disorders. In addition to BHV-2100, we are optimizing other lead compounds for TRPM3-mediated disorders of the peripheral and central nervous systems.

TDP-43

Agreement with Fox Chase Chemical Diversity Center Inc.

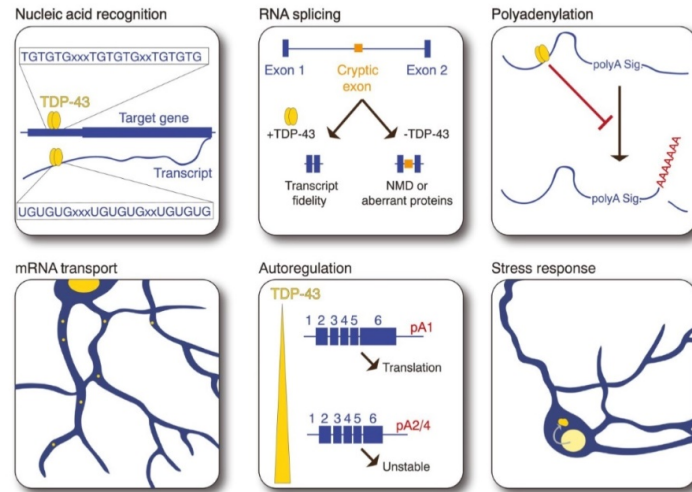
In May 2019, we entered into an agreement with Fox Chase Chemical Diversity Center Inc. (“FCCDC”) for FCCDC’s TAR-DNA protein-43 (“TDP43”) assets (the “FCCDC Agreement”). The FCCDC Agreement provides us with a plan and goal to identify one or more new chemical entity candidates for preclinical development for eventual clinical evaluation for the treatment of one or more TDP-43 proteinopathies. In connection with the FCCDC Agreement, we have established a TDP-43 Research Plan with FCCDC that provides for certain milestones to be achieved by FCCDC, and milestone payments to be made by the Company.

Our Development Program Targeting TDP-43 in Neurodegeneration

TDP-43 is a multifunctional nucleic acid-binding protein that is implicated in neurodegeneration. Mutations in the gene that encodes for TDP-43 cause familial and sporadic ALS and frontotemporal dementia (“FTD”). Cytoplasmic TDP-43 aggregates are the neuropathological hallmark of ALS-FTD spectrum disorders. The Company is evaluating and has not yet finalized potential clinical trial designs, including trial size, and primary and secondary endpoints.

Mechanism of Action of Our TDP-43 Targeting Compounds

TDP-43 is a nucleic acid binding protein that has several molecular and cellular functions. Salient TDP-43 functions implicated in disease pathogenesis are shown in the figure below. The most common motif identified for TDP-43 is thymine-guanine repeats (“[TG]n”), which corresponds to the uracil-guanine repeats (“[UG]n”) ribonucleic acid (“RNA”) binding motif. Interaction with RNA allows TDP-43 to regulate pre-mRNA splicing to inhibit the inclusion of cryptic exons as well as influence polyadenylation site selection. Cytosolic roles for TDP-43 include transport of RNA along neuronal processes and response to stresses, including those affecting proteostasis, which can trigger TDP-43 nuclear efflux and localization to stress granules. A multitude of these basic molecular functions contribute to TDP-43 autoregulation, including splicing and polyadenylation.



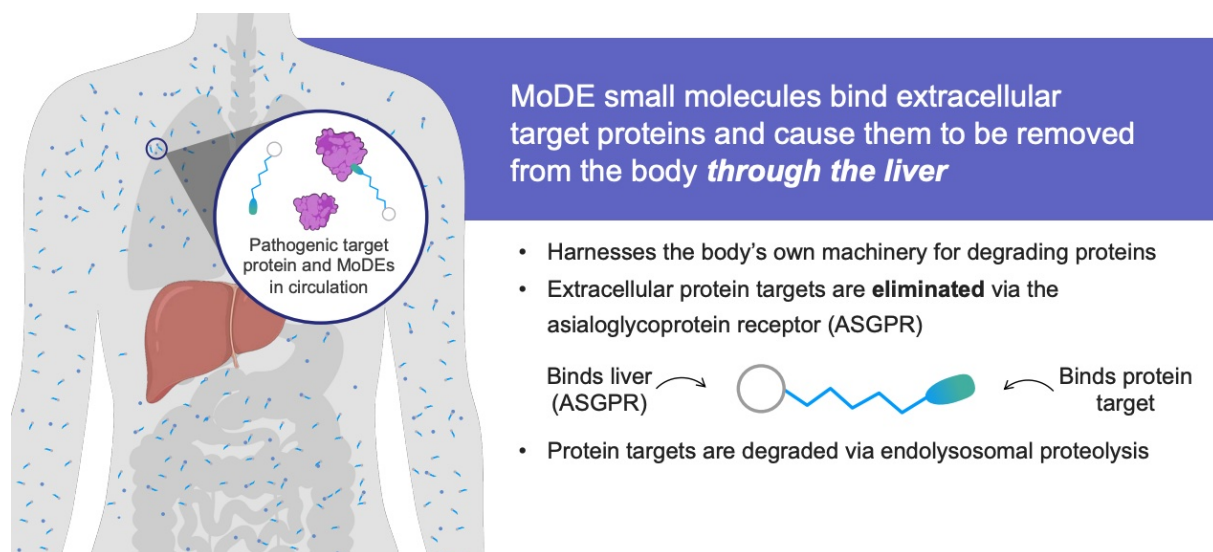
Klim JR. Trends Neurosci. 2021.

The mechanism of action of our small molecule TDP-43 targeting compounds is the disruption of nucleotide binding to TDP-43. Our compounds were identified using a high-throughput screening approach that measured inhibition of oligonucleotide binding to TDP-43 using Amplified Luminescence Proximity Homogenous Assay (AlphaScreen®) technology. Screening was performed on a diverse set of more than 7000 compounds and identified compounds with sub-micromolar affinities that disrupt oligonucleotide binding to TDP-43, by binding to TDP-43 directly themselves (Cassel J. Biomolecular Screening, 2010, 15, 1099-1106). Several chemotypes were identified. Structure activity relationships were developed and refined with a focus on optimizing pharmacology, in vitro and in vivo efficacy (e.g. prolongation of survival in Drosophila, induced motor neurons, and TDP-43 transgenic mouse models), and safety profiles.

Bispecific Molecular Degraders of Extracellular Proteins

Molecular Degraders of Extracellular Proteins (“MoDEs”) are bispecific molecules that target pathologic circulating proteins and direct them to the liver (or other organ systems) for degradation by the endosomal/lysosomal

pathway. Our MoDE platform is being explored for use in a wide range of therapeutic areas, including indications in autoimmune diseases, cancer and infectious disease.



Antibody-based Galactose-deficient IgA ("Gd-IgA") MoDEs

IgA nephropathy ("IgAN") is the most common primary glomerulonephritis that can progress to renal failure and is characterized by immunoglobulin deposits in the renal mesangium comprised exclusively of the IgA1 subclass. Patients with IgAN have increased serum levels of IgA1 with a hinge region containing truncated galactose-deficient O-linked saccharides ("Gd-IgA") and can present with a range of symptoms, from hematuria or proteinuria to severe hypertension owing to renal damage. The clinical progression varies, with 30–40% of patients reaching end-stage renal disease 20–30 years after the first clinical presentation. Currently, no IgAN-specific

therapies are available and patients are managed with the aim of controlling blood pressure and maintaining renal function.

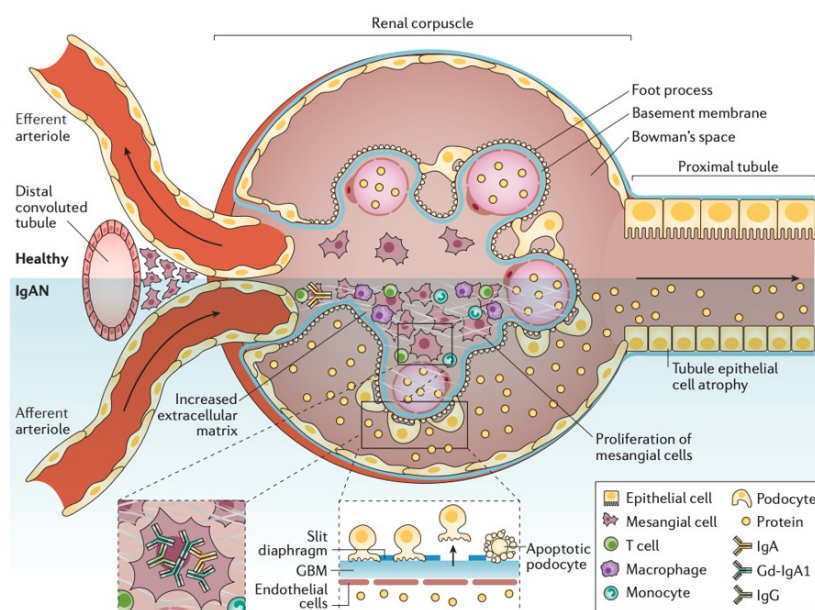


Figure 1 | **The glomerulus in IgA nephropathy.** In a normal glomerulus, normal filtration of plasma occurs and intact podocytes prevent the loss of proteins. In IgA nephropathy (IgAN), deposition (or possibly *in situ* formation) of pathogenic polymeric IgA1 immune complexes in the glomerular mesangium induces proliferation of mesangial cells and increases the synthesis of extracellular matrix. Humoral mediators attract infiltrating macrophages, monocytes and T cells. Humoral mediators also downregulate the expression of podocyte proteins, leading to apoptosis and protein loss. GBM, glomerular basement membrane; Gd-IgA1, galactose-deficient IgA1.

Lai, Nat Rev Dis Primers (2016)

We are leveraging our MoDE platform to develop novel bispecific molecules for the treatment of IgA nephropathy (“IgAN”) that remove potentially disease-causing Gd-IgA in patients and prevent harmful kidney deposits. We have taken a published rodent format IgG antibody that recognizes Gd-IgA and converted it into a partially-humanized, liver-targeted degrader MoDE using MATE conjugation (see below) that potently binds Gd-IgA and causes its endocytosis in human liver cells. Further work is ongoing to progress this as a potential IgAN treatment. The Company is evaluating and has not yet finalized potential clinical trial designs, including trial size, and primary and secondary endpoints.

To broaden our internal efforts, 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 IgAN 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.

Multimodal Antibody Therapy Enhancer Conjugation Technology

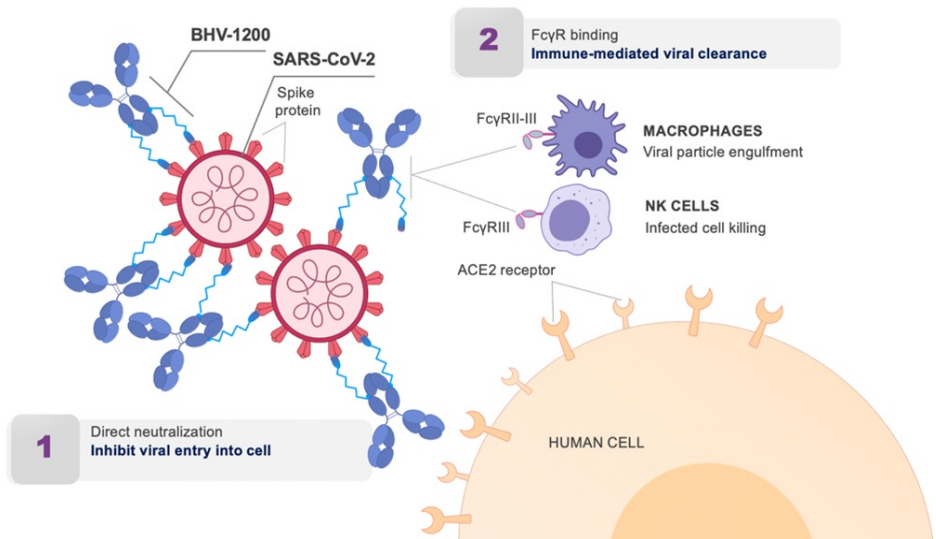
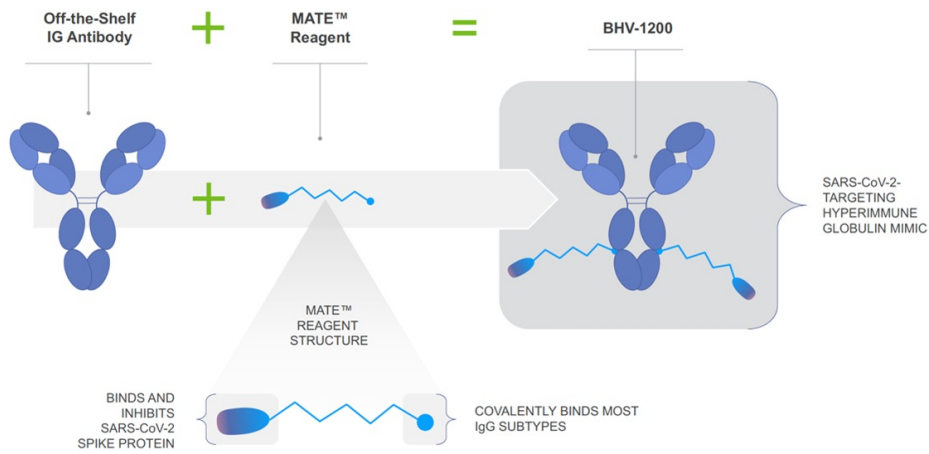
Antibody Drug Conjugates

We are using the Multimodal Antibody Therapy Enhancer (“MATE”) conjugation technology to generate site-specific antibody drug conjugates (“ADC”)s from native IgG1 proteins that we believe will show superior stability in comparison with those using current industry-standard cysteine maleimide conjugation. Our expectation is that the enhanced *in vivo* stability and expected superior physicochemical properties of these ADCs will lead to increased therapeutic indices (more cytotoxic payload reaching cancer cells and less reaching normal tissues). Over

15 site-specific ADCs using the well validated vcMMAE payload linker system have been prepared and are undergoing biological testing in comparison with industry standard maleimide conjugated ADCs.

Our proprietary 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. We used published synthetic binders for SARS-CoV2 that had been designed to establish a much wider area and number of contacts with the spike protein than other agents like monoclonal antibodies. In February 2021, we announced that BHV-1200 developed with our proprietary MATE platform 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 by an academic collaborator demonstrated that BHV-1200 substantially reduced viral entry into cells. We are currently evaluating BHV-1200 as a clinical candidate for the treatment of COVID-19. The Company is evaluating and has not yet finalized potential clinical trial designs, including trial size, and primary and secondary endpoints.

MATE Molecule for COVID-19

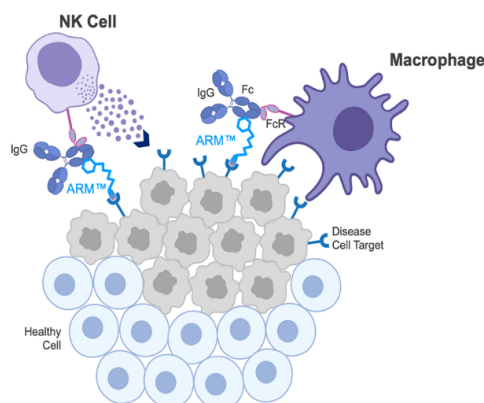


BHV-1100

Antibody Recruiting Molecules

Antibody Recruiting Molecules (“ARMs”) are bispecific molecules that recruit endogenous antibodies to target cancer, virally infected cells, and disease-causing microorganisms for immune-mediated clearance. These molecules are engineered as modular components that are readily interchangeable, giving the platform tremendous flexibility for a variety of indications and therapy areas.

By recruiting antibodies to coat the disease cell target, ARMs mark it for removal by the body’s innate antibody-mediated immune mechanisms (antibody dependent cellular cytotoxicity and antibody dependent cellular phagocytosis).



Platform advantages

Similar to biologics, ARMs directly engage patients’ immune system to destroy disease cells by connecting target disease cells with components of the immune system. However, unlike biologics, ARMs are smaller in size than an antibody potentially allowing for enhanced tumor penetration and biodistribution, and may offer manufacturing advantages including enhanced shelf stability.

ARM™ NK Combination Therapy.

ARMs provide target specificity to Natural Killer (“NK”) cell therapies without needing to design chimeric antigen receptors (“CARs”) or other methods of genetic manipulation. NK cells are a type of immune effector cell that can recognize and destroy non-self targets and certain diseased cells. NK cells do not target specific protein epitopes like T cells of the adaptive immune system. Our ARMs are being used to provide antigen target specificity to NK cell therapies (both allogeneic and autologous) with the goal of enhancing efficacy and safety. ARM NK combination therapy directs NK cells to a disease target of interest.

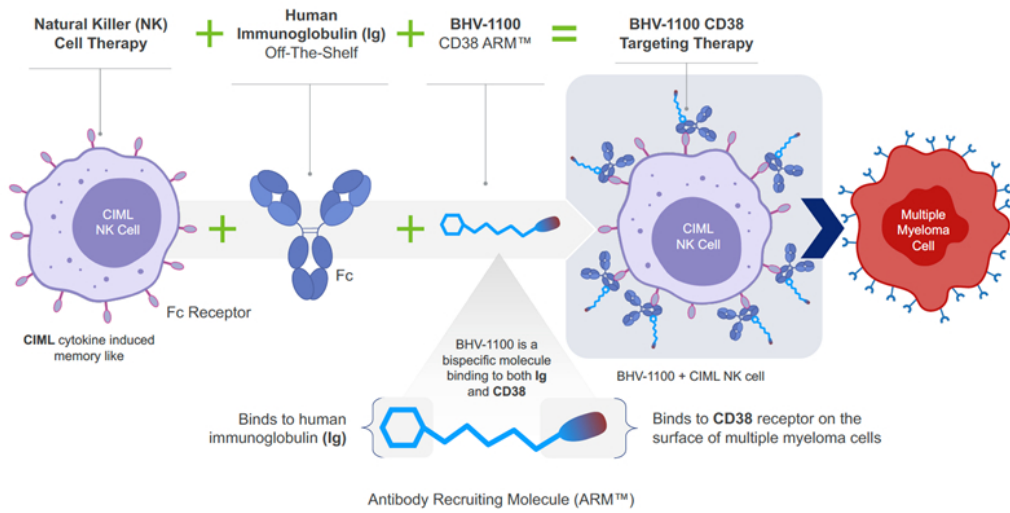
Our Clinical Trial for BHV-1100 in Newly Diagnosed Multiple Myeloma Patients

We have initiated dosing in a Phase 1a/1b trial in newly diagnosed multiple myeloma patients. Our ARM, BHV-1100, in combination with autologous cytokine induced memory-like (“CIML”) NK cells and immune globulin (“Ig”), is expected to target and kill multiple myeloma cells expressing the cell surface protein CD38. The trial is supported by compelling preclinical data showing that BHV-1100 enhanced recruitment of autologous CIML NK cells increases killing of multiple myeloma cells.

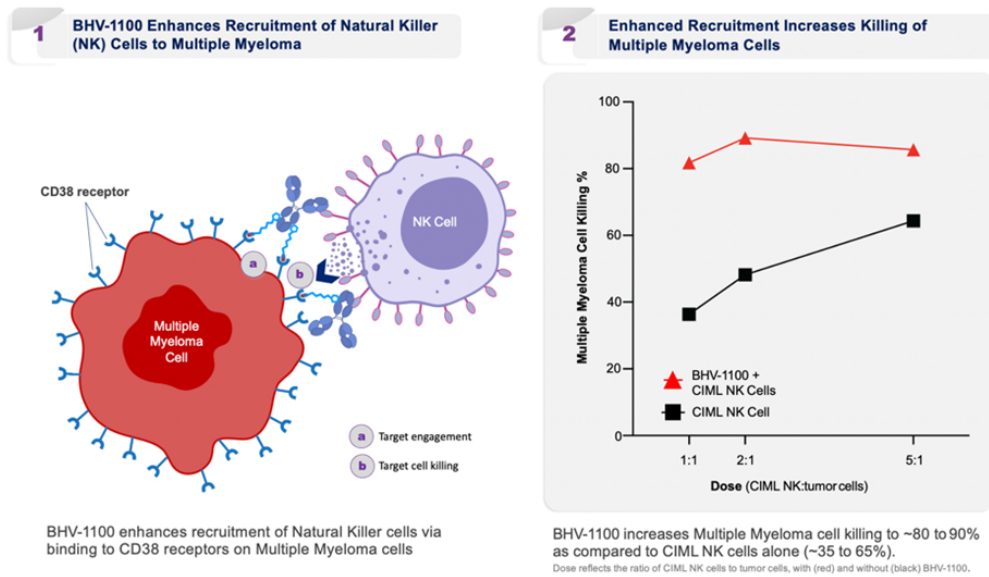
This open-label single center Phase 1a/1b study assesses the safety and tolerability as well as exploratory efficacy endpoints in newly diagnosed multiple myeloma patients who have tested positive for minimal residual disease (“MRD+”) in first or second remission prior to autologous stem cell transplant (“ASCT”). We expect to

enroll 30 newly diagnosed multiple myeloma patients. The primary outcome measures are dose limiting toxicities following combination product administration (time frame: 90 to 100 days post-combination product administration) and incidence and severity of side effects related to the combination product.

BHV-1100 Binds CD38 and Ig to Create a Targeting Therapy to Kill Multiple Myeloma Cells



BHV-1100 Enhances Recruitment of NK Cells and Increases Killing of Multiple Myeloma Cells



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”). 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.

Extracellular MT has been implicated in the pathogenesis of autoimmune and inflammatory diseases. MTs are a family of low molecular weight, cysteine-rich, metal-binding proteins that have a wide range of functions in cellular homeostasis and immunity. MT has traditionally been considered to be an intracellular protein that can be found in both the cytoplasm and nucleus; however, MT also can be found in extracellular spaces, particularly in disease states involving chronic cellular stress where intracellular MT production is upregulated by inflammatory cytokines, and extracellular MT acts as a danger signal, attracting leukocytes and modulating the immune response. In preclinical studies, UC1MT has been observed to block this extracellular pool of MT and the resulting MT-mediated inflammation and immunomodulation. The Company is evaluating and has not yet finalized potential clinical trial designs, including trial size, and primary and secondary endpoints.

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 creating new classes of precision therapies targeting chronic inflammation and immune dysregulation by leveraging the human gut as a drug discovery tool. 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 early 2023, as well as to explore additional disease targets. 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. In June 2022, we and Artizan executed a non-binding indication of interest (“Artizan Side Letter”) which describes terms under which we and Artizan would amend the 2020 Artizan Agreement to eliminate certain milestone payments required by us in exchange for limiting our option to the selection of the first (ARZC-001) licensed product. The Company is evaluating and has not yet finalized potential clinical trial designs, including trial size, and primary and secondary endpoints.

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 if our product candidates receive marketing approval.

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

Commercialization

We intend to develop and, if approved by the FDA, commercialize our product candidates in the United States, and we may enter into distribution or licensing arrangements for commercialization rights for other regions. With respect to the product candidates in our Kv7 ion channel activators, glutamate modulation and myostatin inhibition platforms, we currently intend to build a neurological specialty sales force to manage commercialization for these product candidates, potentially in combination with a larger pharmaceutical partner, to maximize patient coverage in the United States and to support global expansion.

Members of our management team and Board have deep experience leading neuroscience research and have been involved in the development and commercialization of drugs such as Abilify, Opdivo and, most recently, Nurtec ODT.

Our chief executive officer, Vlad Coric, had been the Chief Executive Officer of Former Parent since 2015, leading Former Parent's development and successful commercial launch of Nurtec ODT (rimegepant) in the U.S., which received FDA approval for the acute and preventative treatment of migraine in February 2020 and May 2021, respectively. Under Dr. Coric's leadership, Former Parent entered into several strategic arrangements, including its Collaboration and License agreement with Pfizer, Inc. for the development of rimegepant and zavegepant outside of the United States.

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 many 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 U.S., Europe, Japan, Korea, China, Hong Kong and Australia.

Kv7

In April 2022, we acquired Channel Biosciences, LLC. This acquisition included Channel's Kv7 channel targeting platform and related patents and patent applications. The patents and patent applications are directed to the composition of matter of compounds that are activators of Kv7.2/Kv7.3 and their use in treating diseases such as epilepsy. U.S. Patent 10,851,067 (the "'067 Patent'"), issued December 1, 2020, specifically claims BHV-7000 and will expire in March 2039, not including possible patent term extensions. Ex-U.S. counterparts to the '067 patent are pending in Australia, Brazil, Canada, China, European Union, United Kingdom, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Singapore and South Africa. If granted, the ex-U.S. patents will expire in March 2039, not including possible patent term extensions in countries where such extensions are available. In addition, U.S. Patent 9,481,653 (the "'653 patent'"), issued November 1, 2016, claims a class of compounds including BHV-7000 and will expire in September 2035, not including possible patent term extensions. Ex-US counterparts to the '653 patent are granted in Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, United Kingdom, Ireland, Iceland, Italy, Netherlands, Norway and Sweden. The ex-U.S. patents will expire in September 2035, not including possible patent term extensions in countries where such extensions are available.

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. This patent expires in February 2036, not including possible patent term extensions. Ex-US counterparts to the '791 patent have been granted in Albania, Armenia, Austria, Australia, Azerbaijan, Belgium, Bulgaria, Belarus, Canada, Switzerland, China, Cyprus, Czechia, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hong Kong, Croatia, Hungary, Ireland, Israel, Italy, Japan, Kyrgyzstan, Kazakhstan, Lithuania, Luxembourg, Latvia, Monaco, North Macedonia, Malta, Mexico, Netherlands, Norway, Philippines, Poland, Portugal, Romania, Serbia, Russia, Sweden, Slovenia, Slovakia, Tajikistan, Turkmenistan, Turkey and South Africa, and patent applications are pending in Brazil, India, Republic of Korea, Macao and Singapore. The ex-US patents and patent applications will expire in February 2036, not including possible patent term extensions in countries where such extensions are available. In addition, the use of these compounds for treating OCD, ALS, SCA, depression, Alzheimer's Disease and other diseases are 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 troriluzole and methods of using the formulations to treat various diseases, including, for example, the use of troriluzole with immunotherapies to treat cancer, including among others U.S. Patent 11,400,155, issued August 2, 2022, which expires in May 2037, not including possible patent term extensions. Ex-US counterparts to the '155 patent have been granted in Albania, Austria, Australia, Belgium, Bulgaria, Switzerland, China, Cyprus, Czechia, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Hong Kong, Croatia, Hungary, Ireland, Israel, Italy, Republic of Korea, Lithuania, Luxembourg, Latvia, Monaco, North Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, and Slovakia and patent applications are pending in Brazil, Canada, India, Japan, Mexico, Philippines, Singapore and South Africa. The ex-US patents and patent applications will expire in May 2037, not including possible patent term extensions in countries where such extensions are available.

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. U.S. Patent 7,829,707, issued November 9, 2010, U.S. Patent 8,859,568, issued October 14, 2014, and U.S. Patent 9,580,429, issued February 28, 2017, are directed to compositions of matter of verdiperstat and other compounds, pharmaceutical compositions of verdiperstat and methods of treating diseases. The U.S. patents expire in December 2025 not including patent term adjustments and extensions. Ex-US counterparts to the U.S. patents have been granted in Australia, Brazil, Canada, Switzerland, China, Germany, Spain, France, United Kingdom, Hong Kong, India, Italy, Japan, Republic of Korea, Mexico, Netherlands, Russia, Sweden, and Turkey. The ex-US patents and patent applications will expire in December 2025, not including possible patent term extensions in countries where such extensions are available. U.S. Serial No. 17/766539, filed April 5, 2022, is directed to novel prodrug forms of verdiperstat. Ex-US counterparts to the '539 application have been filed in Australia, Brazil, Canada, China, European Union, United Kingdom, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Singapore and South Africa. The ex-US patents and patent applications will expire in October 2040, not including possible patent term extensions in countries where such extensions are available.

MoDEs Platform, ARMs, MATEs

In January 2021, we entered into a worldwide, exclusive license agreement with Yale University for the development and commercialization of a novel Molecular Degradator of Extracellular Protein platform. The platform pertains to the clearance of disease-causing protein and other biomolecules by targeting them for lysosomal degradation using multi-functional molecules. The platform is differentiated from existing approaches in that it does not rely on ubiquitin ligases, and it allows for a broad range of targets to be degraded. The patent portfolio is directed to the composition of matter of bifunctional degraders and their use in degrading circulating proteins and treating diseases. U.S. Serial No. 17/046221, which relates to bifunctional small molecules to target selective degradation of circulating proteins, filed October 8, 2020, was filed in the United States, Canada, China, European Union and Hong Kong and, if granted, will expire in April 2039, not including possible patent term extensions in countries where such extensions are available. U.S. Serial No. 17/768166, filed April 11, 2022, which relates to bifunctional compounds as degraders of autoantibodies, was filed in the United States, United Arab Emirates, Australia, Brazil, Canada, China, European Union, Israel, Japan, Republic of Korea, Mexico, Philippines, Saudi Arabia, Singapore, and South Africa and, if granted, will expire in October 2040, not including possible patent term extensions in countries where such extensions are available. U.S. Serial No. 17/046192, filed October 8, 2020, which relates to bifunctional molecules to degrade circulating proteins, was filed in the United States, Canada, European Union and Hong Kong, and, if granted, will expire in April 2039, not including possible patent term extensions in countries where such extensions are available. U.S. Serial No. 17/768145, filed April 11, 2022, which relates to engineered antibodies as molecular degraders through cellular receptors, was filed in the United States, United Arab Emirates, Australia, Brazil, Canada, China, countries of the Eurasian Patent Organization, European Union, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Philippines, Saudi Arabia, South Africa and Singapore and, if granted, will expire in October 2040, not including possible patent term extensions in countries where such extensions are available. PCT/US2022/017319, filed February 22, 2022, which relates to targeted bifunctional degraders, is pending in the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in February 2042, not including possible patent term extensions in countries where such extensions are available. PCT/US2022/019658, which relates to bifunctional degraders of galactose deficient immunoglobulins, filed March 10, 2022, is pending in the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in March 2042, not including possible patent term extensions in countries where such extensions are available.

We also acquired Kleo Pharmaceuticals, Inc. in January 2021. This acquisition included Kleo's proprietary technology platforms which are modular in design and enable rapid generation of novel immunotherapies that can be optimized against specified biological targets and combined with existing cell- or antibody-based therapies. These include Antibody Recruiting Molecules and Monoclonal Antibody Therapy Enhancers, which complement the MoDEs technology licensed from Yale. U.S. Serial No. 17/769924, filed November 19, 2020, which relates to directed conjugation technologies, was filed in the United States, United Arab Emirates, Australia, Brazil, Canada, China, countries of the Eurasian Patent Organization, European Union, Israel, India, Japan, Republic of Korea,

Mexico, New Zealand, Philippines, Saudi Arabia, South Africa and Singapore and, if granted, will expire in November 2040, not including possible patent term extensions in countries where such extensions are available. PCT/US2021/024186, filed March 25, 2021, which relates to technologies for treating COVID infections, is pending in the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in March 2041, not including possible patent term extensions in countries where such extensions are available. PCT/US2022/015390, filed February 6, 2022, which relates to technologies for preventing or treating infections, is pending in the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in February 2042, not including possible patent term extensions in countries where such extensions are available. PCT/US2022/029533, filed May 17, 2022, which relates to compositions including conjugated therapy enhancers, is pending in the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in May 2042, not including possible patent term extensions in countries where such extensions are available. PCT/US2022/029535, filed May 17, 2022, which relates to agents for directed conjugation techniques and conjugated products, is pending in the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in May 2042, not including possible patent term extensions in countries where such extensions are available. PCT/US2022/030070, filed May 19, 2022, which relates to antibody drug conjugates using MATE technology for delivering cytotoxic agents, is pending in the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in May 2042, not including possible patent term extensions in countries where such extensions are available.

TDP-43

We have pending patent applications covering the composition of matter of compounds targeting TDP-43 in neurodegeneration. TDP-43, TAR-DNA protein-43, is a multifunctional nucleic acid-binding protein that is implicated in neurodegeneration. Mutations in the gene that encodes for TDP-43 cause familial and sporadic amyotrophic lateral sclerosis (“ALS”) and frontotemporal dementia (“FTD”). Cytoplasmic TDP-43 aggregates are the neuropathological hallmark of ALS-FTD spectrum disorders. U.S. Serial No. 17/635421, filed February 15, 2022, which relates to compounds that target TDP-43, was filed in the United States, Australia, Brazil, Canada, China, countries of the Eurasian Patent Organization, European Union, Israel, India, Japan, Republic of Korea, Mexico, Philippines, South Africa and Singapore and, if granted, will expire in August 2040, not including possible patent term extensions in countries where such extensions are available. PCT/US2022/017116, filed February 20, 2022, which relates to compounds that target TDP-43 for the treatment of ALS and related disorders, is pending in the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in February 2042, not including possible patent term extensions in countries where such extensions are available.

IBD and Parkinson's Disease

In December 2020, we entered into an option and license agreement with Artizan Biosciences directed toward the development and commercialization of novel treatments for inflammatory bowel disease (“IBD”) and other gastrointestinal inflammatory disorders, e.g., Crohn’s disease, in the U.S. Under the terms of the agreement, we have the rights to exercise an option on up to three product candidates. In June 2021, we entered into a separate worldwide, exclusive license agreement under the IgA-SEQ patented technology with Artizan to develop and commercialize certain of their compounds for use in Parkinson’s Disease. U.S. Patent 9,758,838, issued September 12, 2017, U.S. Patent 10,428,392, issued October 1, 2019, U.S. Patent 10,774,392, issued September 15, 2020, and U.S. Patent 11,299,790, issued April 12, 2022, relate to compositions and methods for identifying secretory antibody microbes. These patents expire in March 2034, not including possible patent term extensions. U.S. Patent 10,925,953, issued February 23, 2021, Serial No. 15/507357, which relates to compositions and methods for treating an inflammatory disease or disorder, was also filed in the European Union, will expire in August 2035, not including possible patent term extensions. U.S. Serial No. 17/253333, filed July 3, 2019, which relates to compositions and methods for treating inflammatory diseases, was filed in the United States, Australia, Brazil, Canada, China, European Union, Hong Kong, Israel, Japan, Republic of Korea, Mexico, New Zealand, Russia, South Africa and Singapore and, if granted, will expire in July 2039, not including possible patent term extensions in countries where such extensions are available. PCT/US2021/050048, filed September 13, 2021, which relates to small molecule

inhibitors of bacterial toxins, is pending the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The counterpart application is also pending in Taiwan. The patent applications, if granted, will expire in September 2041, not including possible patent term extensions in countries where such extensions are available. PCT/US2022/012472, filed January 14, 2022, which relates to compositions and methods for treating and preventing diseases or disorders using inter-species interactions, is pending in the United States Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing.

TRPM3

In January 2022, we entered into an exclusive global license and research agreement to develop and commercialize 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 Katholieke Universiteit Leuven (KU Leuven). PCT/EP2021/082853, filed November 24, 2021, which relates to aryl derivatives for treating TRPM3 mediated disorders, is pending in Taiwan and the European Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in November 2041, not including possible patent term extensions in countries where such extensions are available. PCT/EP2021/082865, filed November 24, 2021, which relates to heterocycle derivatives for treating TRPM3 mediated disorders, is pending in Taiwan and the European Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in November 2041, not including possible patent term extensions in countries where such extensions are available. PCT/EP2021/082858, filed November 24, 2021, which relates to aryl derivatives for treating TRPM3 mediated disorders, is pending in Taiwan and the European Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in November 2041, not including possible patent term extensions in countries where such extensions are available. PCT/EP2021/082867, filed November 24, 2021, which relates to heterocycle derivatives for treating TRPM3 mediated disorders, is pending in Taiwan and the European Receiving Office of the Patent Cooperation Treaty and all countries were designated for filing. The patent applications, if granted, will expire in November 2041, not including possible patent term extensions in countries where such extensions are available. U.S. Patent 9,194,863, issued November 24, 2015, which relates to screening methods for analgesic agents, has also been granted in Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, United Kingdom, Ireland, Italy, Netherlands and Sweden. The patents, will expire in May 2032, not including possible patent term extensions in countries where such extensions are available.

Myostatin

In December 2021, we entered into a worldwide license agreement with Bristol Myers Squibb for the global development and commercialization rights to taldefgrobep alfa, 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.

U.S. Patent 8,853,154 issued October 7, 2014, U.S. Patent 8,933,199, issued January 13, 2015, U.S. Patent 8,993,265, issued March 31, 2015, U.S. Patent 9,493,546, issued November 15, 2016, U.S. Patent 9,662,373, issued May 30, 2017, U.S. Patent 10,245,302, issued April 2, 2019, and U.S. Patent 10,406,212, issued September 10, 2019, are directed to fibronectin based scaffold domain proteins that bind to myostatin. The U.S. patents expire in September 2033, not including possible patent term extensions. Ex-US counterparts to the U.S. patents have been granted in Austria, Australia, Belgium, Bulgaria, Switzerland, Chile, China, Colombia, Czechia, Germany, Denmark, Algeria, Spain, Finland, France, United Kingdom, Greece, Hong Kong, Croatia, Hungary, Indonesia, Ireland, Israel, India, Italy, Japan, Republic of Korea, Lithuania, Morocco, Macao, Mexico, Malaysia, Netherlands, Norway, New Zealand, Peru, Philippines, Poland, Portugal, Romania, Serbia, Russia, Sweden, Slovenia, Slovakia, Tunisia, Turkey and Taiwan; and patent applications are pending in Argentina, Brazil, Canada, Egypt, Singapore, Thailand, Uruguay, Venezuela, Vietnam and South Africa. The ex-US patents will expire in September 2033, not including possible patent term extensions in countries where such extensions are available. U.S. Serial No. 16/607688, filed May 3, 2018, which relates to stable formulations fibronectin based scaffold domain proteins that bind to myostatin, was filed in the United States, Australia, Canada, China, European Union, Hong Kong, Israel,

Japan, Republic of Korea, Mexico, Singapore and Taiwan and, if granted, will expire in May 2038, not including possible patent term extensions in countries where such extensions are available.

License Agreements

The following is a summary of all license agreements that the Company has entered into. As of June 30, 2022, the Company has potential future developmental, regulatory, and commercial milestone payments under these agreements of up to approximately \$123.9 million, \$412.1 million, and \$533.8 million, respectively. As of June 30, 2022 the Company has not made any developmental, regulatory, or commercial milestone payments under these agreements.

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

In August 2015, we 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 to us their worldwide patent rights to over 300 prodrugs of glutamate modulating agents, including troriluzole, as well as other innovative technologies. Under the ALS Biopharma Agreement, we are obligated to use commercially reasonable efforts to commercialize and develop markets for the products covered by the ALS patents. The Company is obligated to pay up to \$4.0 million in aggregate potential milestones under the ALS Biopharma Agreement, comprised of \$3.0 million upon the achievement of specified regulatory milestones with respect to the first licensed product and \$1.0 million upon the achievement of specified regulatory milestones with respect to subsequently developed products. We are also obligated to pay 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 and can also be terminated if certain events occur, e.g., material breach or insolvency.

2016 License Agreement with AstraZeneca

In October 2016, we entered into an exclusive license agreement (the “2016 AstraZeneca Agreement”) with AstraZeneca, pursuant to which AstraZeneca granted us 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-5500. In exchange for these rights, we 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.

The Company is obligated to pay up to \$210.0 million in aggregate potential milestones under the 2016 AstraZeneca Agreement, comprised of development milestones with respect to Rett syndrome of up to \$30.0 million, development milestones for any indication other than Rett syndrome up to \$60.0 million, and commercial milestones based on net sales of all products licensed under the agreement that total up to \$120.0 million. We have also agreed to pay royalties in two tiers, with each tiered royalty in the range from 0-10% of net sales of products licensed under the agreement. If we receive revenue from sublicensing any of its rights under the 2016 AstraZeneca Agreement, we are also obligated to pay a portion of that revenue to AstraZeneca. We are also responsible for 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. In July 2019, Former Parent assigned its rights and obligations under the 2016 AstraZeneca Agreement to our subsidiary, Biohaven Therapeutics Ltd (“BTL”).

2018 License Agreement with AstraZeneca

In September 2018, we entered into an exclusive license agreement (the “2018 AstraZeneca Agreement”) with AstraZeneca, pursuant to which AstraZeneca granted us 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, we paid AstraZeneca an upfront cash payment of \$3.0 million and issued 109,523 shares valued at \$4.0 million on the date of settlement. The Company is obligated to pay up to \$105.0 million in aggregate potential milestone under the 2018 AstraZeneca Agreement, comprised of regulatory milestones totaling up to \$55.0 million and commercial milestones totaling up to \$50.0 million. In addition, we will pay AstraZeneca royalties in three tiers, with each tiered royalty in the range from 0-10% of net sales of specified approved products, subject to specified reductions. Verdiperstat is currently being studied in the HEALEY ALS Platform Trial, which is the first-ever platform trial in ALS designed to evaluate multiple investigational treatments simultaneously, thus accelerating the development of effective and breakthrough treatments for people living with ALS. We are solely responsible, and have agreed to use commercially reasonable efforts, for all development, regulatory and commercial activities related to verdiperstat. We may sublicense its rights under the agreement and, if we do so, will be obligated to pay a portion of any milestone payments received from the sublicense to AstraZeneca in addition to any milestone payments we 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. Each royalty term begins on the date of the first commercial sale of the licensed product in the applicable country and ends on the later of 10 years from such first commercial sale or the expiration of the last to expire of the applicable patents in that country.

Agreement with Catalent U.K. Swindon Zydis Limited

In March 2015, we entered into a development and license agreement with Catalent, pursuant to which we obtained certain license rights to the Zydis ODT technology in BHV-0223. We made an upfront payment of \$0.3 million to Catalent upon entering into the agreement and we are obligated to pay Catalent aggregate potential milestones up to \$1.6 million under the agreement, comprised of \$0.8 million in regulatory milestones and \$0.8 million in commercial milestones. We are also obligated to make royalty payments of a low single-digit percentage based on net sales of products licensed under the agreement. In July 2019, Former Parent assigned all rights and obligations under this agreement to our subsidiary, BTL.

The development and license agreement terminates on a country-by-country basis upon the later of (i) 10 years after the launch of the most recently launched product in such country and (ii) the expiration of the last valid claim covering each product in such country, unless earlier voluntarily terminated by us. The agreement automatically extends for one-year terms unless either party gives advance notice of intent to terminate. In addition, Catalent may terminate the agreement either in its entirety or terminate the exclusive nature of the agreement on a country-by-country basis if we fail to meet specified development timelines, which we may extend in certain circumstances.

License Agreement with Yale University for Riluzole and Troriluzole

We are party to an exclusive license agreement (the “Yale Agreement”) with Yale University to obtain a license to certain patent rights and know-how 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, Former Parent 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 Former Parent, in addition to the obligation to issue shares to prevent anti-dilution. The obligation to contingently issue equity to Yale was no longer outstanding as of December 31, 2018.

The Yale Agreement was amended and restated, and assigned to BTL, in May 2019. As amended, the Company is obligated to pay up to \$2.0 million in specified potential regulatory milestones. We are also obligated to pay 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, we may develop products based on riluzole or troriluzole. The amended and restated agreement retains a minimum annual royalty of up to \$1.0 million per year, beginning after the first sale of product under the agreement. If we grant any

sublicense rights under the Yale Agreement, we must pay Yale a low single-digit percentage of sublicense income that it receives.

License Agreement with Yale University for MoDE Platform

In January 2021, we entered a worldwide, exclusive license agreement with Yale University for the development and commercialization of a novel Molecular Degradator of Extracellular Protein (“MoDE”) platform (the “Yale MoDE Agreement”). Under the license agreement, we 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, we paid Yale University an upfront cash payment of \$1.0 million and issued 11,668 common shares valued at approximately \$1.0 million. Under the agreement, we may develop products based on the MoDE platform. The agreement includes an obligation to pay a minimum annual royalty of up to \$1.0 million per year, and low single digit royalties on the net sales of licensed products. If we grant any sublicense rights under the Yale Agreement, we must pay Yale a low single-digit percentage of sublicense income that it receives. The Company is obligated to pay aggregate potential milestones of up to \$3.8 million under the Yale MoDE Agreement, comprised of development milestones of up to \$0.8 million and commercial milestones of up to \$3.0 million. 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 and can also be terminated if certain events occur, e.g., material breach or insolvency.

License Agreement with the University of Connecticut

In October 2018, we announced we signed an exclusive, worldwide option and license agreement (the “UConn Agreement”) with the University of Connecticut (“UConn”), for the development and commercialization rights to UC1MT, a therapeutic antibody targeting extracellular metallothionein. Under this agreement, we have the option to acquire an exclusive, worldwide license to UC1MT and its underlying patents to develop and commercialize throughout the world in all human indications. If we choose to exercise the option, we would be obligated to pay UConn upon the achievement of specified regulatory and commercial milestones, and royalties of a low single-digit percentage of net sales of licensed products sold by the Company, its affiliates or its sublicenses. We are not currently obligated to pay any milestones under the UConn Agreement, as we have not elected to exercise the option described above.

Fox Chase Chemical Diversity Center Inc. Agreement

In May 2019, we entered into an agreement with the FCCDC in which we purchased certain intellectual property relating to the TDP-43 protein from FCCDC. The FCCDC Agreement provides us with a plan 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, Former Parent issued 100,000 of its common shares to FCCDC valued at \$5.6 million. In addition, we are obligated to pay FCCDC milestone payments totaling up to \$4.5 million with \$1.0 million for each additional NDA filing. Former Parent also issued a warrant to FCCDC, granting FCCDC the option to purchase up to 100,000 of our 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, we 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 us up to approximately \$3.8 million over a period of up to 30 months as success fees for research activities by FCCDC. In addition to the milestone payments, we 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. We may also license the rights developed under the FCCDC Agreement and, if we do so, will be obligated to pay a portion of any payments received from such licensee to FCCDC in addition to any milestones we would otherwise be obligated to pay. We are also responsible for the prosecution and maintenance of the patents related to the TDP-43 assets.

In aggregate, the Company is obligated to pay potential milestones of up to \$8.3 million under the FCCDC Agreement, comprised of development milestones up to \$3.8 million and regulatory milestones up to \$4.5 million, as described above.

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.

Artizan Agreements

In December 2020, we entered into an Option and License Agreement with Artizan Biosciences Inc. (the “2020 Artizan Agreement”). Pursuant to the 2020 Artizan Agreement, we acquired an option (“Option”) to obtain a royalty-based license from Artizan to manufacture, use and commercialize certain products in the United States for the treatment of diseases, including, for example, inflammatory bowel disease and other gastrointestinal inflammatory disorders, e.g., Crohn’s disease. The Option is exercisable throughout the development phase of the products at an exercise price of approximately \$4.0 million to \$8.0 million, which varies based on the market potential of the products. We and Artizan have also formed a joint steering committee to oversee, review and coordinate the product development activities with regard to all products for which we have (or have exercised in the future) the Option. We are not currently obligated to pay any milestones under the 2020 Artizan Agreement, as we have not elected to exercise the option described above.

In December 2020, simultaneously with the Option and License Agreement, we entered into a Series A-2 Preferred Stock Purchase Agreement with Artizan. Under the agreement, we paid Artizan 61,494 shares of Biohaven Pharmaceutical Holding Co. Ltd. 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.

In June 2021, we entered into a Development and License Agreement with Artizan Biosciences Inc. (the “2021 Artizan Agreement”). Pursuant to the 2021 Artizan Agreement, we acquired an exclusive, worldwide license under Artizan’s IgA-SEQ patented technology and know-how to develop, manufacture and commercialize certain of Artizan’s compounds for use in Parkinson’s Disease. Under the agreement, we are responsible for funding the development of the compounds, obtaining regulatory approvals, manufacturing the compounds and commercializing the compounds. We are also responsible for the prosecution, maintenance and enforcement of Artizan’s patents. Under the 2021 Artizan Agreement, we are obligated to pay Artizan milestones of \$20.0 million for the first licensed compound to achieve U.S. marketing authorization and \$10.0 million for each subsequent U.S. approval. In addition, we will pay Artizan commercialization milestones totaling up to \$150.0 million and royalties in the low to mid single digits. The 2021 Artizan Agreement terminates on a country-by-country basis on the later of 10 years from the first commercial sale of licensed product in such country or the expiration of Artizan’s patents in such country and can also be terminated if certain events occur, e.g., material breach or insolvency.

In June 2022, we entered into an Amendment to the Series A-2 Preferred Stock Purchase Agreement with Artizan. Under the Amendment, we made a cash payment of \$4.0 million in exchange for 22,975,301 shares of series A-2 preferred stock of Artizan out of a total of 45,950,601 shares of series A-2 preferred stock of Artizan for a total raise of \$8.0 million (the “A2 Extension Raise”). Along with the Amendment, we and Artizan executed a non-binding indication of interest (“Artizan Side Letter”) which describes terms under which we and Artizan would amend the 2020 Artizan Agreement to eliminate certain milestone payments required by us in exchange for limiting our option to the selection of the first (ARZC-001) licensed product. The Artizan Side Letter requires Artizan to commit at least 80% of the funds raised in the A-2 Extension Raise to a certain program and to raise \$35.0 million of additional capital within a certain time.

In aggregate, the Company is obligated to pay potential milestones of up to \$170.0 million, comprised of regulatory milestones up to \$20.0 million and commercial milestones up to \$150.0 million.

Reliant Agreement

In July 2021, we entered into a development and license agreement with Reliant Biosciences, LLC (the “Reliant Agreement”) pursuant to which we acquired an exclusive, worldwide license under Reliant’s patents and know-how

and sublicense under the University of Alabama's patents and know-how to collaborate on a program to develop and commercialize conjugated antibodies using Biohaven Labs' multifunctional molecules for therapeutic uses relating to IgA nephropathy and treatment of other diseases and conditions. Under the Reliant Agreement, we paid Reliant an upfront payment in the form of issuance of common shares valued at approximately \$3.7 million. In aggregate, we are obligated to pay Reliant potential development and regulatory milestones of up to \$36.5 million. Reliant will also be eligible to receive royalties of a low single-digit percentage of net sales of licensed products. The Reliant Agreement terminates four years after the effective date if an IND had not been filed, but otherwise continues on a country-by-country basis on the later of 15 years from the effective date or the expiration of the licensed patent in such country and can also be terminated if certain events occur, e.g., material breach or insolvency.

KU Leuven Agreement

In January 2022, we entered into an exclusive license and research collaboration agreement (the "KU Leuven Agreement") with Katholieke Universiteit Leuven ("KU Leuven") to develop and commercialize 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, 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 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. As consideration, we paid KU Leuven an upfront cash payment of \$3.0 million and Former Parent issued 15,340 shares valued at \$1.8 million. In aggregate, we are obligated to pay KU Leuven potential development, regulatory, and commercialization milestones 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. The 2021 KU Leuven Agreement terminates on a country-by-country basis on the later of 12 years from the first commercial sale of licensed product in such country, expiration of all regulatory exclusivity for the licensed product in the country, or the expiration of the licensed patents in such country and can also be terminated if certain events occur, e.g., material breach or insolvency.

Taldefgrobep Alfa License Agreement

In February 2022, we entered into a 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 acquired exclusive, worldwide rights under BMS' patents and know-how to develop and commercialize taldefgrobep alfa. In aggregate, we are obligated to pay BMS up to \$200.0 million of potential milestone payments, comprised of up to \$200.0 million for regulatory approval milestones. BMS will also be eligible to receive tiered, sales-based royalty percentages from the high teens to the low twenties. There were no upfront payments to BMS related to the Taldefgrobep Alfa License Agreement. Under the agreement, we are responsible for funding the development of the compounds, obtaining regulatory approvals, manufacturing the compounds and commercializing the compounds. We are also responsible for the prosecution, maintenance and enforcement of BMS' patents. The Taldefgrobep Alfa License Agreement terminates on a country-by-country basis on the later of 12 years from the first commercial sale of licensed product in such country or the expiration of BMS' patents in such country or the expiration of regulatory exclusivity and can also be terminated if certain events occur, e.g., material breach or insolvency.

Rutgers University License Agreement

In June 2016, we 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. In April 2022, we provided notice of termination of the Rutgers Agreement which became effective in July 2022. The Rutgers Agreement provided for payments by us to Rutgers of up to \$0.8 million in the aggregate upon the achievement of specified clinical and regulatory milestones and royalties of a low single-digit percentage of net sales of licensed products sold by us, its affiliates or its sublicensees, subject to a minimum amount of up to \$0.1 million per year.

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 safety 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 with a specific disease or condition 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. These clinical studies are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product approval and labeling.

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 troriluzole development program, 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 six 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. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or request a hearing. 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 regulatory data protection ("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 five-year 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 ACA, which includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, 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 biologically-derived 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 six 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. 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, healthcare professionals who participate in our clinical research programs, 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 (“HITECH”) enacted as part of the American Recovery and Reinvestment Act of 2009 and its implementing regulations, which imposes certain obligations, including mandatory contractual terms, on entities subject to the law, such as healthcare providers, health plans, and healthcare clearinghouses and their respective business associates to safeguard the privacy, security and transmission of individually identifiable health information from any unauthorized use or disclosures;
- 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, and other programs such as 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 some of which 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. Healthcare reform legislation has strengthened these federal and state healthcare laws. For example, the ACA amended 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. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states, without specifically ruling on the ACA’s constitutionality.

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. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011 (known as Medicare sequestration) and subsequent extensions, which began in 2013 and will remain in effect through 2030 (with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, with a subsequent one quarter phase-in of 1%) 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 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. President Biden continues to push for reforms that would address the high cost of drugs. In response to an Executive Order from President Biden, the Secretary of HHS recently issued a comprehensive plan for addressing high drug prices that describes a number of legislative approaches and identifies administrative tools to address the high cost of drugs. And Democrats recently included drug pricing reform provisions reflecting elements of the plan in a broader spending package in late 2021—such as capping Medicare Part D patients’ out-of-pocket costs, establishing penalties for drug prices that increase faster than inflation in Medicare, and authorizing the federal government to negotiate prices on certain select, high-cost drugs under Medicare Parts B and D. 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. In August 2022, Congress passed the Inflation Reduction Act of 2022, which included, among other things, a provision allowing Medicare to negotiate drug prices directly with pharmaceutical manufacturers.

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. 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, six of our eight directors are independent.

At the management level, we have implemented a cross-functional Sustainability Working Group, which meets on a regular basis and report to the Board periodically. We have a Chief Talent & Sustainability Officer who works closely with the working group and coordinates 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 on a quarterly basis.

Environmental Commitment

We are committed to protecting the environment and attempt to mitigate 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

For third-party vendor selection and oversight, we have adopted 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

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 comprised 190 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 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.

We strive to provide an inclusive workplace to foster growth and innovation. Our Diversity, Equity and Inclusion (“DEI”) Plan “Roadmap to Belonging” will include 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 we have made strides to diversify our senior leadership, with the number of females in scientific leadership positions becoming a strength of our organization.

We have established both an office-based and field-based response to protect our employees from COVID-19 infection. 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. 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.

Corporate Information

We are a business company limited by shares organized under the laws of the British Virgin Islands. 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 is located at 215 Church Street, New Haven, Connecticut 06510 and our telephone number is (203) 404-0410. Our website address is www.biohaven.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in making an investment decision regarding our common shares. On September 16, 2022, the Company changed its name from “Biohaven Research Ltd.” to “Biohaven Ltd.”

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 our 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 operations. The lease commenced on May 13, 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, we entered into a license agreement in Dublin, Ireland for approximately 1,000 square feet of office space to support our 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 had a term of 36 months. In April 2022, we entered into an addendum to the license agreement, in which the parties agreed to terminate the license on August 31, 2022. Pursuant to the

addendum, the Company's access to the space and its monetary obligations under the license ended on May 31, 2022.

In January 2021, in connection with our acquisition of the remaining interest in 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 from January 2021, 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, with an option to extend.

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, with an automatic renewal unless either party decides to terminate the agreement.

In April 2022, in connection with our acquisition of Channel Biosciences, LLC ("Channel Biosciences"), we acquired the lease on approximately 20,000 square feet of office and research space in Pittsburgh, Pennsylvania. The lease term expires in October 2024, with an option to extend.

In May 2022, we assumed a lease in Dublin, Ireland for approximately 6,000 square feet of office space to support our operations. The new Dublin office lease replaces the Dublin office license that will terminate on August 31, 2022. The lease assignment took effect in May 2022 and the lease has a remaining term of 59 months from May 2022, with no option to extend.

In June 2022, we entered into a lease agreement in West Palm Beach, Florida for approximately 9,000 square feet of office space, which will be used for executive and corporate office functions. The lease is expected to commence in late 2024, following substantial completion of tenant improvements, and has a term of 120 months, with an option to extend.

In October 2022, we entered into a lease agreement in Cambridge, Massachusetts for approximately 27,000 square feet of lab and office space, which will be used for general office, laboratory and research and development purposes. The lease commenced on October 19, 2022, and has a term of 120 months, with an option to extend.

We believe that our current facilities are suitable and adequate to meet our current needs and we believe that suitable additional or substitute space will be available as needed to accommodate any future expansions.

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 June 30, 2022, there were no such matters which we believe would have a material adverse impact on our business, operating results or financial condition.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the JOBS Act, and we are eligible to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." These exemptions generally include, but are not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We plan to take advantage of some or all of the reduced regulatory and reporting requirements that will be available to us as long as we qualify as an emerging growth company, except that we have irrevocably elected not to

take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act.

We will, in general, remain as an emerging growth company for up to five full fiscal years following the Distribution. We would cease to be an emerging growth company and, therefore, become ineligible to rely on the above exemptions, if we:

- have more than \$1.235 billion in annual revenue in a fiscal year;
- issue more than \$1 billion of non-convertible debt during the preceding three-year period; or
- become a “large accelerated filer” as defined in Exchange Act Rule 12b-2, which would occur after: (i) we have filed at least one annual report pursuant to the Exchange Act; (ii) we have been an SEC-reporting company for at least twelve months; and (iii) the market value of our common shares that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter.

Smaller Reporting Company Status

Additionally, we are a “smaller reporting company,” as defined in Rule 12b-2 under the Exchange Act. As such, we are eligible for exemptions from various reporting requirements applicable to other public companies that are not smaller reporting companies, including, but not limited to, reduced disclosure obligations regarding executive compensation.

We will remain a smaller reporting company as long as either:

- (i) the market value of our common shares held by non-affiliates is less than \$250 million as of the last business day of our most recently completed second fiscal quarter; or
- (ii) our annual revenue is less than \$100 million during the most recently completed fiscal year and the market value of our common shares held by non-affiliates is less than \$700 million as of the last business day of our most recently completed second fiscal quarter.

MANAGEMENT

Directors and Executive Officers

The following table sets forth information concerning our directors and executive officers, including their ages as of the date of this prospectus:

Name	Age	Position
<i>Executive Officers:</i>		
Vlad Coric, M.D.	51	Chief Executive Officer and Chairman of the Board
Matthew Buten	61	Chief Financial Officer
Kimberly Gentile	56	Senior Vice President of Clinical Operations
Bruce Car	61	Chief Scientific Officer
<i>Non-Management Directors:</i>		
Michael T. Heffernan	57	Director
Gregory H. Bailey, M.D.	66	Director
Robert J. Hugin	67	Director
John W. Childs	80	Director
Julia P. Gregory	69	Director
Kishan Mehta	36	Director
Irina Antonijevic	57	Director

Executive Officers

Vlad Coric, M.D.

Dr. Coric, age 51, has served as our chief executive officer and as a director since incorporation, and was previously the chief executive officer and a director of Former Parent. Dr. Coric has more than 22 years of drug development experience at Yale School of Medicine, Bristol-Myers Squibb, Biohaven and the Former Parent. He has been involved in multiple drug development programs, including marketed drugs or filed NDAs such as Nurtec ODT (rimegepant; oral calcitonin related peptide antagonist), zavegepant (intranasal calcitonin related peptide antagonist), Abilify® (aripiprazole; partial dopamine agonist), Opdivo® (nivolumab; anti-PD1), Yervoy® (Ipilimumab; anti-CTLA-4), Daklinza® (daclatasvir; NS5A inhibitor), and Sunvepra® (asunaprevir; NS3 inhibitor). From January 2007 to September 2015, he served as a group director of global clinical research at Bristol-Myers Squibb Company, or BMS, focusing both in oncology global clinical research and neuroscience global clinical research. Under Dr. Coric's leadership, Biohaven has developed a broad therapeutic portfolio comprised of early- and late-stage product candidates targeting neurological and neuropsychiatric diseases, epilepsy, bipolar and major depressive disorder, OCD, SCA and SMA. Dr. Coric also led Biohaven's acquisition of its novel Kv7 channel platform and the sale of the Former Parent to Pfizer in 2022. Since July 2001, Dr. Coric has also continued to serve as an associate clinical professor of psychiatry at Yale School of Medicine. He previously served as the chief of the Yale Clinical Neuroscience Research Unit and the director of the Yale Obsessive-Compulsive Disorder Research Clinic. He has served as president of the Connecticut Psychiatric Society. He also serves on the boards of directors of Vita Therapeutics, Inc., Pyramid Biosciences, Inc. and OLM School of Madison. Dr. Coric received his M.D. from Wake Forest University School of Medicine. He completed his internship at Yale-New Haven Hospital and residency training at the Yale Psychiatry Residency Training Program, where he also served as the program-wide chief resident for the Yale Department of Psychiatry, and chief resident on the PTSD firm at the West-Haven Connecticut Veterans Administration Hospital. Dr. Coric was an honors scholar in neurobiology and physiology at the University of Connecticut where he received a B.S. degree. We believe that Dr. Coric's operational experience with our Company gained from serving as our chief executive officer, as well as his extensive experience in the biopharmaceutical industry, qualifies him to serve as a member of our Board.

Matthew Buten

Mr. Buten serves as our chief financial officer, and previously he served as the chief financial officer of Former Parent since 2021. Mr. Buten previously served as Managing Director of Foresite Capital Management from December 2012 to December 2021. Prior to joining Foresite Capital Management, Mr. Buten served as a healthcare portfolio manager at Catapult Capital Management LLC / Millennium LP from June 2007 to June 2012. Prior to that, Mr. Buten was co-founder and co-manager of Sapphire Capital Partners LLP, a co-founder and a partner at Argus Partners, a Managing Director and Head of Healthcare Investment Banking for Needham & Company, LLC and as a Director in Investment Banking at Smith Barney Inc. Mr. Buten holds a Bachelor of Science in economics (B.S.) from The Wharton School of the University of Pennsylvania.

Kimberly Gentile

Ms. Gentile serves as our senior vice president, clinical operations and prior to that she served as the senior vice president, clinical operations of Former Parent since February 2014. Before coming to Biohaven, Ms. Gentile served as associate director, project manager, global clinical operations at BMS from 2000 to February 2014. Prior to this, she was a senior clinical trial manager at SCIREX Corporation from 1996 to June 2000. Ms. Gentile received her B.S. in Psychology from Salem State University.

Bruce Car, Ph.D.

Dr. Car joined Biohaven on August 1, 2022, having served since January 2020 as Chief Scientific Officer at Agios Pharmaceuticals, where the research focus was initially oncology and genetically defined diseases (GDD), later driving the portfolio to sole GDD approaches. Prior to Agios, Bruce spent 25 years at Bristol-Myers Squibb (BMS) and its legacy companies, working across all therapeutic areas and drug modalities. For more than two decades, he held roles of increasing responsibility in drug discovery, covering all therapeutic areas, drug platforms, India R&D site, and different stages of discovery. In early 2017, he became the first head of the BMS Translational Medicine function, where he built a cohesive team of over 300 scientists and specialists covering biomarkers through data science and pharmaco-diagnostics. During his tenure with BMS, Dr. Car contributed to progressing approximately 250 internally discovered drug candidates and over 18 drug registrations. Dr. Car left BMS as the interim head of Drug Discovery. Dr. Car received a degree in Veterinary Medicine from The University of Melbourne, Victoria, Australia ('83), and his Ph.D ('89) from Cornell University, NY, USA. He holds specialty certifications in anatomic and clinical pathology. Dr. Car undertook his postdoctoral studies in immunology and inflammation at the Theodor Kocher Institute, University of Berne and ETH/University of Zurich in Switzerland.

Non-Management Directors***Michael T. Heffernan***

Michael T. Heffernan, Lead Independent Director, age 57, has served as a director of our Company since September 2022, and prior to that served as a director of Former Parent since January 2020. Mr. Heffernan has over 25 years of leadership experience in the biotech and pharmaceutical industries. Mr. Heffernan is the Founder and Chairman of the Board of Collegium Pharmaceutical, Inc. (NASDAQ: COLL), where he previously served as President and Chief Executive Officer from October 2002 until July 2018. In addition, he is actively managing Avenge Bio, Inc. an Immuno-Oncology company that he co-founded in March 2019. Prior to his time at Collegium Pharmaceutical, Inc. Mr. Heffernan served as President and Chief Executive Officer of Onset Dermatologics LLC, a dermatology company that he founded in November 2005 and spun out of Collegium Pharmaceutical, Inc. to create PreCision Dermatology Inc. in December 2010. PreCision Dermatology Inc. was later sold to Bausch Health Companies Inc. (formerly Valeant Pharmaceuticals International Inc.) in July 2014. Prior to that, Mr. Heffernan held positions as co-founder and Chief Executive Officer of Clinical Studies Ltd., a pharmaceutical contract research organization that was sold to PhyMatrix Corp., a public healthcare services company, and Chief Executive Officer and Chairman of PhyMatrix Corp. Mr. Heffernan began his career at Eli Lilly and Company where he served in numerous sales and marketing roles. Mr. Heffernan has been an advisor, investor and board member in a number of biopharmaceutical and healthcare services companies. His recent board memberships include: TyRx, Inc. (sold to Medtronic plc), PreCision Dermatology Inc. (sold to Bausch Health Companies Inc.), Ocata Therapeutics, Inc. (sold to Astellas Pharma Inc.), and Veloxis Pharmaceuticals, Inc. (sold to Asahi Kasei Corporation). He is a member of

the board of Akebia Therapeutics, Inc. (NASDAQ: AKBA), Synlogic, Inc. (NASDAQ: SYBX) and Trevi Therapeutics Inc. (NASDAQ: TRVI). We believe that Mr. Heffernan's extensive experience as a senior executive in the commercial pharmaceutical industry qualifies him to serve as a member of our Board.

Gregory H. Bailey, M.D.

Gregory H. Bailey, M.D., age 66, has served as a director of the Company since September 2022, and prior to that served as a director of Former Parent since January 2014. Since co-founding the company in October 2016, Dr. Bailey has served as CEO of Juvenescence Limited, a life science and biotech company developing therapies to increase healthy human longevity. Dr. Bailey is a co-founder and has served as managing partner of MediqVentures since January 2014, the chairman and director of Portage Biotech, Inc. (OTCBB: PTGEF) since June 2013, a director of Portage Pharmaceuticals Limited since June 2013, and director of Manx Financial Group since March 2018. He has been a managing partner of Palantir Group, Inc., a merchant bank involved in a number of biotech company startups and financings since April 2002. Dr. Bailey was a founder of SalvaRx Group Plc and has served on its board of directors since May 2015. Dr. Bailey was also the co-founder of Ascent Healthcare Solutions, VirnetX Inc. (NYSE American: VHC), and DuraMedic Inc. He was the initial financier and an independent director of Medivation, Inc., from 2005 to December 2012. He has also served on the board of directors of AgeX Therapeutics, Inc. (NYSE American: AGE) since 2018. Dr. Bailey practiced emergency medicine for ten years before entering finance. He received his medical degree from the University of Western Ontario. We believe that Dr. Bailey's extensive venture capital industry experience and technical background, along with his experience with public companies and biopharmaceutical companies, qualifies him to serve as a member of our Board.

Robert J. Hugin

Robert J. Hugin, age 67, has served as a director of our Company since September 2022, and prior to that served as a director of Former Parent since June 2020, served as Chief Executive Officer of Celgene Corporation, a biopharmaceutical company, from June 2010 until March 2016, as Chairman of its Board of Directors from June 2011 to March 2016 and as Executive Chairman from March 2016 to January 2018. Prior to June 2010, Mr. Hugin held a number of management roles at Celgene, including President from May 2006 to July 2014, Chief Operating Officer from May 2006 to June 2010 and Senior Vice President and Chief Financial Officer from June 1999 to May 2006, and served as a director of Celgene from December 2001 through January 2018. Prior to that, Mr. Hugin was a Managing Director at J.P. Morgan & Co. Inc., which he joined in 1985. Mr. Hugin is currently a member of the board of directors of Chubb Limited. In the past five years, Mr. Hugin also served as a director of Allergan plc, Danaher Corporation and The Medicines Company. We believe that Mr. Hugin's extensive experience as a chief executive officer in the biopharmaceutical industry qualifies him to serve as a member of our Board.

John W. Childs

John W. Childs, age 80, has served as a director of our Company since September 2022, and prior to that served as a director of Former Parent since January 2014. Mr. Childs is the Chairman of J.W. Childs Associates, L.P., a private equity and special situation investment firm founded in 1995, currently focusing on life science, real estate and consumer brands investments. Previously, Mr. Childs was Senior Managing Director of the Thomas H. Lee Company from 1987 to 1995, where he had broad responsibilities for originating, analyzing, negotiating, and managing leveraged buyout transactions, such as Snapple and General Nutrition Company. Prior to that Mr. Childs held various executive positions in the investment area at the Prudential Insurance Company of America, ultimately serving as Senior Managing Director in charge of the Capital Markets Group. He is currently a Director of Realm, LLC, a premium Napa wine company, Biohaven Pharmaceuticals, Pyramid Biosciences, OMAX Health, VeraDermics and Basin Holdings. Prior to their sale, he was Chairman of the Board of Kosta Browne, Sunny Delight and CHG Healthcare Services. Mr. Childs is also on the board of Delta Waterfowl, Waterfowl Research Foundation and the Wild Salmon Center, focusing on wildlife conservation. Mr. Childs has a B.A. from Yale University and a M.B.A. from Columbia University. We believe that Mr. Childs's extensive experience in private equity, venture capital and life science qualifies him to serve as a member of the Board.

Julia P. Gregory

Julia P. Gregory, age 69, has served as a director of our Company since September 2022, and prior to that served as a director of Former Parent since August 2017. Ms. Gregory has been Chairman and CEO of Isometry Advisors, Inc., a biotechnology financial, strategy and management advisory firm, since April 2016. Ms. Gregory formerly served as Chief Executive Officer at ContraFect Corporation (NASDAQ: CFRX) from November 2013 through March 2016 and as a member of ContraFect's Board of Directors from April 2014 through March 2016. Prior to her appointment as CEO, she served as ContraFect's Executive Vice President and Chief Financial Officer from July 2012 to November 2013. Prior to her time at ContraFect, she served as President and CEO of Five Prime Therapeutics, Inc. (NASDAQ: FPRX) from 2009 until August 2011, and as Executive Vice President, Corporate Development and Chief Financial Officer of Lexicon Pharmaceuticals, Inc. (NASDAQ: LXX) from 2000 to 2008. Ms. Gregory has 20 years of investment banking experience, starting at Dillon, Read & Co. and subsequently at Punk, Ziegel & Company, where she served as the head of investment banking and head of its life sciences practice. Ms. Gregory served on the Board of Directors of the Sosei Group Corporation (TSE: 4565.T) through March 2020, and as Executive Chair of Cavion, Inc. (sold to Jazz Pharmaceuticals plc. in August 2019). Ms. Gregory currently serves on the Boards of Directors of public companies Nurix Therapeutics, Inc. (NASDAQ: NRIX), Freeline Therapeutics Holdings plc (NASDAQ: FRLN), and IMV, Inc. (NASDAQ: IMV; TSX: IMV.TO). Ms. Gregory obtained a Masters of Business Administration from the Wharton School at the University of Pennsylvania, and earned her B.A. at George Washington University. We believe that Ms. Gregory's industry leadership and expertise in strategy development and implementation, investment banking and business development qualify her to serve as a member of our Board.

Kishan Mehta

Kishan Mehta, age 36, has served as a director of our Company since September 2022, and prior to that served as a director of Former Parent since June 2021. Mr. Mehta is the Portfolio Manager of the Averill strategy at Suvretta Capital Management, LLC. Mr. Mehta has over a decade of experience in the healthcare industry. Since 2021, Mr. Mehta has also served as President and a director of four Nasdaq-listed special-purpose acquisition companies affiliated with Suvretta, Social Capital Suvretta Holdings Corp. I, Social Capital Suvretta Holdings Corp. II, Social Capital Suvretta Holdings Corp. III, and Social Capital Suvretta Holdings Corp. IV. Prior to becoming the Portfolio Manager of the investment strategy, he served as a strategic advisor to the Company where he advised the firm on various business development, corporate strategy, and capital structure decisions. From 2016 to 2018, Mr. Mehta served as a Portfolio Manager at Surveyor Capital, a division of Citadel, where he managed a beta and factor neutral, healthcare-focused long/short equity portfolio. From 2012 to 2016, he was an Analyst at Adage Capital, where he focused on public/private investments in therapeutics. Prior to that, Mr. Mehta had a similar role at Apothecary Capital, a division of BBT Capital. From 2007 to 2010, Mr. Mehta worked as a Mergers & Acquisitions Analyst at Evercore Partners, focusing on pharmaceuticals. We believe that Mr. Mehta's extensive experience in finance, equity investments and life science companies qualifies him to serve on the Board.

Irina Antonijevic

Irina Antonijevic, age 57, has served as a director of our Company since September 2022, and prior to that served as a director of Former Parent since May 2022. Dr. Antonijevic is currently Chief Medical Officer ("CMO") and Head of R&D at Triplet Therapeutics, a company developing novel therapeutics for repeat expansion disorders such as Huntington's disease, spinocerebellar ataxias and Myotonic Dystrophy. Prior to that, she served as VP of Translational Medicine and Development at Wave Life Sciences, CMO at vasopharm GmbH, developing a treatment for severe traumatic brain injury, and Head of Early Development, MS, Neurology and Ophthalmology at Sanofi Genzyme. Dr. Antonijevic has been a member of the supervisory board of 4SC AG since 2012, and of Paion AG from 2017 through early 2022. Dr. Antonijevic is board certified in Psychiatry and completed her residency in psychiatry and neurology at the Max Planck Institute for Psychiatry. Dr. Antonijevic obtained her *venia legendi* from the Berlin University and her PhD from the University of Edinburgh, United Kingdom. We believe that Dr. Antonijevic's extensive experience in neuroscience research and drug development qualifies her to serve as a member of our Board.

Board Composition

Our Board is divided into three classes and has eight members. Dr. Vlad Coric is the chairman of the Board. There are no family relationships between any of our executive officers and directors. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class will have a three-year term. Vacancies on the Board may be filled only by persons elected by a majority of the remaining directors. A director elected by the Board to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified. Our directors are divided among the three classes as follows:

- Class I consists of Michael T. Heffernan, Dr. Irina Antonijevic and Robert J. Hugin, and their term will expire at our 2023 annual meeting of shareholders;
- Class II consists of Dr. Gregory Bailey, John Childs, and Julia Gregory, and their term will expire at our 2024 annual meeting of shareholders; and
- Class III consists of Dr. Vlad Coric and Kishan Mehta, and their term will expire at our 2025 annual meeting of shareholders.

If the number of directors changes, any increase or decrease will be apportioned among the classes so as to maintain the number of directors in each class as nearly as possible. Any additional directors of a class elected to fill a vacancy resulting from an increase in such class will hold office for a term that coincides with the remaining term of that class. Decreases in the number of directors will not shorten the term of any incumbent director.

These board provisions could make it more difficult for third parties to gain control of our company by making it difficult to replace members of the Board.

Director Independence

Six of the eight members of our Board, except the Chief Executive Officer, who is an employee of the Company, and Mr. Mehta, meet the criteria for independence as defined by the rules of the NYSE and the Code of Business Conduct and Ethics for Employees, Executive Officers and Directors that is adopted by our Board (see discussion below under “—Code of Business Conduct and Ethics for Employees, Executive Officers and Directors”).

Board Committees

Our Board has established an audit committee, a compensation committee, and a nominating/corporate governance committee. Each of the committees reports to the Board as it deems appropriate, and as the Board may request. The composition, duties and responsibilities of these committees are set forth below. In the future, our Board may establish other committees, as it deems appropriate, to assist it with its responsibilities.

Audit Committee

Our audit committee reviews our internal accounting procedures and consults with and reviews the services provided by our independent registered public accountants. Our audit committee consists of three directors, John W. Childs, Julia Gregory, and Robert J. Hugin. Julia P. Gregory is the chairman of the audit committee and our Board has determined that all three directors are each an “audit committee financial expert” as defined by SEC rules and regulations. Our Board has determined that all members of our audit committee are independent directors under New York Stock Exchange listing rules and under Rule 10A-3 under the Exchange Act. We intend to continue to evaluate the requirements applicable to us and we intend to comply with the future requirements to the extent that they become applicable to our audit committee. The principal duties and responsibilities of our audit committee include:

- appointing and retaining an independent registered public accounting firm to serve as independent auditor to audit our financial statements, overseeing the independent auditor's work and determining the independent auditor's compensation;

- approving in advance all audit services and non-audit services to be provided to us by our independent auditor;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, and auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and discussing with management and our independent auditor the results of the annual audit and the independent auditor's review of our quarterly financial statements; and
- conferring with management and our independent auditor about the scope, adequacy and effectiveness of our internal accounting controls, the objectivity of our financial reporting and our accounting policies and practices.

Compensation Committee

Our compensation committee reviews and determines the compensation of all our executive officers. Our compensation committee consists of three directors, John Childs, Michael T. Heffernan and Robert J. Hugin, each of whom is a non-employee member of our Board as defined in Rule 16b-3 under the Exchange Act. Michael T. Heffernan is the chairman of the compensation committee. Our Board has determined that the composition of our compensation committee satisfies the applicable independence requirements under, and the functioning of our compensation committee complies with the applicable requirements of, the New York Stock Exchange rules and SEC rules and regulations. We intend to continue to evaluate and intend to comply with all future requirements applicable to our compensation committee. The principal duties and responsibilities of our compensation committee include:

- establishing and approving, and making recommendations to the Board regarding, performance goals and objectives relevant to the compensation of our chief executive officer, evaluating the performance of our chief executive officer in light of those goals and objectives and setting, or recommending to the full Board for approval, the chief executive officer's compensation, including incentive-based and equity-based compensation, based on that evaluation;
- setting the compensation of our other executive officers, based in part on recommendations of the chief executive officer;
- exercising administrative authority under our stock plans and employee benefit plans;
- establishing policies and making recommendations to our Board regarding director compensation;
- reviewing and discussing with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings; and
- preparing a compensation committee report on executive compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

Nominating/Corporate Governance Committee

Our nominating and corporate governance committee consists of five directors, Dr. Gregory Bailey, Julia Gregory, Michael T. Heffernan, Irina Antonijevic, and Robert J. Hugin. Dr. Gregory Bailey is the chairman of the nominating and corporate governance committee. Subject to our compliance with the phase-in provisions below, our Board has determined that the composition of our nominating and corporate governance committee satisfies the applicable independence requirements under, and the functioning of our nominating and corporate governance committee complies with the applicable requirements of, the New York Stock Exchange standards and SEC rules and regulations. Upon the listing of our common shares on the NYSE, a majority of the members of our nominating and corporate governance committee satisfied the applicable independence requirements of the NYSE. We are permitted to phase in our compliance with the independent nominating and corporate governance committee

requirements of the NYSE, which requires all members to be independent within one year of listing. We will comply with the phase-in requirements of the NYSE rules, and within one year of our listing on the NYSE, all members of our nominating and corporate governance committee will be independent under NYSE rules. We will continue to evaluate and will comply with all future requirements applicable to our nominating and corporate governance committee. The nominating and corporate governance committee's responsibilities will include:

- assessing the need for new directors and identifying individuals qualified to become directors;
- recommending to the Board the persons to be nominated for election as directors and to each of the Board's committees;
- assessing individual director performance, participation and qualifications;
- developing and recommending to the Board corporate governance principles;
- monitoring the effectiveness of the Board and the quality of the relationship between management and the Board; and
- overseeing an annual evaluation of management's and the Board's performance.

Leadership Structure and Risk Oversight

Management is responsible for the day-to-day management of risks the Company faces, while the Board, as a whole and through its committees, provides risk oversight. In its risk oversight role, the Board must satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed, including assessing major risk factors relating to the Company and its performance, and reviewing measures to address and mitigate risks. While the full Board is charged with overseeing risk management, various committees of the Board and members of management also have responsibilities with respect to our risk oversight. In particular, the audit committee plays a large role in monitoring and assessing our financial, legal and operational risks, and receives regular reports from the management team regarding comprehensive organizational risk as well as particular areas of concern. Our audit committee charter gives the audit committee responsibilities and duties that include discussing with management, the internal audit department and the independent auditors our major financial risk exposures and the steps management has taken to monitor and control such exposures, including our risk assessment and risk management policies.

Our Board is committed to sound and effective corporate governance practices. The Company's management and our Board reviewed our corporate governance practices in light of the Sarbanes-Oxley Act of 2002. Based on that review, the Board maintains codes of ethics and conduct, corporate governance guidelines, committee charters, complaint procedures for accounting and auditing matters. The Company is listed on the NYSE, and therefore, it has modeled its corporate governance practices after the listing requirements of NYSE.

Compensation Committee Interlocks and Inside Participation

None of the members of our compensation committee is or has at any time during the past year been an officer or employee of ours. None of our executive officers currently serves or in the past year has served as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our Board or compensation committee.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

We adopted a code of business conduct and ethics (the "Code of Conduct"), applicable to all of our employees, executive officers and directors. The Code of Conduct is available on our website at www.biohaven.com. The information that appears on our website is not part of, and is not incorporated into, this prospectus. The nominating and corporate governance committee of our Board is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

Non-Employee Director Compensation

Our Board will adopt a director compensation policy for our non-employee directors.

As we were not formed as of December 31, 2021, we did not have any directors or pay any compensation to non-employee directors with respect to service on our Board during the year ended December 31, 2021.

Historical information concerning the compensation paid to or earned by directors of Former Parent may not be directly relevant to or indicative of the compensation that any such directors will receive (as applicable) as directors of the Company following the Distribution, but is available in Former Parent's previous annual proxy statements filed with the SEC. Disclosure of the compensation that Former Parent directors received during the year ended December 31, 2021 is included in the proxy statement that Former Parent filed on March 11, 2022.

EXECUTIVE COMPENSATION

Summary Compensation Table

As a newly formed entity, we did not have any executive officers or pay any compensation during the year ended December 31, 2021. Historical information concerning the compensation paid to or earned by named executive officers of Former Parent may not be directly relevant or indicative of the compensation that any such officers will receive (as applicable) as named executive officers of the Company following the Distribution, but is available in Former Parent's previous annual proxy statements filed with the SEC. Disclosure of the compensation that Former Parent named executive officers received during the year ended December 31, 2021 is included in the proxy statement that Former Parent filed on March 11, 2022. Detailed information on the compensation arrangements of our named executive officers for 2022 will be provided in our 2023 proxy statement.

See "Management—Directors and Executive Officers" of this prospectus for the list of individuals who currently serve as executive officers of the Company.

Executive Compensation

Equity Incentive Plans

We believe that equity-based compensation is an important component of the executive compensation program of the Company because we believe it is important to maintain a strong link between executive incentives and the creation of stockholder value. Accordingly, we adopted the 2022 Equity Incentive Plan, which we refer to as the "2022 Plan," and the 2022 Employee Share Purchase Plan, which we refer to as the "ESPP". The material terms of these plans are set forth below.

2022 Equity Incentive Plan

Our Board adopted our 2022 Equity Incentive Plan, or 2022 Plan on September 29, 2022, and our shareholders approved the 2022 Plan on September 28, 2022. The 2022 Plan became effective immediately prior to the Distribution.

Share Awards. The 2022 Plan provides for the grant of incentive share options, or ISOs, nonstatutory share options, or NSOs, share appreciation rights, restricted share awards, restricted share unit awards, performance-based share awards, and other forms of equity compensation, which we refer to collectively as share awards. Additionally, the 2022 Plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants of us and our affiliates.

Share Reserve. Initially, the aggregate number of common shares that may be issued pursuant to share awards under the 2022 Plan will equal 9,190,000 common shares on a fully diluted basis. Additionally, the number of common shares reserved for issuance under our 2022 Plan will be increased on January 1 of each year, beginning on January 1, 2023 and continuing through and including January 1, 2032, by a number of common shares equal to 4.00% of the total number of shares of our common shares outstanding on a fully diluted basis on December 31 of the preceding calendar year or such smaller number of common shares as determined by our Board.

Reversion of Shares. If a share award granted under the 2022 Plan expires or otherwise terminates without being exercised in full, or is settled in cash, the common shares not acquired pursuant to the share award again will become available for subsequent issuance under the 2022 Plan. In addition, the following types of shares under the 2022 Plan may become available for the grant of new share awards under the 2022 Plan: (1) common shares that are forfeited to or repurchased by us prior to becoming fully vested; (2) common shares withheld or reacquired to satisfy income or employment withholding taxes; or (3) common shares used to pay the exercise or purchase price of a share award. Shares issued under the 2022 Plan may be previously unissued shares or reacquired shares bought by us on the open market. As of the date hereof, 9,110,000 option awards have been granted and no common shares have been issued under the 2022 Plan.

Non-Employee Director Compensation Limit. Under the 2022 Plan, the maximum number of common shares subject to share awards granted under the 2022 Plan or otherwise during any one calendar year to any of our non-employee directors, taken together with any cash fees paid by us to such non-employee director during such calendar year for services on the Board, will not exceed \$1,000,000 in total value (calculating the value of any such share awards based on the grant date fair value of such share awards for financial reporting purposes); *provided, however*, that (i) this limit will equal \$1,500,000 with respect to the calendar year during which a non-employee director is newly appointed as a member of the Board (including with respect to the 2022 calendar year); and (ii) the independent members of the Board may make exceptions to this limit for a member participating in a special committee, *provided* that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation.

Administration. Our Board, or a duly authorized committee thereof, has the authority to administer the 2022 Plan. Our Board may also delegate to one or more of our officers the authority to (1) designate employees (other than other officers) to be recipients of certain awards, and (2) determine the number of common shares to be subject to such awards. Subject to the terms of the 2022 Plan, our Board or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of awards to be granted and the terms and conditions of the awards, including the period of their exercisability and vesting schedule applicable to an award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under our 2022 Plan. Subject to the terms of our 2022 Plan, the plan administrator has the authority to reduce the exercise, purchase or strike price of any outstanding share award, cancel any outstanding share award in exchange for new share awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

Share Options. ISOs and NSOs are granted pursuant to share option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a share option, within the terms and conditions of the 2022 Plan, provided that the exercise price of a share option generally cannot be less than 100% of the fair market value of our common shares on the date of grant. Options granted under the 2022 Plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of share options granted under the 2022 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's share option agreement provide otherwise, if an optionholder's service relationship with us, or any of our affiliates, ceases for any reason other than disability or death, the optionholder may generally exercise any vested options for a period of 3 months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder's service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common shares issued upon the exercise of a share option will be determined by the plan administrator and may include (1) cash, check, bank draft or money order, (2) a broker-assisted cashless exercise, (3) the tender of common shares previously owned by the optionholder, (4) a net exercise of the option if it is an NSO, and (5) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder's death.

Tax Limitations on Incentive Share Options. The aggregate fair market value, determined at the time of grant, of our common shares with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our share plans and the share plans of any of our affiliates may not exceed \$100,000.

Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own shares possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the shares subject to the option on the date of grant, and (2) the term of the ISO does not exceed five years from the date of grant.

Restricted Share Awards. Restricted share awards are granted pursuant to restricted share award agreements adopted by the plan administrator. Restricted share awards may be granted in consideration for (1) cash, check, bank draft or money order, (2) services rendered to us or our affiliates, or (3) any other form of legal consideration. Common shares acquired under a restricted share award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. A restricted share award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted shares that have not vested will be forfeited or repurchased by us upon the participant's cessation of continuous service for any reason.

Restricted Share Unit Awards. Restricted share unit awards are granted pursuant to restricted share unit award agreements adopted by the plan administrator. Restricted share unit awards may be granted in consideration for any form of legal consideration. A restricted share unit award may be settled by cash, delivery of shares, a combination of cash and shares as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted share unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted share unit award. Except as otherwise provided in the applicable award agreement, restricted share units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

Share Appreciation Rights. Share appreciation rights are granted pursuant to share appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a share appreciation right, which generally cannot be less than 100% of the fair market value of our common shares on the date of grant. Upon the exercise of a share appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common shares on the date of exercise over the strike price, multiplied by (2) the number of common shares with respect to which the share appreciation right is exercised. A share appreciation right granted under the 2022 Plan vests at the rate specified in the share appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of share appreciation rights granted under the 2022 Plan, up to a maximum of 10 years. Unless the terms of a participant's share appreciation right agreement provides otherwise, if a participant's service relationship with us or any of our affiliates ceases for any reason other than disability or death, the participant may generally exercise any vested share appreciation right for a period of 3 months following the cessation of service. The share appreciation right term may be further extended in the event that exercise of the share appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested share appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In no event may a share appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2022 Plan permits the grant of performance-based share and cash awards, the payment of which are contingent upon the attainment of certain performance goals established by our Board.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (1) in the award agreement at the time the award is granted or (2) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (a) to exclude restructuring and/or other nonrecurring charges; (b) to exclude exchange rate effects; (c) to exclude the effects of changes to generally accepted accounting principles; (d) to exclude the effects of any statutory adjustments to corporate tax rates; (e) to exclude the effects of any items that

are unusual in nature or occur infrequently as determined under generally accepted accounting principles; (f) to exclude the dilutive effects of acquisitions or joint ventures; (g) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (h) to exclude the effect of any change in the outstanding common shares by reason of any share dividend or split, share repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common shareholders other than regular cash dividends; (i) to exclude the effects of share based compensation and the award of bonuses under our bonus plans; (j) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (k) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; (l) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item; and (m) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the FDA or any other regulatory body. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

Other Share Awards. The plan administrator may grant other awards based in whole or in part by reference to our common shares. The plan administrator will set the number of shares under the share award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a share split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the 2022 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of ISOs, (4) the class and maximum number of shares subject to share awards that can be granted in a calendar year and (5) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding share awards.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to share awards:

- arrange for the assumption, continuation or substitution of a share award by a surviving or acquiring entity or parent company;
- arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;
- accelerate the vesting of the award and provide for its termination prior to the effective time of the corporate transaction;
- arrange for the lapse of any reacquisition or repurchase right held by us;
- cancel or arrange for the cancellation of the award in exchange for such cash consideration, if any, as our Board may deem appropriate; or
- make a payment equal to the excess of (a) the value of the property the participant would have received upon exercise of the award over (b) the exercise price otherwise payable in connection with the award, *provided* that the payment may be \$0 if the value of the property is equal to or less than the exercise price, and payments may be delayed to the same extent that payment of consideration to the holders of common shares in connection with the corporate transaction is delayed as a result of escrows, earn outs, holdbacks or other contingencies and in compliance with Section 409A.

Our plan administrator is not obligated to treat all awards, even those that are of the same type, in the same manner.

Under the 2022 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our assets, (2) a sale or other disposition of at least 50% of our outstanding securities, (3) a

merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the common shares outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change in Control. Under the 2022 Plan, unless the plan administrator determines otherwise or as otherwise provided in an award agreement, in the event of a change in control, then contingent upon the effectiveness of the change in control, all outstanding share-based awards will become fully vested (including the lapsing of all restrictions and conditions) and, as applicable, exercisable and with respect to any share-based award subject to performance-based vesting, all performance goals or other vesting criteria will be deemed achieved at one hundred percent (100%) of target levels. Under the 2022 Plan, a change in control is generally (1) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (2) a consummated merger, consolidation or similar transaction immediately after which our shareholders cease to own more than 50% of the combined voting power of the surviving entity; (3) a consummated sale, lease or exclusive license or other disposition of all or substantially of our assets; (4) a complete dissolution or liquidation of the Company, except for a liquidation into a parent corporation, or (5) when a majority of our Board becomes comprised of individuals who were not serving on our Board on the date of adoption of the 2022 Plan, or the incumbent Board, or whose nomination, appointment, or election was not approved by a majority of the incumbent Board still in office.

Amendment and Termination. Our Board has the authority to amend, suspend, or terminate our 2022 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No ISOs may be granted after the 10th anniversary of the date our Board adopted our 2022 Plan.

2022 Employee Share Purchase Plan

Our Board adopted our 2022 Employee Share Purchase Plan, or ESPP on September 29, 2022, and our shareholders approved the ESPP on September 28, 2022. The ESPP became effective on the date of the Distribution. The purpose of the ESPP is to secure the services of new employees, to retain the services of existing employees and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code.

Share Reserve. The ESPP authorizes the issuance of up to 393,769 of our common shares on a fully diluted basis pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of common shares reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2023 through January 1, 2032 in an amount equal to 1% of the total number of common shares outstanding on a fully diluted basis on December 31 of the preceding calendar year; *provided*, that prior to the date of any such increase, our Board may determine that such increase will be less than such amount. As of the date hereof, no common shares have been purchased under the ESPP.

Administration. Our Board has delegated concurrent authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase common shares on specified dates during such offerings. Under the ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which common shares will be purchased for employees participating in the offering. An offering under the ESPP may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, between 1% and 15% of their earnings (as defined in the ESPP) for the purchase of our common shares under the ESPP. Unless otherwise determined by our Board, common shares will be purchased for the accounts of employees participating in the ESPP at a price per share equal to the lower of (a) 85% of the fair market value of a common share on the first date of an offering or (b) 85% of the fair market value of a common share on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our Board, including: (1) being customarily employed for more than 20

hours per week; (2) being customarily employed for more than five months per calendar year; or (3) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of \$25,000 worth of our common shares based on the fair market value per common share at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the Board will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year, (3) the number of shares and purchase price of all outstanding purchase rights, and (4) the number of shares that are subject to purchase limits under ongoing offerings.

Corporate Transactions. In the event of certain significant corporate transactions, including: (1) a sale of all or substantially all of our assets, (2) the sale or disposition of 50% of our outstanding securities, (3) the consummation of a merger or consolidation where we do not survive the transactions and (4) the consummation of a merger or consolidation where we do survive the transaction but the common shares outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our shares under the ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase common shares within 10 business days prior to such corporate transaction, and such purchase rights will terminate immediately.

ESPP Amendments, Termination. Our Board has the authority to amend or terminate our ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain shareholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

Equity Incentive Awards

On October 3, 2022, following the Distribution, we granted equity-based incentive awards designed to align our executives' interests with those of our shareholders in the form of stock options. The awards were granted to the following executive officers and in the following amounts: Dr. Coric: 950,000 options; Mr. Buten: 300,000 options; and Ms. Gentile: 300,000 options. The options were each granted with an exercise price equal to the Company share price on October 3, 2022 and will vest in four equal installments, with one-quarter vesting on the date of grant and each remaining one-quarter on the first, second and third anniversary of the date of grant, subject to the grantee's continued employment through each vesting date. As of the date hereof, the award values for each executive officer have not yet been finalized.

Treatment of Outstanding Awards

In connection with and effective as of the Distribution, each outstanding option (each, a "Pre-Spin Former Parent Option") to purchase common shares of Former Parent ("Former Parent Common Shares") was adjusted so that such Pre-Spin Former Parent Option is an option to acquire Biohaven common shares (a "Biohaven Option") and an option to acquire Former Parent Common Shares (a "Post-Spin Former Parent Option"), and each outstanding restricted stock unit (a "Pre-Spin Former Parent RSU") was adjusted so that such restricted stock unit is a restricted stock unit in respect of Biohaven common shares (a "Biohaven RSU") and a restricted stock unit in respect of Former Parent Common Shares (a "Post-Spin Former Parent RSU"), in each case as set forth below, except as otherwise expressly provided in the Merger Agreement.

Each Post-Spin Former Parent Option was in respect of the number of shares underlying the applicable Pre-Spin Former Parent Option and at an exercise price equal to the product, rounded up to the nearest cent, of (A) the

exercise price of the applicable Pre-Spin Former Parent Option multiplied by (B) the quotient obtained by dividing (1) the volume-weighted average trading price of a Former Parent Common Share exclusive of the value attributable to Biohaven during the period commencing on the first trading day following the record date for the Distribution through and including the last trading day prior to the effective time of the Distribution (“Former Parent Per Share Value”) by (2) the volume-weighted average trading price of a Former Parent Common Share inclusive of the value attributable to Biohaven during the period commencing on the first trading day following the record date for the Distribution through and including the last trading day prior to the effective time of the Distribution (the “Combined Per Share Value”).

Each Biohaven Option was in respect of a number of Biohaven common shares equal to the number of shares underlying the applicable Pre-Spin Former Parent Option multiplied by 0.5 (the “Distribution Ratio”), rounded down to the nearest whole number of shares and at an exercise price equal to the price, rounded up to the nearest cent, determined by dividing (A) the product of (1) the exercise price of the Pre-Spin Former Parent Option multiplied by (2) the quotient obtained by dividing (a) the amount by which (i) the Combined Per Share Value exceeds (ii) the Former Parent Per Share Value by (b) the Combined Per Share Value, by (B) the Distribution Ratio.

Each Post-Spin Former Parent RSU was in respect of a number of restricted stock units subject to the applicable Pre-Spin Former Parent RSU, with any applicable performance conditions deemed achieved at 100%.

Each Biohaven RSU was in respect of a number of restricted stock units equal to (1) the number of shares subject to the applicable Pre-Spin Former Parent RSU, with any applicable performance conditions deemed achieved at 100%, multiplied by (2) the Distribution Ratio, rounded down to the nearest whole number of shares.

At the effective time of the Merger, each Post-Spin Former Parent Option, Post-Spin Former Parent RSU, Biohaven Option and Biohaven RSU accelerated and vested in full, except as otherwise expressly provided in the Merger Agreement. Biohaven RSUs will be settled in common shares, and Biohaven will settle the Biohaven Options into Biohaven common shares (by reducing the number of Biohaven common shares issued by a number of Biohaven common shares sufficient to satisfy the option exercise price).

Our Board adopted the Legacy Equity Award Settlement Plan on September 29, 2022, or the Legacy Award Plan, and our shareholders approved the Legacy Award Plan on September 28, 2022. The Legacy Award Plan became effective on October 3, 2022. The Legacy Award Plan is intended solely to provide for the grant and settlement of the Biohaven Options and Biohaven RSUs issued in respect of Pre-Spin Former Parent Options and Pre-Spin Former Parent RSUs, as described in this section. The aggregate number of Biohaven common shares that may be issued under the Legacy Award Plan may not exceed 4,981,801, and the actual number of Biohaven common shares that will be issued in settlement of Biohaven Options and Biohaven RSUs issued in respect of Pre-Spin Former Parent Options and Pre-Spin Former Parent RSUs will equal approximately 3,535,571.

Our Board may suspend or terminate the Legacy Award Plan at any time, and the Legacy Award Plan will be terminated following the settlement of Biohaven Options and Biohaven RSUs in respect of Pre-Spin Former Parent Options and Pre-Spin Former Parent RSUs into common shares as described above. Except as described here, the Legacy Award Plan has the same terms and conditions as the Biohaven Pharmaceutical Holding Company Ltd. 2017 Equity Incentive Plan, which are described in Former Parent’s Amendment No. 1 to Form S-1 filed with the SEC on April 24, 2017.

Employment Agreements and Offer Letters

The Company, or a member of its group, has entered into certain employment and individual agreements with its employees, including the employment agreements entered into between the Company’s wholly owned subsidiary, Biohaven Pharmaceuticals, Inc. and the Company’s executive officers.

Employment Agreements with Dr. Coric

The Company and its wholly owned subsidiary, Biohaven Pharmaceuticals, Inc., have each entered into an employment agreement with Dr. Coric. The employment agreements with Dr. Coric provide for an initial three-year

term of employment, with automatic one-year renewal periods, unless either party provides notice of non-renewal at least 90 days before the renewal date.

Under the Company's employment agreement with Dr. Coric, if the Company terminates Dr. Coric's employment, or if his employment is terminated due to death or disability, he is entitled to a lump-sum severance payment in the amount of \$350,000. Further, all stock options held by Dr. Coric will be deemed to be fully vested and exercisable on his termination date, and the exercise period of such stock options will be extended for a period of two years following the termination date (or if earlier, the end of the term of the award). These severance payments are in addition to any severance payments due to Dr. Coric under his agreement with Biohaven Pharmaceuticals, Inc., as described below. In connection with the closing of the Merger and Dr. Coric ceasing to be the Former Parent's Chief Executive Officer, Former Parent will pay Dr. Coric \$300,000 in full satisfaction of its obligations under Dr. Coric's employment agreement with the Former Parent, subject to Dr. Coric's execution of a release of claims. Dr. Coric has agreed to donate the net after tax portion of such severance payments to a charitable organization selected by Dr. Coric.

Under the employment agreement between the Company's wholly owned subsidiary, Biohaven Pharmaceuticals, Inc., and Dr. Coric, if Dr. Coric's employment with Biohaven Pharmaceuticals, Inc. is terminated without "Just Cause" (as defined therein), due to death or disability, or if Dr. Coric terminates his employment for "Good Reason" (as defined therein), subject to the execution and non-revocation of a release of claims against Biohaven Pharmaceuticals, Inc., Dr. Coric would receive (i) severance payments in equal monthly installments equal to his current base salary for 15 months following termination (or 18 months in the case of a termination within 12 months following a change in control), (ii) continued health insurance coverage for up to 15 months (or 18 months in case of a termination within 12 months following a change of control), reduced to the extent Dr. Coric receives comparable benefits elsewhere during the period, (iii) continued life insurance coverage for 15 months (or 18 months in the case of a termination within 12 months following a change of control), (iv) full vesting of all stock options, which would remain exercisable for 24 months following termination (or, with respect to a qualifying termination within 12 months following a change in control, with respect to all time-based equity awards, with stock options remaining exercisable for 12 months following termination and any performance awards continuing to be governed by their award agreements) and (v) solely upon a termination without "Just Cause" or for "Good Reason", within 12 months following a change in control, an amount equal to 1.5 times his target bonus opportunity for the performance year in which the termination occurs, payable in equal installments over 18 months following termination. The closing of the Merger was deemed to be a change in control for this purpose.

In connection with the Distribution, we entered into an employment agreement with Dr. Coric (in addition to Dr. Coric's agreement with Biohaven Pharmaceuticals, Inc.) to replace Dr. Coric's current employment agreement with the Former Parent. Under our employment agreement with Dr. Coric, he serves as Chief Executive Officer of the Company. As compensation for serving as Chief Executive Officer of the Company, Dr. Coric will receive a number of options as determined by our Board. If the Company terminates Dr. Coric's employment, or if his employment is terminated due to death or disability, he will be entitled to the same severance and option vesting benefits as he was entitled to pursuant to his employment agreement with the Former Parent, as described above. These severance payments are in addition to any severance payments due to Dr. Coric under his agreement with Biohaven Pharmaceuticals, Inc., as described above. Dr. Coric will also be subject to one-year non-competition and non-solicitation covenants.

Employment Agreements with Mr. Buten

Under the employment agreement between the Company's wholly owned subsidiary, Biohaven Pharmaceuticals, Inc., and Mr. Buten, if Mr. Buten's employment with Biohaven Pharmaceuticals, Inc. is terminated without "Just Cause," due to death or disability, or if he terminates his employment for "Good Reason," each in the absence of a "Change in Control" (as each is defined therein), subject to the execution and non-revocation of a release of claims against the Company, he is entitled to receive severance payments equal to 1.5 times the sum of the applicable base salary rate in effect plus his target bonus opportunity, payable in equal monthly installments over 18 months, plus he would also be eligible to receive a pro-rata bonus payment for the year in which he is terminated, to be determined and made at the sole discretion of the Board, equal to his target bonus opportunity, if any, which would have been awarded to him had he remained employed for the applicable performance period. In addition,

upon such termination, Mr. Buten is entitled to continued health and life insurance coverage for the period during which he receives severance payments, reduced, in the case of health benefits, to the extent he receives comparable benefits elsewhere during the period. In addition, under his employment agreement, all stock options and other equity incentive awards granted to Mr. Buten would become fully vested and exercisable upon such termination, and remain exercisable for 24 months following the date of his termination (or, if earlier, the end of the term of the award). Upon termination due to disability, the amount of severance paid to Mr. Buten is reduced by any disability benefits he receives under Biohaven Pharmaceuticals, Inc.'s disability insurance policies.

Under his employment agreement, if Mr. Buten's employment with Biohaven Pharmaceuticals, Inc. is terminated without "Just Cause" or if he terminates his employment for "Good Reason," each within 12 months following a "Change in Control" (as each is defined therein), subject to the execution and non-revocation of a release of claims against Biohaven Pharmaceuticals, Inc., he will be entitled to receive (i) an amount equal to 1.5 times the sum of his current base salary plus his target bonus opportunity, to be paid in equal installments over 18 months, (ii) a pro-rata bonus payment for the year in which he is terminated, to be determined and made at the sole discretion of the Board, equal to his target bonus opportunity, if any, which would have been awarded to him had he remained employed for the applicable performance period, and (iii) payment equal to his target bonus opportunity, to be paid in equal installments over 12 months. In addition, upon such termination, Mr. Buten is entitled to continued health and life insurance coverage during the period during which he receives severance payments, reduced to the extent he receives comparable benefits elsewhere during the severance period. All time-based vesting equity awards held by Mr. Buten as of the date of his termination will be deemed to be fully vested and exercisable on the termination date, and he may exercise such awards for 12 months following the termination date (or if earlier, the end of the term of the award). Performance awards will be governed by the terms of the applicable award agreement. Upon termination due to disability, the amount of severance paid to Mr. Buten is reduced by any disability benefits he receives under Biohaven Pharmaceuticals, Inc.'s disability insurance policies.

In connection with the Distribution, we entered into an employment agreement with Mr. Buten (in addition to Mr. Buten's agreement with Biohaven Pharmaceuticals, Inc.). Under our employment agreement with Mr. Buten, he serves as Chief Financial Officer of the Company. As compensation for serving as Chief Financial Officer of the Company, Mr. Buten will receive a number of options as determined by our Board. If the Company terminates Mr. Buten's employment, or if his employment is terminated due to death or disability, he will be entitled to a lump-sum severance payment in the amount of \$350,000 and all stock options held by Mr. Buten will be deemed to be fully vested and exercisable on his termination date, and the exercise period of such stock options will be extended for a period of two years following the termination date (or if earlier, the end of the term of the award). These severance payments are in addition to any severance payments due to Mr. Buten under his agreement with Biohaven Pharmaceuticals, Inc., as described above. Mr. Buten will also be subject to one-year non-competition and non-solicitation covenants.

Employment Agreement with Ms. Gentile

Under the employment agreement between the Company's wholly owned subsidiary, Biohaven Pharmaceuticals, Inc., and Ms. Gentile, if Biohaven Pharmaceuticals, Inc. terminates her employment without "Cause" or if she terminates her employment for "Good Reason," as each is defined therein, subject to the execution of a release of claims against Biohaven Pharmaceuticals, Inc., she is entitled to an amount equal to six months of her base salary, to be paid consistent with the Company's normal payroll schedule over six months. Ms. Gentile's employment agreement does not contain differing severance entitlements before or after a change in control.

Offer of Employment with Bruce Car

In connection with the Distribution, we entered into an amended and restated offer of employment with Mr. Car pursuant to which he serves as Chief Scientific Officer of the Company. Upon a termination of employment by the Company without "Just Cause," due to Mr. Car's death or disability or by Mr. Car for "Good Reason," subject to execution and non-revocation of a release, Mr. Car will be eligible to receive (i) an amount equal to the sum of Mr. Car's base salary and target bonus, payable in substantially equal installments over twelve months, (ii) continued health insurance coverage for up to twelve months following termination, (iii) a prorated target bonus for the year of termination, payable at the same time bonuses are paid to similarly-situated employees, (iv) payment of life

insurance premiums for 12 months following termination and (v) accelerated vesting of shares underlying time-based equity awards that would have vested in the twelve months following termination. Upon a termination of employment by the Company without “Just Cause” or by Mr. Car for “Good Reason” within 12 months of a “Change in Control,” subject to execution and non-revocation of a release, Mr. Car will be eligible to receive (i) an amount equal to the sum of Mr. Car’s base salary and target bonus, payable in substantially equal installments over twelve months, (ii) continued health insurance coverage for up to twelve months following termination, (iii) a prorated target bonus for the year of termination, payable at the same time bonuses are paid to similarly-situated employees, (iv) an amount equal to Mr. Car’s target bonus, paid in twelve monthly installments and (v) accelerated vesting of all time-based vesting equity awards. Pursuant to the offer of agreement, following a termination of employment Mr. Car will also be subject to one-year non-competition and non-solicitation covenants.

Other Executive Officer Arrangements

The compensation arrangements for our other anticipated executive officers generally provide for the following primary elements of compensation: (i) annual base salary, (ii) an annual cash incentive opportunity, (iii) eligibility for annual long-term incentive awards, and (iv) severance entitlements.

Detailed information on the compensation arrangements of our named executive officers for 2022 will be provided in our 2023 proxy statement.

Limitation of Liability and Indemnification of Officers and Directors

We adopted the Amended Memorandum and Articles of Association, which became effective and contain provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by British Virgin Islands law.

Any amendment to, or repeal of, these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to that amendment or repeal.

The Amended Memorandum and Articles of Association provide that we will indemnify, to the fullest extent permitted by law, any person who is or was a party or is threatened to be made a party to any action, suit or proceeding by reason of the fact that he is or was one of our directors or officers or is or was serving at our request as a director or officer of another corporation, partnership, joint venture, trust, or other enterprise. The Amended Memorandum and Articles of Association also provide that we may indemnify to the fullest extent permitted by law any person who is or was a party or is threatened to be made a party to any action, suit, or proceeding by reason of the fact that he is or was one of our employees or agents or is or was serving at our request as an employee or agent of another corporation, partnership, joint venture, trust, or other enterprise. Our Amended Memorandum and Articles of Association also provide that we must advance expenses incurred by or on behalf of a director or officer in advance of the final disposition of any action or proceeding, subject to very limited exceptions.

Further, in connection with the Spin-Off, we entered into indemnification agreements with each of our directors and executive officers that may be broader than the specific indemnification provisions contained under British Virgin Islands law. These indemnification agreements require us, among other things, to indemnify our directors and executive officers against liabilities that may arise by reason of their status or service. These indemnification agreements also require us to advance all expenses incurred by the directors and executive officers in investigating or defending any such action, suit, or proceeding. We believe that these agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

The limitation of liability and indemnification provisions that are included in our Amended Memorandum and Articles of Association and in indemnification agreements that we entered into with our directors and executive officers may discourage shareholders from bringing a lawsuit against our directors and executive officers for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against our directors and executive officers, even though an action, if successful, might benefit us and other shareholders. Further, a shareholder’s investment may be harmed to the extent that we pay the costs of settlement and damage awards against directors and executive officers as required by these indemnification provisions. At present, we are not aware of any pending litigation or proceeding involving any person who is or was one of our directors, officers, employees

or other agents or is or was serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

We have obtained insurance policies under which, subject to the limitations of the policies, coverage is provided to our directors and executive officers against loss arising from claims made by reason of breach of fiduciary duty or other wrongful acts as a director or executive officer, including claims relating to public securities matters, and to us with respect to payments that may be made by us to these directors and executive officers pursuant to our indemnification obligations or otherwise as a matter of law.

Certain of our non-employee directors may, through their relationships with their employers, be insured and/or indemnified against certain liabilities incurred in their capacity as members of our Board.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell our common shares on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Related-Person Transaction Policy

In connection with the Spin-Off, we adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy became effective immediately upon the completion of the Distribution. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our Board, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct, which became effective as of the Distribution date, our employees and directors have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our Board, will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our Board, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our Board, determines in the good-faith exercise of its discretion.

Certain Related Party Transactions

Except as described below, there have been no transactions since January 1, 2021 in which we have been a participant in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or holders of more than 5% of our share capital post-Distribution, or any members of their immediate family, had or will have a direct or indirect material interest, other than the compensation arrangements referenced in the Distribution Agreement and contemplated by the Transition Services Agreement, as described under "The Separation and Distribution", and the compensation arrangements described under "Executive Compensation" and "Director Compensation."

Transition Services Agreement

The Company entered into the Transition Services Agreement with the Former Parent under which the Company or one of its affiliates will provide the Former Parent, and the Former Parent or one of its affiliates will provide the Company, with certain transition services for a limited time to ensure an orderly transition following the Spin-Off. The services that the Company and the Former Parent agreed to provide to each other under the Transition Services Agreement include certain finance, information technology, clinical study support, human resources and compensation, facilities, financial reporting and accounting and other services. The Company will pay the Former Parent, and the Former Parent will pay the Company, for any such services received by the Former Parent or the Company, as applicable, at agreed amounts as set forth in the Transition Services Agreement.

United States Distribution Services Agreement

The Company entered into a United States Distribution Services Agreement with the Former Parent (the “Distribution Services Agreement”), pursuant to which the Company shall continue to serve as the Former Parent’s distributor and agent for the distribution of the pharmaceutical product Nurtec ODT in the United States for a limited period of time following the Spin-Off. Under the Distribution Services Agreement, the Former Parent and Pfizer Inc. have agreed to indemnify the Company for, among other things, losses resulting from the conduct of the distribution business or actions taken at the direction of the Former Parent.

Outsourcing & Employee Transfer Agreement

The Company entered into Outsourcing & Employee Transfer Agreements, one with Pfizer Inc., Bulldog (BVI) Ltd., the Former Parent and Biohaven Pharmaceuticals, Inc. (“U.S. Employer”), and the other with Pfizer Inc., Bulldog (BVI) Ltd., Former Parent, and BioShin (Shanghai) Consulting Services Co., Ltd. (“Chinese Employer”), pursuant to which the Chinese Employer and the U.S. Employer will, among other things, provide Pfizer Inc. with the services of, and remain the employers of, certain of their employees for a limited period of time following the Spin-Off. During such period, Pfizer Inc. or one of its affiliates will pay the U.S. Employer for employee-related expenses for its employees (including the cost of salary and wages) and will pay the Chinese Employer a service fee based on employee-related expenses for its employees (including the cost of salary and wages).

Indemnification Agreements

Our Amended Memorandum and Articles of Association contain certain provisions limiting the liability of directors and providing that we will indemnify each of our directors to the fullest extent permitted under the BVI Act. Our Amended Memorandum and Articles of Association also provide our Board with discretion to indemnify our officers and employees when determined appropriate by the Board.

In addition, we have entered into indemnification agreements with each of our directors and executive officers. For more information regarding these agreements, see “Indemnification of Directors and Officers.”

PRINCIPAL SHAREHOLDERS

The following table sets forth the beneficial ownership of our common shares that are owned as of October 14, 2022 for:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common shares;
- each of our named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

Except as otherwise noted below, the address for persons listed in the table is c/o Biohaven Ltd., 215 Church Street, New Haven, CT 06510.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
<i>Principal Shareholders:</i>		
BlackRock, Inc. ⁽¹⁾	2,317,640	5.9 %
<i>Named Executive Officers and Directors:</i>		
Vlad Coric, M.D. ⁽²⁾⁽³⁾	1,708,029	4.3 %
Matthew Buten ⁽³⁾⁽⁴⁾	98,796	— %
Kimberly Gentile ⁽⁵⁾	170,969	— %
Bruce Car ⁽⁶⁾	75,000	— %
Michael T. Heffernan ⁽⁷⁾	46,428	— %
Gregory H. Bailey, M.D. ⁽³⁾⁽⁸⁾	1,339,221	3.4 %
Robert J. Hugin ⁽⁹⁾	44,209	— %
John W. Childs ⁽³⁾⁽¹⁰⁾	1,827,501	4.6 %
Julia P. Gregory ⁽¹¹⁾	47,392	— %
Kishan Mehta ⁽³⁾⁽¹²⁾	53,912	— %
Irina Antonijevic ⁽¹³⁾	33,785	— %
All current directors and executive officers as a group (11 persons)	5,445,242	13.8 %

- (1) The amounts shown and the following information were provided by BlackRock, Inc. ("BlackRock") pursuant to a Schedule G filed with the SEC on February 3, 2022 in respect of BlackRock's ownership of Former Parent common shares. BlackRock reported that it had sole voting power and sole dispositive power over 4,635,280 Former Parent common shares. The principal business address of BlackRock, Inc. is 55 East 52nd Street, New York, NY 10055.
- (2) Consists of (i) 569,309 common shares held directly, (ii) 9,565 common shares held by 401(k) plan, (iii) 492,212 common shares held by The Vladimir Coric Family Trust, (iv) 399,443 common shares held by The Vladimir Coric Marital Trust (Elizabeth Ann Coric, Dr. Coric's spouse, serves as the sole trustee of both of the aforementioned trusts) and (v) 237,500 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.
- (3) Number of shares beneficially owned does not reflect shares that such person may acquire in connection with this offering. Vlad Coric, our Chief Executive Officer, Matthew Buten, our Chief Financial Officer, and certain of our directors and their affiliated entities have indicated an interest in purchasing approximately \$100 million, in the aggregate, of our common shares in this offering at the public offering price. Dr. Coric and Mr. Buten have indicated an interest in purchasing approximately \$10 million and \$1 million of our common shares, respectively. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to each of Dr. Coric, Mr. Buten or our directors and their affiliated entities, and any of such persons or their affiliated entities could determine to purchase more, fewer or no shares in this offering.
- (4) Consists of (i) 23,796 common shares held directly and (ii) 75,000 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.
- (5) Consists of (i) 95,969 common shares held directly and (ii) 75,000 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.
- (6) Consists of (i) 75,000 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.
- (7) Consists of (i) 15,178 common shares held directly and (ii) 31,250 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.

- (8) Consists of (i) 1,307,971 common shares held directly and (ii) 31,250 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.
- (9) Consists of (i) 12,959 common shares held directly and (ii) 31,250 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.
- (10) Consists of (i) 1,791,251 common shares held directly, (ii) 5,000 common shares held by the John W Childs 2013 Revocable Trust, and (iii) 31,250 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.
- (11) Consists of (i) 16,142 common shares held directly and (ii) 31,250 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.
- (12) Consists of (i) 22,662 common shares held directly and (ii) 31,250 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.
- (13) Consists of (i) 2,535 common shares held directly and (ii) 31,250 common shares underlying stock options that are vested and exercisable within 60 days of October 14, 2022.

DESCRIPTION OF SHARES

The following descriptions are summaries of the material terms of our Amended Memorandum and Articles of Association. Reference is made to the more detailed provisions of, and the descriptions are qualified in their entirety by reference to, the Amended Memorandum and Articles of Association. Please note that this summary is not intended to be exhaustive. For further information, please refer to the full version of our Amended Memorandum and Articles of Association which is included as an exhibit to the registration statement of which this prospectus is part.

General

We are a BVI business company limited by shares incorporated in the BVI on May 2, 2022, and our affairs are governed by the provisions of an Amended Memorandum and Articles of Association and by the BVI Business Companies Act 2004 (as revised) (as amended or modified from time to time, the “BVI Act”).

As provided in our Amended Memorandum and Articles of Association, subject to the BVI Act, we have full capacity to carry on or undertake any business or activity, do any act or enter into any transaction, and, for such purposes, full rights, powers and privileges. Our registered office is c/o Maples Corporate Services (BVI) Limited, P.O. Box 173, Road Town, Tortola, British Virgin Islands.

Authorized Shares

Our Amended Memorandum and Articles of Association authorize us to issue up to 200,000,000 common shares, no par value, and up to 10,000,000 preferred shares, no par value (each, the “Preferred Share”). Our Board may establish the rights and preferences of the Preferred Shares from time to time. As of October 14, 2022, we had 39,375,944 common shares issued and outstanding and no Preferred Shares issued.

The following are summaries of material provisions of our Amended Memorandum and Articles of Association and the BVI Act insofar as they relate to the material terms of our common shares.

Common Shares

General. The maximum number of shares we are authorized to issue are 210,000,000 divided into 200,000,000 common shares, with no par value each and 10,000,000 Preferred Shares. Holders of common shares have the same rights. All of our outstanding common shares are fully paid and non-assessable.

Our Amended Memorandum and Articles of Association do not provide for pre-emptive rights.

Dividends. The holders of our common shares are entitled to an equal share of such dividends, as may be declared by our Board subject to the BVI Act. Our Amended Memorandum and Articles of Association provide that dividends may be declared and paid at such time, and in such an amount, as the directors determine subject to their being satisfied that the Company will meet the statutory solvency test immediately after the dividend.

Voting Rights. In respect of all matters subject to a shareholders’ vote, each common share is entitled to one vote for each common share registered in his or her name on our register of shareholders. Holders of common shares shall at all times vote together on all resolutions submitted to a vote of the shareholders. Voting at any meeting of shareholders is by show of hands unless a poll is demanded. A poll may be demanded by the chairperson of such meeting or any one shareholder.

A quorum required for a meeting of shareholders consists of at least 50% of the votes of the shares entitled to vote present in person or by proxy at the meeting or, if a corporation or other non-natural person, by its duly authorized representative. Shareholders’ meetings may be held annually. Each general meeting, other than an annual general meeting, shall be an extraordinary general meeting. Directors may call general meetings, and they shall on a shareholders’ requisition forthwith proceed to convene an extraordinary general meeting of the Company. Extraordinary general meetings of the shareholders of the Company may be called, for any purpose as is a proper matter for shareholder action under applicable BVI law, by (i) the Chairperson of the Board, (ii) the Chief Executive Officer, (iii) the Directors pursuant to a resolution of directors or (iv) by shareholders holding not less than 10% of

the votes of the outstanding voting shares entitled to vote at the meeting. The Directors shall determine the time and place, if any, of such general meeting. Advance notice of at least 10 days is required for the convening of our annual general meeting and other general meetings unless such notice is waived in accordance with our Amended Memorandum and Articles of Association.

Appointment and Removal of Directors. In accordance with our Amended Memorandum and Articles of Association, any director may be appointed by resolution of shareholders and may be removed, with cause, by the affirmative vote of at least sixty-six and two-thirds percent (66 2/3%) of the votes of the common shares entitled to vote.

Transfer of Common Shares. Under the BVI Act shares that are listed on a recognized exchange may be transferred without the need for a written instrument of transfer if the transfer is carried out in accordance with the laws, rules, procedures and other requirements applicable to shares listed on the recognized exchange and subject to the Company's Amended Memorandum and Articles of Association.

Under our Amended Memorandum and Articles of Association, our Board may refuse or delay the registration of a transfer of shares where it reasonably determines that it is in the best interest of the Company to do so. Without limiting the generality of the foregoing, our Board may refuse or delay the registration of a transfer of shares if the transferor has failed to pay an amount due in respect of those shares. Where our Board passes a resolution to refuse or delay the registration of a transfer, the Company shall, as soon as practicable, send the transferor and the transferee a notice of the refusal or delay.

Liquidation. On a liquidation or winding up of the Company assets available for distribution among the holders of common shares shall be distributed among the holders of the common shares on a pro rata basis.

Calls on Common Shares and Forfeiture of Common Shares. Our Board may from time to time make calls upon shareholders for any amounts unpaid on their common shares in a notice served to such shareholders at least 14 clear days prior to the specified time of payment. The common shares that have been called upon and remain unpaid are subject to forfeiture.

Redemption of Common Shares. The BVI Act and our Amended Memorandum and Articles of Association permit us to purchase our own shares with the prior written consent of the relevant shareholders, on such terms and in such manner as may be determined by our Board and by a resolution of directors and in accordance with the BVI Act.

Variation of Rights of Shares. Other than with respect to the issuance of the Preferred Shares in accordance with our Amended Memorandum and Articles of Association, all or any of the rights attached to any class or series of shares may, subject to the provisions of the BVI Act, be varied with the consent in writing of all the holders of the issued shares of that class or series or with the sanction of a resolution passed by a majority of the votes cast at a separate meeting of the holders of the shares of that class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issuance of further shares ranking *pari passu* with or superior to such existing class of shares.

Issuance of Additional Shares. Our Amended Memorandum of Association authorizes our Board to issue additional common shares from time to time as our Board shall determine. However, under British Virgin Islands law, our directors may only exercise the rights and powers granted to them under our Amended Memorandum and Articles of Association for a proper purpose and for what they believe in good faith to be in the best interests of our Company.

Inspection of Books and Records. A shareholder of the Company is entitled, on giving written notice to the Company, to inspect (a) the memorandum and articles of association of the Company; (b) the register of shareholders; (c) the register of directors; and (d) the minutes of meetings and resolutions of shareholders and of those classes of shareholders of which he is a shareholder; and to make copies of or take extracts from the documents and records. Subject to the Amended Memorandum and Articles of Association, the directors may, if they are satisfied that it would be contrary to the Company's interests to allow a shareholder to inspect any

document, or part of a document, specified in (b), (c) and (d) above, refuse to permit the shareholder to inspect the document or limit the inspection of the document, including limiting the making of copies or the taking of extracts from the records.

Where a company fails or refuses to permit a shareholder to inspect a document or permits a shareholder to inspect a document subject to limitations, that shareholder may apply to the BVI High Court for an order that he should be permitted to inspect the document or to inspect the document without limitation.

A company is required to keep at the office of its registered agent: its memorandum and articles of association of the company; the register of shareholders or a copy of the register of shareholders; the register of directors or a copy of the register of directors; and copies of all notices and other documents filed by the company in the previous ten years.

Preferred Shares

Our Amended Memorandum and Articles of Association provide that preferred shares may be issued from time to time in one or more series. Our Board is authorized to fix the voting rights, if any, designations, powers, preferences, the relative, participating, optional or other special rights and any qualifications, limitations and restrictions thereof, applicable to the shares of each series. Our Board is able to, without shareholder approval, issue preferred shares with voting and other rights that could adversely affect the voting power and other rights of the holders of the common shares and could have anti-takeover effects. The ability of our Board to issue preferred shares without shareholder approval could have the effect of delaying, deferring or preventing a change of control of us or the removal of existing management. We have no preferred shares issued and outstanding at the date hereof. Although we do not currently intend to issue any preferred shares, we cannot assure you that we will not do so in the future.

Limitations on the Right to Own Shares

There are no limitations on the right to own our common shares.

Disclosure of Shareholder Ownership

There are no provisions in the Amended Memorandum and Articles of Association governing the ownership threshold above which shareholder ownership must be disclosed.

Differences in Corporate Law

The BVI Act, and the other laws of the British Virgin Islands, or the BVI, affecting BVI business companies like us and our shareholders differ from laws applicable to U.S. Delaware corporations and their stockholders.

Anti-Takeover Provisions.

Some provisions of our Amended Memorandum and Articles of Association may discourage, delay or prevent a change of control of our company or management that shareholders may consider favorable, including provisions that:

- establish a classified Board such that not all shareholders of the Board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our Board;
- 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;
- require that shareholder actions must be effected at a duly called shareholder meeting and prohibit actions by our shareholders by written consent;

- limit the ability of shareholders to requisition and convene general meetings of shareholders; and
- authorize our Board to issue preferred shares in one or more series and to designate the price, rights, preferences, privileges and restrictions of such preference shares without any further vote or action by our shareholders 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.

However, under British Virgin Islands law, our directors may only exercise the rights and powers granted to them under our Amended Memorandum and Articles of Association for a proper purpose and for what they believe in good faith to be in the best interests of our Company.

Costs of Claim

Under our Amended Memorandum and Articles of Association, in the event that (i) any Member or prior Member (“Claiming Party”) initiates or asserts any claim or counterclaim (“Claim”) or joins, offers substantial assistance to or has a direct financial interest in any Claim against the Company or its subsidiaries, directors or Members (including any Claim purportedly filed on behalf of the Company or any Member), and (ii) the Claiming Party (or the third party that received substantial assistance from the Claiming Party or in whose Claim the Claiming Party had a direct financial interest) does not obtain a judgment on the merits that substantially achieves, in substance and amount, the full remedy sought, then each Claiming Party shall be obligated, jointly and severally, to reimburse the Company and any such Member or Members for all fees, costs and expenses of every kind and description (including, but not limited to, all reasonable attorneys’ fees and other litigation expenses) that the parties may incur in connection with such Claim.

BVI Corporate Law

The BVI Act, and the other laws of the British Virgin Islands, or the BVI, affecting BVI business companies like us and our shareholders differ from laws applicable to U.S. Delaware corporations and their stockholders.

Mergers and Similar Arrangements

Under the BVI Act two or more BVI companies or a BVI company and non-BVI company, each a “constituent company”, may merge or consolidate. The BVI Act provides for slightly different procedures depending on the nature of the parties to the merger.

A merger involves the merging of two or more companies into one of the constituent companies (to the merger) with one constituent company continuing in existence to become the surviving company post-merger. A consolidation involves two or more companies consolidating into a new company.

A merger is effective on the date that the articles of merger (as described below) are registered by the Registrar of Corporate Affairs in the BVI, or on such later date, not exceeding 30 days from the date of registration as is stated in the articles of merger.

As soon as a merger becomes effective:

- a. the surviving company (so far as is consistent with its memorandum and articles, as amended by the articles of merger) has all rights, privileges, immunities, powers, objects and purposes of each of the constituent companies;
- b. the memorandum and articles of the surviving company are automatically amended to the extent, if any, that changes to its memorandum and articles are contained in the articles of merger;
- c. assets of every description, including choses in action and the business of each of the constituent companies, immediately vest in the surviving company;

- d. the surviving company is liable for all claims, debts, liabilities and obligations of each of the constituent companies;
- e. no conviction, judgment, ruling, order, claim, debt, liability or obligation due or to become due, and no cause existing, against a constituent company or against any shareholder, director, officer or agent thereof, is released or impaired by the merger; and
- f. no proceedings, whether civil or criminal, pending at the time of a merger by or against a constituent company, or against any shareholder, director or officer, or agent thereof, are abated or discontinued by the merger; but
 - i. the proceedings may be enforced, prosecuted, settled or compromised by or against the surviving company or against the shareholder, director, officer or agent thereof, as the case may be; or
 - ii. the surviving company may be substituted in the proceedings for a constituent company.

The registrar shall strike off the Register of Companies a constituent company that is not the surviving company in the merger.

The BVI Act provides that any shareholder of the Company is entitled to payment of the fair value of his shares upon dissenting from a merger, unless the Company is the surviving company of the merger and the shareholder continues to hold the same or similar shares. The following is a summary of the position in respect of dissenters' rights in the event of a merger under the BVI Act.

A dissenter is in most circumstances required to give to the Company written objection to the merger, which must include a statement that the dissenter proposes to demand payment for his shares if the merger takes place. This written objection must be given before the meeting of shareholders at which the merger is submitted to a vote, or at the meeting but before the vote. However, no objection is required from a shareholder to whom the Company did not give notice of the meeting of shareholders or where the proposed merger is authorized by written consent of the shareholders without a meeting.

Within 20 days immediately following the written consent, or the meeting at which the merger was approved, the Company shall give written notice of the consent or resolution to each shareholder who gave written objection or from whom written objection was not required, except those shareholders who voted for, or consented in writing to, the proposed merger.

A shareholder to whom the Company was required to give notice who elects to dissent shall, within 20 days immediately following the date on which the copy of the plan of merger or an outline of the merger is given to him, give to the Company a written notice of his decision to elect to dissent, stating:

- a. his name and address;
- b. the number and classes of shares in respect of which he dissents (which must be all shares that he holds in the Company); and
- c. a demand for payment of the fair value of his shares.

Upon the giving of a notice of election to dissent, the dissenter ceases to have any of the rights of a shareholder except the right to be paid the fair value of his shares, and the right to institute proceedings to obtain relief on the ground that the action is illegal.

The Company shall make a written offer to each dissenter to purchase his shares at a specified price that the Company determines to be their fair value. Such offer must be given within 7 days immediately following the date of the expiration of the period within which shareholders may give their notices of election to dissent, or within 7 days immediately following the date on which the merger is put into effect, whichever is later.

If the Company and the dissenter fail, within 30 days immediately following the date on which the offer is made, to agree on the price to be paid for the shares owned by the dissenter, then within 20 days:

- a. the Company and the dissenter shall each designate an appraiser;
- b. the two designated appraisers together shall designate an appraiser;
- c. the three appraisers shall fix the fair value of the shares owned by the dissenter as of the close of business on the day prior to the date of the meeting or the date on which the resolution was passed, excluding any appreciation or depreciation directly or indirectly induced by the action or its proposal, and that value is binding on the Company and the dissenter for all purposes; and
- d. the Company shall pay to the dissenter the amount in money upon the surrender by him of the certificates representing his shares, and such shares shall be cancelled.

Shareholders' Suits

Under the provisions of the BVI Act, the memorandum and articles of association of a company are binding as between the company and its shareholders and between the shareholders.

If the majority shareholders have infringed a minority shareholder's rights, the minority may seek to enforce its rights either by derivative action or by personal action. A derivative action concerns the infringement of the company's rights where the wrongdoers are in control of the company and are preventing it from taking action, whereas a personal action concerns the infringement of a right that is personal to the particular shareholder concerned.

The BVI Act provides for a series of remedies available to shareholders. Where a company incorporated under the BVI Act conducts some activity which breaches the BVI Act or the company's memorandum and articles of association, the BVI High Court can issue a restraining or compliance order. Shareholders can now also bring derivative, personal and representative actions under certain circumstances.

Generally any other claims against a company by its shareholders must be based on the general laws of contract or tort applicable in the BVI or their individual rights as shareholders as established by the company's memorandum and articles of association.

In certain circumstances, a shareholder has the right to seek various remedies against the company in the event the directors are in breach of their duties under the BVI Act. Pursuant to Section 184B of the BVI Act, if a company or director of a company engages in, proposes to engage in or has engaged in, conduct that contravenes the provisions of the BVI Act or the memorandum or articles of association of the company, the courts of the British Virgin Islands may, on application of a shareholder or director of the company, make an order directing the company or director to comply with, or restraining the company or director from engaging in conduct that contravenes the BVI Act or the memorandum or articles. Furthermore, pursuant to Section 184I(1) of the BVI Act, a shareholder of a company who considers that the affairs of the company have been, are being or likely to be, conducted in a manner that is, or any acts of the company have been, or are likely to be oppressive, unfairly discriminatory, or unfairly prejudicial to him in that capacity, may apply to the courts of the British Virgin Islands for an order which, inter alia, can require the company or any other person to pay compensation to the shareholders.

Comparison of BVI Corporate Law and Delaware U.S. Corporate Law

Set forth below is a summary of the significant differences between the provisions of the laws of the BVI applicable to us and the laws applicable to companies incorporated in Delaware in the United States and their stockholders.

Shareholder Proposals

Under the Delaware General Corporation Law, a shareholder has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special

meeting may be called by the Board or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings. Our Amended Memorandum and Articles of Association allow our shareholders holding not less than 10% of the votes of the outstanding voting shares to requisition a shareholders' meeting. We are not obliged by law to call shareholders' annual general meetings, but our Amended Memorandum and Articles of Association permit the directors to call shareholders' annual general meetings, and we expect to do so in the future. The location of any shareholders' meeting can be determined by the Board and can be held anywhere in the world.

Cumulative Voting

There are no prohibitions in relation to cumulative voting under the laws of the British Virgin Islands but our Amended Memorandum and Articles of Association do not provide for cumulative voting. As a result, our shareholders are not afforded any less protections or rights on this issue than shareholders of a Delaware corporation.

Shareholder Action by Written Consent

Although British Virgin Islands law provides that companies may permit shareholder actions by written consent, our Amended Memorandum and Articles of Association provide that shareholders may not approve corporate matters by way of a written resolution.

Amendment of Memorandum and Articles of Association

Under the Delaware General Corporation Law, a corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. As permitted by British Virgin Islands law, our Amended Memorandum and Articles of Association may be amended with a resolution of our shareholders or, with certain exception by resolutions of directors.

Removal of Directors

Under the Delaware General Corporation Law, a director of a corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. Under our Amended Memorandum and Articles of Association, directors can be removed from office, with cause, by a resolution of shareholders passed at a meeting called for the purpose of removing the director or for purposes including the removal of the director by the affirmative vote of at least sixty-six and two-thirds percent (66 2/3%) of the votes of the common shares entitled to vote.

Transactions with Interested Shareholders

The Delaware General Corporation Law contains a business combination statute applicable to Delaware public corporations whereby, unless the corporation has specifically elected not to be governed by such statute by amendment to its certificate of incorporation, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or group who or which owns or owned 15% or more of the target's outstanding voting shares within the past three years. This has the effect of limiting the ability of a potential acquirer to make a two-tiered bid for the target in which all shareholders would not be treated equally. The statute does not apply if, among other things, prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder. This encourages any potential acquirer of a Delaware public corporation to negotiate the terms of any acquisition transaction with the target's board of directors.

British Virgin Islands law has no comparable statute. As a result, we are not afforded the same statutory protections in the British Virgin Islands as we would be offered by the Delaware business combination statute. However, although British Virgin Islands law does not regulate transactions between a company and its significant shareholders, it does provide that such transactions must be entered into bona fide in the best interests of the company and not with the effect of constituting a fraud on the minority shareholders. See also "Shareholders' Suits"

above. We have adopted a code of business conduct and ethics which requires employees to fully disclose any situations that could reasonably be expected to give rise to a conflict of interest, and sets forth relevant restrictions and procedures when a conflict of interest arises to ensure the best interest of the Company. Our Amended Memorandum and Articles of Association also import the provisions of the Delaware General Corporation Law which prohibits the Company from engaging in certain business combinations with an “interested shareholder” for three years following the date that such person becomes an interested shareholder unless (i) prior to the date on which such shareholder becomes an interested shareholder, the board of directors approves either the business combination or the transaction which resulted in the person becoming an interested shareholder, (ii) upon consummation of the transaction which resulted in the shareholder becoming an interested shareholder, the interested shareholder owned at least 85% of the votes of shares in the Company outstanding at the time the transaction commenced or (iii) at or subsequent to such time the business combination is approved by the Board and authorized at an annual or extraordinary general meeting of shareholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the votes of shares not owned by the interested shareholder.

Directors’ Fiduciary Duties

Under Delaware corporate law, a director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty. The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, a director must prove the procedural fairness of the transaction and that the transaction was of fair value to the corporation.

Under British Virgin Islands law, the directors owe fiduciary duties at both common law and under statute, including a statutory duty to act honestly, in good faith and with a view to our best interests. When exercising powers or performing duties as a director, the director is required to exercise the care, diligence and skill that a reasonable director would exercise in the circumstances taking into account, without limitation, the nature of the company, the nature of the decision and the position of the director and the nature of the responsibilities undertaken by him. In exercising the powers of a director, the directors must exercise their powers for a proper purpose and shall not act or agree to the company acting in a manner that contravenes our memorandum and articles of association or the BVI Act.

Indemnification of Directors and Executive Officers and Limitation of Liability

BVI law does not limit the extent to which a company’s memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the BVI High Court to be contrary to public policy (e.g., for purporting to provide indemnification against the consequences of committing a crime). An indemnity will be void and of no effect and will not apply to a person unless the person acted honestly and in good faith and in what he believed to be in the best interests of the company and, in the case of criminal proceedings, the person had no reasonable cause to believe that his conduct was unlawful. Our Amended Memorandum and Articles of Association permit indemnification of officers and directors for losses, damages, costs and expenses incurred in their capacities as such unless such losses or damages arise from dishonesty or fraud of such directors or officers. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation. In addition, we have entered into indemnification agreements with our directors and executive officers that provide such persons with additional indemnification beyond that provided in our Amended Memorandum and Articles of Association.

Variation of Rights of Shares

Under the Delaware General Corporation Law, a corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise.

Other than with respect to the issuance of the Preferred Shares in accordance with our Amended Memorandum and Articles of Association, all or any of the rights attached to any class or series of shares may, subject to the provisions of the BVI Act, be varied with the consent in writing of all the holders of the issued shares of that class or series or with the sanction of a resolution passed by a majority of the votes cast at a separate meeting of the holders of the shares of that class or series. The rights conferred upon the holders of the shares of any class issued shall not, unless otherwise expressly provided by the terms of issue of the shares of that class, be deemed to be varied by the creation or issue of further shares ranking *pari passu* with or superior to such existing class of shares.

Dissolution; Winding-Up

Under the Delaware General Corporation Law, unless the board of directors approves the proposal to dissolve, dissolution must be approved by shareholders holding 100% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board. Under BVI law, the liquidation of a company may be a voluntary solvent liquidation or an insolvent liquidation under the BVI Insolvency Act. Where a company has been struck off the Register of Companies under the BVI Act continuously for a period of 7 years it is dissolved with effect from the last day of that period.

Voluntary Liquidation

If the liquidation is a solvent liquidation, the provisions of the BVI Act governs the liquidation. A company may only be liquidated under the BVI Act as a solvent liquidation if it has no liabilities or it is able to pay its debts as they fall due and the value of its assets exceeds its liabilities. Subject to the Amended Memorandum and Articles of Association, a liquidator may be appointed by a resolution of directors or resolution of shareholders but if the directors have commenced liquidation by a resolution of directors the shareholders must approve the liquidation plan by a resolution of shareholders save in limited circumstances.

A liquidator is appointed for the purpose of collecting in and realizing the assets of a company and distributing proceeds to creditors.

We expect that in the event of a voluntary liquidation of the Company, after payment of the liquidation costs and any sums then due to creditors, the liquidator would distribute our remaining assets on a *pari passu* basis.

Rights of Non-resident or Foreign Shareholders

There are no limitations imposed by our Amended Memorandum and Articles of Association on the rights of non-resident or foreign shareholders to hold or exercise voting rights on our shares. In addition, there are no provisions in our Amended Memorandum and Articles of Association governing the ownership threshold above which shareholder ownership must be disclosed.

Anti-Money Laundering

If any person resident in the British Virgin Islands knows or suspects that another person is engaged in money laundering or terrorist financing and the information for that knowledge or suspicion came to their attention in the course of their business the person will be required to report his belief or suspicion to the Financial Investigation of the British Virgin Islands, pursuant to the Proceeds of Criminal Conduct Act (as revised). Such a report shall not be treated as a breach of confidence or of any restriction upon the disclosure of information imposed by any enactment or otherwise.

NYSE Listing

Our common shares are listed on NYSE under the trading symbol “BHVN.”

Transfer Agent and Registrar

The transfer agent and registrar for our common shares is American Stock Transfer & Trust Company, LLC. The transfer agent’s address is 6201 15th Avenue, Brooklyn, NY 11219.

SHARES ELIGIBLE FOR FUTURE SALE

Sales or the availability for sale of substantial amounts of our common shares in the public market could adversely affect the prevailing market price for such shares. As of October 3, 2022, we had outstanding an aggregate of approximately 35.5 million common shares, assuming no exercise of outstanding options. All of the common shares are freely tradable without restriction or further registration under the Securities Act unless the shares are owned by our “affiliates” as that term is defined in the rules under the Securities Act. Shares held by “affiliates” may be sold in the public market only if registered or if they qualify for an exemption from registration or in compliance with Rule 144 under the Securities Act (“Rule 144”) which is summarized below.

Rule 144

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act, for at least 90 days, a person (or persons whose shares are required to be aggregated) who is not deemed to have been one of our “affiliates” for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our “affiliates,” is entitled to sell those shares in the public market (subject to the lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the sales proposed to be sold for at least one year, including the holding period of any prior owner other than “affiliates,” then such person is entitled to sell such shares in the public market without complying with any of the requirements of Rule 144 (subject to the lock-up agreement referred to above, if applicable). In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our “affiliates,” as defined in Rule 144, who have beneficially owned the shares proposed to be sold for at least six months are entitled to sell in the public market, within any three-month period, a number of our common shares that does not exceed the greater of:

- one percent (1%) of the number of common shares then outstanding, which will equal approximately 393,759 common shares (calculated on the basis of the number of common shares outstanding as of October 14, 2022, the assumptions described above and no exercise of outstanding options); or
- the average weekly trading volume of our common shares on the New York Stock Exchange during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our “affiliates” or persons selling shares on behalf of our “affiliates” are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

This section describes the material U.S. federal income tax consequences of the ownership of our common shares. This section applies solely to holders that acquire our common shares pursuant to this offering and that will hold such common shares as capital assets for tax purposes. This section addresses only United States federal income taxation and does not discuss all of the tax consequences that may be relevant to a holder in light of such holder's individual circumstances, including non-U.S., state or local tax consequences, estate and gift tax consequences, and tax consequences arising under the Medicare contribution tax on net investment income or the alternative minimum tax. This section does not apply to holders subject to special rules, including:

- a dealer in securities or foreign currencies;
- a regulated investment company;
- a trader in securities that elects to use a mark-to-market method of accounting for securities holdings;
- a tax-exempt organization;
- a bank, financial institution, or insurance company;
- a person that directly, indirectly or constructively owns 5% or more of the combined voting power of our common shares, or of the total value of our common shares;
- a person that holds our common shares as part of a straddle or a hedging, conversion, or other risk reduction transaction for U.S. federal income tax purposes;
- a person that acquires or sells our common shares as a part of wash sale for U.S. federal income tax purposes;
- a person that acquired our common shares pursuant to the exercise of employee share options or otherwise as compensation;
- a person whose functional currency is not the U.S. dollar; or
- investors in this offering who are existing shareholders of our company.

For purposes of this discussion, a "U.S. holder" is a beneficial owner of our common shares that is, for U.S. federal income tax purposes:

- an individual that is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized under the laws of the United States;
- an estate whose income is subject to U.S. federal income tax regardless of its source; or
- a trust if a U.S. court can exercise primary supervision over the trust's administration and one or more persons are authorized to control all substantial decisions of the trust.

This section is based on the Internal Revenue Code of 1986, as amended (the "Code"), its legislative history, existing and proposed regulations, published rulings and court decisions, as well as on applicable tax treaties, all as currently in effect. These authorities are subject to change, possibly on a retroactive basis.

This discussion is intended to provide only a general summary of the material U.S. federal income tax consequences of owning our common shares. We do not intend it to be a complete analysis or description of all potential U.S. federal income tax consequences of owning our common shares. The U.S. federal income tax laws are complex and subject to varying interpretations. Accordingly, the Internal Revenue Service ("IRS") may not agree with the tax consequences described in this Registration Statement.

We have not sought, and do not intend to seek, any ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and no assurance can be given that the IRS will agree with the views expressed herein, or that a court will not sustain any challenge by the IRS in the event of litigation.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the tax treatment of the partnership. A partner in an entity or arrangement treated as a partnership for U.S. federal income tax purposes holding shares should consult its tax advisors with regard to the U.S. federal income tax treatment of our common shares.

U.S. Holders

The tax treatment of our common shares will depend in part on whether or not we are classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes. Except as discussed below under “—PFIC Considerations,” this discussion assumes that we are not classified as a PFIC for U.S. federal income tax purposes.

Taxation of Dividends

Under U.S. federal income tax laws, the gross amount of any distribution we pay out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes), other than certain pro-rata distributions of our shares, will be treated as a dividend that is subject to U.S. federal income taxation. For a noncorporate U.S. holder, dividends that constitute qualified dividend income will be taxable to the holder at the preferential rates applicable to long-term capital gains, provided that the holder holds the shares for more than 60 days during the 121-day period beginning 60 days before the ex-dividend date and meets other holding period requirements. For this purpose, our common shares are treated as stock of a “qualified foreign corporation” if our common shares are readily tradable on an established securities market in the United States. Our common shares are listed on the NYSE, which is treated as an established securities market in the United States for these purposes, in which case dividends that we pay with respect to its common shares would generally constitute qualified dividend income, assuming the holding period requirements are met. However, we can give no assurances in this regard.

A U.S. holder must include any foreign tax withheld, if any, from the dividend payment in this gross amount even though the holder does not in fact receive it. The dividend is taxable to a U.S. holder when the holder receives the dividend, actually or constructively. The dividend will not be eligible for the dividends-received deduction generally allowed to United States corporations in respect of dividends received from other United States corporations. Distributions in excess of current and accumulated earnings and profits, as determined for U.S. federal income tax purposes, will be treated as a non-taxable return of capital to the extent of the holder’s basis in the shares and thereafter as capital gain. We do not currently expect to calculate earnings and profits in accordance with U.S. federal income tax principles. Accordingly, a U.S. holder should expect to generally treat distributions that we make as dividends.

Subject to certain limitations and the following sentence, the foreign tax withheld, if any, and paid over to foreign countries will be creditable or deductible against a U.S. holder’s U.S. federal income tax liability. However, under recently finalized Treasury regulations, it is possible that taxes may not be creditable. Special rules apply in determining the foreign tax credit limitation with respect to dividends that are subject to the preferential tax rates. To the extent a reduction or refund of the tax withheld is available to the holder under foreign law, the amount of tax withheld that could have been reduced or that is refundable will not be eligible for credit against the holder’s U.S. federal income tax liability.

Dividends will generally be income from sources outside the United States and will generally be “passive” income for purposes of computing the foreign tax credit allowable to a U.S. holder. However, if (a) we are 50% or more owned, by vote or value, by United States persons and (b) at least 10% of our earnings and profits are attributable to sources within the United States, then for foreign tax credit purposes, a portion of our dividends would be treated as derived from sources within the United States. With respect to any dividend paid for any taxable year, the United States source ratio of our dividends for foreign tax credit purposes would be equal to the portion of our earnings and profits from sources within the United States for such taxable year, divided by the total

amount of our earnings and profits for such taxable year. There can be no assurance that no portion of our dividends will be treated as derived from sources within the United States pursuant to the rule described in this paragraph.

Taxation of Capital Gains.

If a U.S. holder sells or otherwise disposes of our common shares, the holder will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference between the U.S. dollar value of the amount that the holder realizes and the holder's tax basis, determined in U.S. dollars, in the shares. Capital gain of a noncorporate U.S. holder is generally taxed at preferential rates where the property is held for more than one year. The gain or loss will generally be income or loss from sources within the United States for foreign tax credit limitation purposes.

PFIC Considerations.

We believe that our common shares should not currently be stock of a PFIC for U.S. federal income tax purposes and do not expect to become a PFIC in the foreseeable future. However, 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 determination of whether we are a PFIC and the characterization of our assets as active or passive may depend in part on (i) our current and intended future business plans which are subject to change, (ii) the application of certain "look-through" rules and (iii) the applicability of the "start-up exception." Under the start-up exception, a foreign corporation that would otherwise be treated as a PFIC will not be a PFIC for the first taxable year the corporation has gross income (the "start-up year"), if: (A) no predecessor of the corporation was a PFIC; (B) the corporation satisfies the IRS that it will not be a PFIC for either of the first two taxable years following the start-up year; and (C) the corporation is not in fact a PFIC for either of those years. The applicability of the startup exception to us is uncertain and will not be known until after the end of the two taxable years following such startup year. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may fluctuate considerably from time to time, and is dependent on the application (which inherently involves an element of judgment) of the relevant valuation assumptions and methodologies. 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 raised in this and any other offering. Therefore, we cannot provide any assurance regarding PFIC status for any past, current or future taxable years.

In general, we will be a PFIC with respect to a U.S. holder if for any taxable year in which the holder held our common shares:

- at least 75% of our gross income for the taxable year is passive income; or
- at least 50% of the value, determined on the basis of a quarterly average, of our assets is attributable to assets that produce or are held for the production of passive income.

"Passive income" generally includes dividends, interest, gains from the sale or exchange of investment property rents and royalties (other than certain rents and royalties derived in the active conduct of a trade or business) and certain other specified categories of income. Other than with respect to stock of a domestic corporation that is 25%-owned (by value) by certain foreign corporations, if a foreign corporation owns at least 25% by value of the stock of another corporation, the foreign corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation, and as receiving directly its proportionate share of the other corporation's income.

If we are or become a PFIC, and a U.S. holder did not make a mark-to-market election, as described below, the holder will generally be subject to special rules with respect to:

- any gain the holder realizes on the sale or other disposition of the shares; and
- any excess distribution that we make to the holder (generally, any distributions to the holder during a single taxable year, other than the taxable year in which the holder's holding period in the shares begins, that are

greater than 125% of the average annual distributions received by the holder in respect of the shares during the three preceding taxable years or, if shorter, the holder's holding period for the shares that preceded the taxable year in which the holder receives the distribution).

Under these rules:

- the gain or excess distribution will be allocated ratably over the holder's holding period for the shares;
- the amount allocated to the taxable year in which the holder realized the gain or excess distribution or to prior years before the first year in which we were a PFIC with respect to the holder will be taxed as ordinary income;
- the amount allocated to each other prior year will be taxed at the highest tax rate in effect for that year; and
- the interest charge generally applicable to underpayments of tax will be imposed in respect of the tax attributable to each such year.

Special rules apply for calculating the amount of the foreign tax credit with respect to excess distributions by a PFIC.

If we are or become a PFIC in a taxable year and our common shares are treated as "marketable stock" in such year, a U.S. holder may make a mark-to-market election with respect to the shares. If the U.S. holder makes this election, the holder will not be subject to the PFIC rules described above. Instead, in general, the holder will include as ordinary income each year the excess, if any, of the fair market value of the shares at the end of the taxable year over the holder's adjusted basis in the shares. The holder will also be allowed to take an ordinary loss in respect of the excess, if any, of the adjusted basis of the shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of previously included income as a result of the mark-to-market election). The U.S. holder's basis in the shares will be adjusted to reflect any such income or loss amounts. Any gain that the holder recognizes on the sale or other disposition of the shares would be ordinary income and any loss would be an ordinary loss to the extent of the net amount of previously included income as a result of the mark-to-market election and, thereafter, a capital loss.

A U.S. holder's shares will generally be treated as stock in a PFIC if we are or become a PFIC at any time during the holder's holding period in the shares, even if we are not currently a PFIC.

In addition, notwithstanding any election a U.S. holder makes with regard to the shares, dividends that the holder receives from us will not constitute qualified dividend income to the holder if we are a PFIC (or are treated as a PFIC with respect to the holder) either in the taxable year of the distribution or the preceding taxable year. Dividends that the holder receives that do not constitute qualified dividend income are not eligible for taxation at the preferential rates applicable to qualified dividend income. Instead, the holder must include the gross amount of any such dividend paid by us out of our accumulated earnings and profits (as determined for U.S. federal income tax purposes) in the holder's gross income, and it will be subject to tax at rates applicable to ordinary income.

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 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 QEF 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 U.S. holders of our common shares should assume that a QEF election will not be available.

If a U.S. holder owns shares during any year that we are a PFIC with respect to the holder, the holder may be required to file IRS Form 8621.

U.S. holders should consult their tax advisors as to the application of the PFIC rules in the event that our common shares were treated as stock of a PFIC.

NO ASSURANCE CAN BE GIVEN REGARDING OUR PFIC STATUS FOR ANY CURRENT OR FUTURE TAXABLE YEARS. U.S. HOLDERS SHOULD CONSULT THEIR OWN TAX ADVISORS WITH RESPECT TO THE OPERATION OF THE PFIC RULES AND RELATED REPORTING REQUIREMENTS IN LIGHT OF THEIR PARTICULAR CIRCUMSTANCES, INCLUDING THE ADVISABILITY OF MAKING ANY ELECTION THAT MAY BE AVAILABLE.

Shareholder Reporting.

A U.S. holder that owns “specified foreign financial assets” with an aggregate value in excess of \$50,000 (and in some circumstances, a higher threshold) may be required to file an information report with respect to such assets with its tax return. “Specified foreign financial assets” may include financial accounts maintained by foreign financial institutions, as well as the following, but only if they are held for investment and not held in accounts maintained by financial institutions: (i) stocks and securities issued by non-United States persons, (ii) financial instruments and contracts that have non-United States issuers or counterparties, and (iii) interests in foreign entities. Significant penalties may apply for failing to satisfy this filing requirement. U.S. holders are urged to contact their tax advisors regarding this filing requirement.

Non-U.S. Holders.

Taxation of Dividends

Dividends paid to a non-U.S. holder in respect of our common shares will not be subject to U.S. federal income tax unless the dividends are “effectively connected” with the holder’s conduct of a trade or business within the United States, and the dividends are attributable to a permanent establishment that the holder maintains in the United States if that is required by an applicable income tax treaty as a condition for subjecting the holder to United States taxation on a net income basis. In such cases, the holder generally will be taxed in the same manner as a U.S. holder. For a corporate non-U.S. holder, “effectively connected” dividends may, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or at a lower rate if the holder is eligible for the benefits of an income tax treaty that provides for a lower rate.

Taxation of Capital Gains

A non-U.S. holder will not be subject to U.S. federal income tax on gain recognized on the sale or other disposition of our common shares unless:

- the gain is “effectively connected” with the holder’s conduct of a trade or business in the United States, and the gain is attributable to a permanent establishment that the holder maintains in the United States if that is required by an applicable income tax treaty as a condition for subjecting the holder to United States taxation on a net income basis; or
- the holder is an individual, is present in the United States for 183 or more days in the taxable year of the sale and certain other conditions exist.

For a corporate non-U.S. holder, “effectively connected” gains that the holder recognizes may also, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or at a lower rate if the holder is eligible for the benefits of an income tax treaty that provides for a lower rate.

Backup Withholding and Information Reporting.

For a noncorporate U.S. holder, information reporting requirements, on IRS Form 1099, generally will apply to dividend payments or other taxable distributions made to the holder within the United States, and the payment of proceeds to the holder from the sale of our common shares effected at a United States office of a broker. Additionally, backup withholding may apply to such payments if the holder fails to comply with applicable certification requirements or (in the case of dividend payments) is notified by the IRS that the holder has failed to report all interest and dividends required to be shown on the holder’s federal income tax returns.

A non-U.S. holder is generally exempt from backup withholding and information reporting requirements with respect to dividend payments made to the holder outside the United States by us or another non-United States payor. The non-U.S. holder is also generally exempt from backup withholding and information reporting requirements in respect of dividend payments made within the United States and the payment of the proceeds from the sale of shares effected at a United States office of a broker, as long as either (i) the non-U.S. holder has furnished a valid IRS Form W-8 or other documentation upon which the payor or broker may rely to treat the payments as made to a non-United States person, or (ii) the non-U.S. holder otherwise establishes an exemption.

Payment of the proceeds from the sale of shares effected at a foreign office of a broker generally will not be subject to information reporting or backup withholding. However, a sale effected at a foreign office of a broker could be subject to information reporting in the same manner as a sale within the United States (and in certain cases may be subject to backup withholding as well) if (i) the broker has certain connections to the United States, (ii) the proceeds or confirmation are sent to the United States or (iii) the sale has certain other specified connections with the United States.

A person generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed the person's income tax liability by filing a refund claim with the IRS.

EACH HOLDER SHOULD CONSULT ITS TAX ADVISOR ABOUT THE PARTICULAR CONSEQUENCES OF OWNING OUR COMMON SHARES, INCLUDING THE APPLICATION OF STATE, LOCAL AND FOREIGN TAX LAWS, AND POSSIBLE CHANGES IN TAX LAW THAT MAY AFFECT THE TAX CONSEQUENCES DESCRIBED ABOVE.

UNDERWRITING

We are offering the common shares described in this prospectus through a number of underwriters. J.P. Morgan Securities LLC is acting as book-running manager of the offering and as representative of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of common shares listed next to its name in the following table:

Name	Number of Shares
J.P. Morgan Securities LLC	
Total	20,000,000

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of \$ _____ per share. After the initial offering of the shares to the public, if all of the common shares are not sold at the initial public offering price, the underwriters may change the offering price and the other selling terms. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to 3,000,000 additional common shares from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus to exercise this option to purchase additional shares. If any shares are purchased with this option to purchase additional shares, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional common shares are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common shares less the amount paid by the underwriters to us per share of common shares. The underwriting fee is \$ _____ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Without option to purchase additional shares exercise	With full option to purchase additional shares exercise
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$1.0 million. We have also agreed to reimburse the underwriters for up to \$30,000 in expenses incurred in connection with the review and clearance of this offering by the Financial Industry Regulatory Authority, Inc. ("FINRA"). In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering. The Underwriters have agreed to reimburse us for certain out-of-pocket expenses incurred in connection with this offering.

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

Vlad Coric, our Chief Executive Officer, Matthew Buten, our Chief Financial Officer, and certain of our directors and their affiliated funds have indicated an interest in purchasing approximately \$100 million, in the aggregate, of our common shares in this offering at the public offering price. Dr. Coric and Mr. Buten have indicated an interest in purchasing approximately \$10 million and \$1 million of those common shares, respectively. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, fewer or no shares to each of Dr. Coric, Mr. Buten or our directors and their affiliated funds, and any of such persons or their affiliated funds could determine to purchase more, fewer or no shares in this offering.

We have agreed that, without the prior written consent of J.P. Morgan Securities LLC, we will not, during the period beginning on the date of this prospectus supplement and ending 60 days after the date of this prospectus supplement, or the restricted period:

- offer, issue, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, or file with or confidentially submit to the SEC a registration statement under the Securities Act relating to any securities of the Company that are substantially similar to the common shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, common shares or any such substantially similar securities, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing; or
- enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common shares or any such other securities, whether any such transaction is to be settled by delivery of common shares or such other securities, in cash or otherwise (other than pursuant to employee stock option plans existing on, or upon the conversion or exchange of convertible or exchangeable securities outstanding as of, the date of this prospectus).

All of our directors and executive officers have agreed that, without the prior written consent of J.P. Morgan Securities LLC, they will not, during the period beginning on the date of this prospectus supplement and ending 45 days after the date of this prospectus supplement, or the restricted period:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any common shares beneficially owned (as such term is used in Rule 13d-3 of the Exchange Act), by the undersigned or any other securities so owned convertible into or exercisable or exchangeable for common shares; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common shares or any security convertible into common shares, whether any such transaction described in the foregoing bullet or this bullet is to be settled by delivery of common shares or such other securities, in cash or otherwise; or
- publicly disclose the intention to do any of the foregoing.

whether any such transaction described above is to be settled by delivery of common shares or such other securities, in cash or otherwise, or publicly disclose the intention to do any of the foregoing. In addition, without the prior written consent of the representative on behalf of the underwriters, (i) our directors and officers will not, during the restricted period, make any demand for, or exercise any right, or publicly disclose such person's intention to make any demand or exercise any right, with respect to the registration of any common shares or any security convertible into or exercisable or exchangeable for common shares and (ii) we will not file any registration statement with the SEC relating to the offering of any common shares or any securities convertible into or exercisable or exchangeable for common shares. In addition, our directors and officers agreed and consented to the entry of stop transfer instructions with our transfer agent and registrar against the transfer of each such person's common shares except in compliance with the below restrictions.

The restrictions described in the preceding paragraphs are subject to certain exceptions, including, but not limited to:

- transactions relating to our common shares or other securities acquired in open market transactions after the completion of this offering, provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common shares or any security convertible into common shares is required or voluntarily made during the restricted period;
- transfers of common shares or any security convertible into common shares to an immediate family member or a trust for the direct or indirect benefit of the director or officer or such immediate family member of the director or officer, provided that each transferee signs and delivers a lock-up agreement, and provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common shares or any security convertible into common shares is required or voluntarily made during the restricted period;
- transfers of common shares or any security convertible into common shares as a bona fide gift or charitable contribution, provided that each transferee signs and delivers a lock-up agreement, and provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common shares or any security convertible into common shares is required or voluntarily made during the restricted period;
- transfers of common shares or any security convertible into common shares by will or intestacy, provided that each transferee signs and delivers a lock-up agreement, and provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common shares or any security convertible into common shares is required or voluntarily made during the restricted period;
- if the transferor is a corporation, partnership or other business entity, distributions of common shares or any security convertible into common shares to limited partners, members, shareholders or holders of similar equity interests in the transferor, provided that each distributee signs and delivers a lock-up agreement, and provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common shares or any security convertible into common shares is required or voluntarily made during the restricted period;
- if the transferor is a trust, transfers or distributions of common shares or any securities convertible into or exercisable or exchangeable for common shares to a trustor or beneficiary of the trust or to the estate of a beneficiary of such trust, provided that each transferee signs and delivers a lock-up agreement, and provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common shares or any security convertible into common shares is required or voluntarily made during the restricted period;
- the exercise of a stock option granted under a stock incentive plan or stock purchase plan described in this prospectus supplement, and the receipt from the company of common shares upon such exercise, insofar as such option is outstanding as of the date of the lock-up agreement or the date of this prospectus supplement, provided that the underlying shares shall continue to be subject to the restrictions on transfer set forth in the lock-up agreement, and provided that, if required, any public report or filing under Section 16 of the Exchange Act clearly indicates in the footnotes thereto that the filing relates to the exercise of a stock option, that no common shares were sold by the reporting person and that the common shares received upon exercise of the stock option are subject to a lock-up agreement with the underwriters;
- the disposition of common shares to us, or the withholding of common shares by us, in a transaction exempt from Section 16(b) of the Exchange Act solely to the extent required for the payment of taxes due with respect to the vesting or expiration of options or the vesting of restricted stock or restricted stock units granted under a stock incentive plan, stock purchase plan or pursuant to a contractual employment arrangement described in this prospectus supplement, insofar as such options, restricted stock or restricted stock units are outstanding as of the date of the lock-up agreement or the date of this prospectus supplement, provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in

beneficial ownership of common shares or any security convertible into common shares is required or voluntarily made during the restricted period;

- transfers to us in connection with the repurchase of common shares in connection with the termination of the director or officer's employment with us pursuant to contractual agreements with us as in effect as of the date of this prospectus supplement, provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common shares or any security convertible into common shares is required or voluntarily made during the restricted period;
- transfers of common shares or any security convertible into or exercisable or exchangeable for common shares pursuant to a domestic order, divorce decree or court order, provided that each transferee signs and delivers a lock-up agreement, and provided that, if required, any public report or filing under Section 16 of the Exchange Act shall clearly indicate in the footnotes thereto that the filing relates to the transfer of such securities pursuant to a domestic order, divorce decree or court order, that no such securities were sold by the reporting person and that the securities so transferred are subject to a lock-up agreement with the underwriters;
- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of common shares, provided that (i) such plan does not provide for the transfer of common shares during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the director, officer or us regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common shares may be made under such plan during the restricted period;
- transfers of common shares made pursuant to a written trading plan established prior to the date of the lock-up agreement in accordance with Rule 10b5-1 under the Exchange Act, provided that, to the extent a public announcement or filing under the Exchange Act is required of or voluntarily made by or on behalf of the director, officer or us regarding a transfer pursuant to such plan, such announcement or filing shall include a statement to the effect that such transfer was made pursuant to such plan;
- a merger, consolidation or other similar transaction, occurring after the closing of the offering, in which all holders of the common shares may participate, involving a change of control of the company and approved by our Board, provided that, in the event that such change of control transaction is not completed, the person's common shares shall remain subject to the restrictions contained in the lock-up agreement and title to the person's common shares shall remain with the person (for purposes of the foregoing, "change of control" means the transfer (whether by tender offer, merger, consolidation or other similar transaction), in one transaction or a series of related transactions, to a person or group of affiliated persons (other than the underwriters pursuant to this offering), of our voting securities if, after such transfer, such person or group of affiliated persons would hold at least 90% of our or the surviving entity's outstanding voting securities); and
- transactions relating to common shares or other securities convertible or exercisable into common shares purchased in the offering, provided that no filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common shares or any security convertible into common shares is required or voluntarily made during the restricted period.

J.P. Morgan Securities LLC, in its sole discretion, may release the common shares and other securities subject to the lock-up agreements described above at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Our common shares are listed on the NYSE under the symbol "BHVN."

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling common shares in the open market for the purpose of preventing or

retarding a decline in the market price of the common shares while this offering is in progress. These stabilizing transactions may include making short sales of common shares, which involves the sale by the underwriters of a greater number of common shares than they are required to purchase in this offering, and purchasing common shares on the open market to cover positions created by short sales. Short sales may be “covered” shorts, which are short positions in an amount not greater than the underwriters’ option to purchase additional shares referred to above, or may be “naked” shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their option to purchase additional shares, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common shares in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common shares, including the imposition of penalty bids. This means that if the representatives of the underwriters purchase common shares in the open market in stabilizing transactions or to cover short sales, the representatives can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common shares or preventing or retarding a decline in the market price of the common shares, and, as a result, the price of the common shares may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the New York Stock Exchange, in the over-the-counter market or otherwise.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

Selling Restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Notice to prospective investors in the European Economic Area

In relation to each Member State of the European Economic Area (each, a “Relevant State”), no securities have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of our representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129 (as amended).

Notice to prospective investors in the United Kingdom

In relation to the United Kingdom, no shares have been offered or will be offered pursuant to this offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares that either (i) has been approved by the Financial Conduct Authority, or (ii) is to be treated as if it had been approved by the Financial Conduct Authority in accordance with the transitional provision in Regulation 74 of the Prospectus (Amendment etc.) (EU Exit) Regulations 2019, except that offers of shares may be made to the public in the United Kingdom at any time under the following exemptions under the UK Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or
- (c) in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000, or the FSMA, provided that no such offer of the shares shall require the Issuer or any representative to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

In addition, this prospectus is only being distributed to, and is only directed at, and any investment or investment activity to which this prospectus relates is available only to, and will be engaged in only with, persons who are outside the United Kingdom or persons in the United Kingdom (i) having professional experience in matters relating to investments who fall within the definition of “investment professionals” in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order; or (ii) who are high net worth entities falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as “relevant persons”). Persons who are not relevant persons should not take any action on the basis of this prospectus and should not act or rely on it.

Any person in the United Kingdom that is not a relevant person should not act or rely on the information included in this document or use it as basis for taking any action. In the United Kingdom, any investment or investment activity that this document relates to may be made or taken exclusively by relevant persons.

Notice to prospective investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration

Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to prospective investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectus under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectus under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, or FINMA, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to prospective investors in the Dubai International Financial Centre, or DIFC

This document relates to an Exempt Offer in accordance with the Markets Rules 2012 of the Dubai Financial Services Authority, or the DFSA. This document is intended for distribution only to persons of a type specified in the Markets Rules 2012 of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for this document. The securities to which this document relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this document you should consult an authorized financial advisor.

In relation to its use in the DIFC, this document is strictly private and confidential and is being distributed to a limited number of investors and must not be provided to any person other than the original recipient, and may not be reproduced or used for any other purpose. The interests in the securities may not be offered or sold directly or indirectly to the public in the DIFC.

Notice to prospective investors in the United Arab Emirates

The shares have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved

by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

Notice to prospective investors in Australia

This prospectus:

- does not constitute a disclosure document or a prospectus under Chapter 6D.2 of the Corporations Act 2001 (Cth), or the Corporations Act;
- has not been, and will not be, lodged with the Australian Securities and Investments Commission, or ASIC, as a disclosure document for the purposes of the Corporations Act and does not purport to include the information required of a disclosure document for the purposes of the Corporations Act; and
- may only be provided in Australia to select investors who are able to demonstrate that they fall within one or more of the categories of investors, available under section 708 of the Corporations Act, or the Exempt Investors.

The shares may not be directly or indirectly offered for subscription or purchased or sold, and no invitations to subscribe for or buy the shares may be issued, and no draft or definitive offering memorandum, advertisement or other offering material relating to any shares may be distributed in Australia, except where disclosure to investors is not required under Chapter 6D of the Corporations Act or is otherwise in compliance with all applicable Australian laws and regulations. By submitting an application for the shares, you represent and warrant to us that you are an Exempt Investor.

As any offer of shares under this document will be made without disclosure in Australia under Chapter 6D.2 of the Corporations Act, the offer of those securities for resale in Australia within 12 months may, under section 707 of the Corporations Act, require disclosure to investors under Chapter 6D.2 if none of the exemptions in section 708 applies to that resale. By applying for the shares you undertake to us that you will not, for a period of 12 months from the date of issue of the shares, offer, transfer, assign or otherwise alienate those shares to investors in Australia except in circumstances where disclosure to investors is not required under Chapter 6D.2 of the Corporations Act or where a compliant disclosure document is prepared and lodged with ASIC.

Notice to prospective investors in Japan

The shares have not been and will not be registered pursuant to Article 4, Paragraph 1 of the Financial Instruments and Exchange Act. Accordingly, none of the shares nor any interest therein may be offered or sold, directly or indirectly, in Japan or to, or for the benefit of, any “resident” of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to or for the benefit of a resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the Financial Instruments and Exchange Act and any other applicable laws, regulations and ministerial guidelines of Japan in effect at the relevant time.

Notice to prospective investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to “professional investors” as defined in the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong), or the SFO, of Hong Kong and any rules made thereunder; or (b) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong), or the CO, or which do not constitute an offer to the public within the meaning of the CO. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares

which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” as defined in the SFO and any rules made thereunder.

Notice to prospective investors in Singapore

Each underwriter has acknowledged that this prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, each underwriter has represented and agreed that it has not offered or sold any shares or caused the shares to be made the subject of an invitation for subscription or purchase and will not offer or sell any shares or cause the shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, whether directly or indirectly, to any person in Singapore other than:

- (a) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time, or the SFA) pursuant to Section 274 of the SFA;
- (b) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA; or
- (c) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:
 - (i) to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 276(4)(i)(B) of the SFA;
 - (ii) where no consideration is or will be given for the transfer;
 - (iii) where the transfer is by operation of law;
 - (iv) as specified in Section 276(7) of the SFA; or
 - (v) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018.

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the CMP Regulations 2018, unless otherwise specified before an offer of shares, we have determined, and hereby notify all relevant persons (as defined in Section 309A(1) of the SFA), that the shares are “prescribed capital markets products” (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice

SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Notice to prospective investors in Bermuda

Shares may be offered or sold in Bermuda only in compliance with the provisions of the Investment Business Act of 2003 of Bermuda which regulates the sale of securities in Bermuda. Additionally, non-Bermudian persons (including companies) may not carry on or engage in any trade or business in Bermuda unless such persons are permitted to do so under applicable Bermuda legislation.

Notice to prospective investors in Saudi Arabia

This document may not be distributed in the Kingdom of Saudi Arabia except to such persons as are permitted under the Offers of Securities Regulations as issued by the board of the Saudi Arabian Capital Market Authority, or CMA, pursuant to resolution number 2-11-2004 dated 4 October 2004 as amended by resolution number 1-28-2008, as amended, or the CMA Regulations. The CMA does not make any representation as to the accuracy or completeness of this document and expressly disclaims any liability whatsoever for any loss arising from, or incurred in reliance upon, any part of this document. Prospective purchasers of the securities offered hereby should conduct their own due diligence on the accuracy of the information relating to the securities. If you do not understand the contents of this document, you should consult an authorized financial adviser.

Notice to prospective investors in the British Virgin Islands

The shares are not being, and may not be offered to the public or to any person in the British Virgin Islands for purchase or subscription by or on behalf of us. The shares may be offered to companies incorporated under the BVI Business Companies Act (As Revised), or companies incorporated in British Virgin Islands, but only where the offer will be made to, and received by, the relevant BVI Company entirely outside of the British Virgin Islands. This prospectus has not been, and will not be, registered with the Financial Services Commission of the British Virgin Islands. No registered prospectus has been or will be prepared in respect of our common shares for the purposes of the Securities and Investment Business Act (As Revised) or the Public Issuers Code of the British Virgin Islands.

Notice to prospective investors in China

This prospectus will not be circulated or distributed in the PRC and the shares will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Notice to prospective investors in Korea

The shares have not been and will not be registered under the Financial Investments Services and Capital Markets Act of Korea, or the FSCMA, and the decrees and regulations thereunder and the shares have been and will be offered in Korea as a private placement under the FSCMA. None of the shares may be offered, sold or delivered directly or indirectly, or offered or sold to any person for re-offering or resale, directly or indirectly, in Korea or to any resident of Korea except pursuant to the applicable laws and regulations of Korea, including the FSCMA and the Foreign Exchange Transaction Law of Korea, or the FETL, and the decrees and regulations thereunder. The shares have not been listed on any securities exchanges in the world including, without limitation, the Korea Exchange in Korea. Furthermore, the purchaser of the shares shall comply with all applicable regulatory requirements (including but not limited to requirements under the FETL) in connection with the purchase of the shares. By the purchase of the shares, the relevant holder thereof will be deemed to represent and warrant that if it is in Korea or is a resident of Korea, it purchased the shares pursuant to the applicable laws and regulations of Korea.

Notice to prospective investors in Malaysia

No prospectus or other offering material or document in connection with the offer and sale of our common shares has been or will be registered with the Securities Commission of Malaysia, or the Commission, for the Commission's approval pursuant to the Capital Markets and Services Act 2007. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of our

common shares may not be circulated or distributed, nor may our common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Malaysia other than (i) a closed end fund approved by the Commission, (ii) a holder of a Capital Markets Services Licence, (iii) a person who acquires our common shares, as principal, if the offer is on terms that our common shares may only be acquired at a consideration of not less than RM250,000 (or its equivalent in foreign currencies) for each transaction, (iv) an individual whose total net personal assets or total net joint assets with his or her spouse exceeds RM3 million (or its equivalent in foreign currencies), excluding the value of the primary residence of the individual, (v) an individual who has a gross annual income exceeding RM300,000 (or its equivalent in foreign currencies) per annum in the preceding twelve months, (vi) an individual who, jointly with his or her spouse, has a gross annual income of RM400,000 (or its equivalent in foreign currencies), per annum in the preceding twelve months, (vii) a corporation with total net assets exceeding RM10 million (or its equivalent in a foreign currencies) based on the last audited accounts, (viii) a partnership with total net assets exceeding RM10 million (or its equivalent in foreign currencies), (ix) a bank licensee or insurance licensee as defined in the Labuan Financial Services and Securities Act 2010, (x) an Islamic bank licensee or takaful licensee as defined in the Labuan Financial Services and Securities Act 2010 and (xi) any other person as may be specified by the Commission; provided that, in the each of the preceding categories (i) to (xi), the distribution of our common shares is made by a holder of a Capital Markets Services Licence who carries on the business of dealing in securities. The distribution in Malaysia of this prospectus is subject to Malaysian laws. This prospectus does not constitute and may not be used for the purpose of public offering or an issue, offer for subscription or purchase, invitation to subscribe for or purchase any securities requiring the registration of a prospectus with the Commission under the Capital Markets and Services Act 2007.

Notice to prospective investors in Taiwan

The shares have not been and will not be registered with the Financial Supervisory Commission of Taiwan pursuant to relevant securities laws and regulations and may not be sold, issued or offered within Taiwan through a public offering or in circumstances which constitutes an offer within the meaning of the Securities and Exchange Act of Taiwan that requires a registration or approval of the Financial Supervisory Commission of Taiwan. No person or entity in Taiwan has been authorized to offer, sell, give advice regarding or otherwise intermediate the offering and sale of the shares in Taiwan.

Notice to prospective investors in South Africa

Due to restrictions under the securities laws of South Africa, no “*offer to the public*” (as such term is defined in the South African Companies Act, No. 71 of 2008 (as amended or re-enacted, or the South African Companies Act) is being made in connection with the issue of the shares in South Africa. Accordingly, this document does not, nor is it intended to, constitute a “*registered prospectus*” (as that term is defined in the South African Companies Act) prepared and registered under the South African Companies Act and has not been approved by, and/or filed with, the South African Companies and Intellectual Property Commission or any other regulatory authority in South Africa. The shares are not offered, and the offer shall not be transferred, sold, renounced or delivered, in South Africa or to a person with an address in South Africa, unless one or other of the following exemptions stipulated in section 96 (1) applies:

Section 96 (1)(a) the offer, transfer, sale, renunciation or delivery is to:

- (i) persons whose ordinary business, or part of whose ordinary business, is to deal in securities, as principal or agent;
- (ii) the South African Public Investment Corporation;
- (iii) persons or entities regulated by the Reserve Bank of South Africa;
- (iv) authorized financial service providers under South African law;
- (v) financial institutions recognized as such under South African law;

- (vi) a wholly-owned subsidiary of any person or entity contemplated in (c), (d) or (e), acting as agent in the capacity of an authorized portfolio manager for a pension fund, or as manager for a collective investment scheme (in each case duly registered as such under South African law); or
- (vii) any combination of the person in (i) to (vi); or

Section 96 (1)(b) the total contemplated acquisition cost of the securities, for any single addressee acting as principal is equal to or greater than ZAR1,000,000 or such higher amount as may be promulgated by notice in the Government Gazette of South Africa pursuant to Section 96(2)(a) of the South African Companies Act.

Information made available in this prospectus should not be considered as “*advice*” as defined in the South African Financial Advisory and Intermediary Services Act, 2002.

Notice to prospective investors in Israel

In the State of Israel, this prospectus shall not be regarded as an offer to the public to purchase shares of common shares under the Israeli Securities Law, 5728-1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728-1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions, or the Addressed Investors; or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728-1968, subject to certain conditions, or the Qualified Investors. The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728-1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common shares to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors. Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728-1968. In particular, we may request, as a condition to be offered common shares, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728-1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728-1968 and the regulations promulgated thereunder in connection with the offer to be issued common shares; (iv) that the common shares that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728-1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728-1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor’s name, address and passport number or Israeli identification number.

VALIDITY OF THE SECURITIES

The validity of the common shares will be passed upon for us by Maples and Calder, our special British Virgin Islands counsel. Certain other legal matters will be passed upon for us by Sullivan & Cromwell LLP, New York, New York, and for the underwriters by Ropes & Gray LLP, Boston, Massachusetts.

EXPERTS

The combined financial statements of Biohaven Ltd. (formerly Biohaven Research Ltd.) at December 31, 2021 and 2020, and for the years then ended, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits and schedules, under the Securities Act that registers our common shares to be sold in this offering. This prospectus does not contain all the information contained in the registration statement and the exhibits and schedules filed as part of the registration statement. For further information with respect to us and our common shares, we refer you to the registration statement of which this prospectus forms part and the exhibits and schedules filed as part of the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copies of the contract or document that have been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

We are subject to the information reporting requirements of the Exchange Act, and we have filed and will file reports and other information with the SEC. These reports and other information are available on the SEC's website at <http://www.sec.gov>. We also maintain a website at www.biohaven.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

Information that we file with the SEC after the date of this prospectus may supersede the information in this prospectus. You may read these reports, proxy statements and other information and obtain copies of such documents and information as described above.

No person is authorized to give any information or to make any representations other than those contained in this prospectus, and if given or made, such information or representations must not be relied upon as having been authorized. Neither the delivery of this prospectus nor any distribution of securities made hereunder shall imply that there has been no change in the information set forth or in our affairs since the date hereof.

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Biohaven Ltd. (formerly Biohaven Research Ltd.)

Opinion on the Financial Statements

We have audited the accompanying combined balance sheets of Biohaven Ltd. (formerly Biohaven Research Ltd.) (the Company) as of December 31, 2021 and 2020, the related combined statements of operations and comprehensive loss, changes in equity and cash flows for the years then ended, and the related notes (collectively referred to as the “combined financial statements”). In our opinion, the combined 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.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2022.

Hartford, Connecticut
July 1, 2022

BIOHAVEN LTD.
(A BUSINESS OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.)
COMBINED BALANCE SHEETS
(Amounts in thousands)

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash	\$ 76,057	\$ 82,506
Prepaid expenses	6,734	7,240
Other current assets	12,032	10
Total current assets	94,823	89,756
Property and equipment, net	13,010	7,579
Equity method investment	—	1,176
Intangible assets	18,400	—
Goodwill	1,390	—
Other non-current assets	14,438	12,988
Total assets	\$ 142,061	\$ 111,499
Liabilities and equity		
Current liabilities:		
Accounts payable	\$ 4,775	\$ 2,758
Accrued expenses and other current liabilities	37,160	27,119
Total current liabilities	41,935	29,877
Other non-current liabilities	5,435	4,841
Total liabilities	47,370	34,718
Commitments and contingencies (Note 8)		
Contingently redeemable non-controlling interests	60,000	60,000
Equity:		
Net investment from Parent	34,691	16,781
Total equity	34,691	16,781
Total liabilities and equity	\$ 142,061	\$ 111,499

The accompanying notes are an integral part of these combined financial statements.

BIOHAVEN LTD.
(A BUSINESS OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.)
COMBINED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands)

	Year Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 181,486	\$ 98,460
General and administrative	37,414	16,046
Total operating expenses	218,900	114,506
Loss from operations	(218,900)	(114,506)
Other income (expense):		
Gain (loss) from equity method investment	5,261	(4,162)
Other income, net	1,209	—
Total other income (expense), net	6,470	(4,162)
Loss before provision for income taxes	(212,430)	(118,668)
Provision for income taxes	1,366	—
Net loss and comprehensive loss	<u>\$ (213,796)</u>	<u>\$ (118,668)</u>

The accompanying notes are an integral part of these combined financial statements.

BIOHAVEN LTD.
(A BUSINESS OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.)
COMBINED STATEMENTS OF CHANGES IN EQUITY
(Amounts in thousands)

	Net Investment from Parent
Balance as of December 31, 2019	\$ 14,451
Net loss	(118,668)
Net transfers from Parent	120,998
Balance as of December 31, 2020	16,781
Net loss	(213,796)
Net transfers from Parent	231,706
Balance as of December 31, 2021	\$ 34,691

The accompanying notes are an integral part of these combined financial statements.

BIOHAVEN LTD.
(A BUSINESS OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.)

COMBINED STATEMENTS OF CASH FLOWS

(Amounts in thousands)

	Year Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (213,796)	\$ (118,668)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	65,639	29,500
Depreciation and amortization	1,393	72
Issuance of Parent common shares as payment for license and consulting agreements	7,929	—
(Gain) loss from equity method investment	(5,261)	4,162
Other non-cash items	(3,408)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(9,073)	(2,419)
Other non-current assets	(109)	(5,594)
Accounts payable	1,025	222
Accrued expenses and other current liabilities	7,882	14,855
Other non-current liabilities	1,939	1,913
Net cash used in operating activities	<u>(145,840)</u>	<u>(75,957)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(938)	(1,097)
Payments for leasehold improvements	—	(1,600)
Cash acquired in business acquisition	1,882	—
Net cash provided by (used in) investing activities	<u>944</u>	<u>(2,697)</u>
Cash flows from financing activities:		
Net transfers from Parent	138,052	92,242
Proceeds from sale of contingently redeemable non-controlling interests	—	60,000
Other	395	—
Net cash provided by financing activities	<u>138,447</u>	<u>152,242</u>
Net (decrease) increase in cash and restricted cash	(6,449)	73,588
Cash and restricted cash at beginning of period	83,506	9,918
Cash and restricted cash at end of period	<u>\$ 77,057</u>	<u>\$ 83,506</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 107	\$ —
Cash paid for income taxes	\$ 16,594	\$ 2,758

The accompanying notes are an integral part of these combined financial statements.

NOTES TO COMBINED FINANCIAL STATEMENTS

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

1. Nature of the Business and Basis of Presentation

On May 9, 2022, Biohaven Pharmaceutical Holding Company Ltd. (“Biohaven” or the “Parent”), Pfizer Inc. (“Pfizer”) and a wholly owned subsidiary of Pfizer (“Merger Sub”), entered into an Agreement and Plan of Merger (the “Merger Agreement”), which provides for the acquisition by Pfizer of the Parent through the merger of Merger Sub with and into the Parent (the “Merger”). In connection with the Merger Agreement, the Parent and Biohaven Ltd. (“SpinCo” or “the Company”) entered into a Separation and Distribution Agreement, dated as of May 9, 2022 (the “Distribution Agreement”). In connection with the Distribution Agreement, the Board of Directors of the Parent approved and directed the Parent’s management to effect the spin-off of the business, operations, and activities that are not the CGRP Business (as defined below), including Kv7 ion channel activators, glutamate modulation, MPO inhibition and myostatin inhibition platforms, preclinical product candidates, and certain corporate infrastructure currently owned by the Parent, or collectively the “Biohaven Research Business”.

To implement the spin-off, the Parent expects to transfer the related license agreements, intellectual property and corporate infrastructure, including certain non-commercial employee agreements, share based awards and other corporate agreements (the “Business”) to Biohaven Ltd, through a series of internal restructuring transactions, which we refer to as the pre-closing reorganization. Descriptions of historical business activities in these Notes to Combined Financial Statements are presented as if these transfers had already occurred, and the Parent’s activities related to such assets and liabilities had been performed by the Company.

To effect the spin-off, each of the Parent’s shareholders will receive one of our common shares for every two common shares of the Parent held prior to the spin-off. Upon completion of the spin-off, the Company will be a stand-alone, publicly traded company focused on the development of its Kv7 ion channel activator, glutamate modulation, MPO inhibition and myostatin inhibition platforms, which it believes have the potential to alter existing treatment approaches across a diverse set of neurological indications with high unmet need in both large markets and orphan indications.

The spin-off would generally result in (a) the Company directly or indirectly owning, assuming, or retaining certain assets and liabilities of the Parent and its subsidiaries related to the Parent’s pipeline assets and businesses and (b) the Parent directly or indirectly owning, assuming, or retaining all other assets and liabilities, including those associated with the Parent’s platform for the research, development, manufacture and commercialization of calcitonin gene-related receptor antagonists, including rimegepant, zavegepant and the Heptares Therapeutics Limited preclinical CGRP portfolio and related assets (the “CGRP Business”).

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts may require additional capital, additional personnel and infrastructure, and further regulatory and other capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Upon formation and to date, Biohaven Ltd. has had nominal assets, and no liabilities or results of operations and has 100 common shares of no par value outstanding.

Basis of Presentation

The accompanying combined financial statements present, on a historical basis, the combined assets, liabilities, expenses and cash flows directly attributable to the Business which have been prepared from the Parent’s combined financial statements and accounting records and are presented on a stand-alone basis as if the operations have been conducted independently from the Parent. Historically, separate financial statements have not been prepared for the Company and it has not operated as a standalone business from the Parent.

NOTES TO COMBINED FINANCIAL STATEMENTS

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

The combined financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”).

The combined financial statements of operations and comprehensive loss include all costs directly related to the Business, including costs for facilities, functions and services utilized by the Company. The combined statements of operations and comprehensive loss also include allocations for various expenses related to the Parent’s corporate functions, including research and development, human resources, information technology, facilities, tax, shared services, accounting, finance and legal. These expenses were allocated on the basis of direct usage or benefit when specifically identifiable, with the remainder allocated on a proportional cost allocation method primarily based on employee labor hours or direct expenses. Management believes the assumptions underlying the combined financial statements, including the expense methodology and resulting allocation, are reasonable for all periods presented. However, the allocations may not include all of the actual expenses that would have been incurred by the Company and may not reflect its combined results of operations, financial position and cash flows had it been a standalone company during the periods presented. It is not practicable to estimate actual costs that would have been incurred had the Company been a standalone company and operated as an unaffiliated entity during the periods presented. Actual costs that might have been incurred had the Company been a standalone company would depend on a number of factors, including the organizational structure, what corporate functions the Company might have performed directly or outsourced and strategic decisions the Company might have made in areas such as executive management, legal and other professional services, and certain corporate overhead functions.

The income tax amounts in the combined financial statements have been calculated on a separate return method and are presented as if the Company’s operations were separate taxpayers in the respective jurisdiction. Therefore, tax expense, cash tax payments, and items of current and deferred taxes may not be reflective of the Company’s actual tax balances prior to or subsequent to the distribution.

In connection with the separation, the Company and Biohaven expect to enter into a transition services agreement whereby the Company will provide certain transition services to Biohaven and Biohaven will provide certain transition services to the Company. The Company expects to incur certain costs to establish itself as a standalone public company, as well as ongoing additional costs associated with operating as an independent, publicly traded company.

The combined balance sheets include assets and liabilities that have been determined to be specifically identifiable or otherwise attributable to the Company, including certain assets that were historically held at the corporate level in the Parent. All intracompany transactions within the Company have been eliminated. All intercompany transactions between the Company and the Parent are considered to be effectively settled in the combined financial statements at the time the transactions are recorded. The total net effect of these intercompany transactions considered to be settled is reflected in the combined statement of cash flows within financing activities and in the combined balance sheets as “Net investment from Parent.” See Note 9, Related Party Transactions for additional information regarding related party transactions.

Our equity balance in these combined financial statements represents the excess of total assets over liabilities. Net investment from Parent is primarily impacted by contributions from Parent which are the result of net funding provided by or distributed to Parent.

Cash on the combined balance sheets represents cash balances from the standalone entities established to operate the Business and that will be contributed to the Company in connection with the spin-off. The Company is a co-obligor, jointly and severally with the Parent on Biohaven’s third-party long-term debt obligations with Sixth Street Specialty Lending, Inc. Biohaven’s third-party long-term debt and related interest expense are not reflected in the combined financial statements because the Company has not agreed to pay a specified amount of the borrowings on the basis of its arrangement with the Parent, nor is the Company expected to pay any portion of the Parent’s third-party debt, and the borrowings are not specifically identifiable to SpinCo. See Note 8, Commitments and Contingencies for additional information regarding debt.

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Going Concern

In accordance with Accounting Standards Codification (“ASC”) 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the combined financial statements are issued.

Through July 1, 2022, the Company has funded its operations primarily with proceeds from Biohaven Pharmaceutical Holding Co., its Parent, and the Company expects the Parent to continue to fund its cash needs through the date of Distribution. The Company has incurred recurring losses since its inception, including net losses of \$213,796 and \$118,668 during the years ended December 31, 2021 and 2020, respectively. The Company expects to continue to generate operating losses for the foreseeable future. As of July 1, 2022, the issuance date of these combined financial statements, the Company expects that its continued funding from Parent will be sufficient to fund operating expenses, financial commitments and other cash requirements for at least one year after the issuance date of these financial statements. Following the Distribution, the Company’s viability will be dependent on its ability to raise additional capital to finance its operations.

To execute its business plans, the Company will require funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through the sale of public or private equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company’s shareholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

2. Summary of Significant Accounting Policies***Use of Estimates***

The preparation of combined 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 combined financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected in these combined financial statements include, but are not limited to, the valuation of intangible assets, determining the allocations of costs and expenses from the Parent and the accrual for research and development expenses. 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.

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash. Periodically, the Company maintains deposits in government insured financial institutions in excess of government insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash.

NOTES TO COMBINED FINANCIAL STATEMENTS

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Restricted Cash

Restricted cash primarily consists of collateral held by a bank for a letter of credit ("LOC") issued in connection with the leased office space in Yardley, Pennsylvania. See Note 8 "Commitments and Contingencies" for additional information on the real estate lease. The following represents a reconciliation of cash in the combined balance sheets to total cash and restricted cash for the years ended December 31, 2021 and 2020, respectively, in the combined statements of cash flows:

	December 31,	
	2021	2020
Cash	\$ 76,057	\$ 82,506
Restricted cash (included in other current assets)	250	—
Restricted cash (included in other non-current assets)	750	1,000
Total cash and restricted cash at the end of the period in the combined statement of cash flows	<u>\$ 77,057</u>	<u>\$ 83,506</u>

Acquisitions

The Company's combined financial statements include the operations of acquired businesses after the completion of the acquisitions. The Company accounts 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 Gain (loss) from equity method investment in the combined statement of operations and comprehensive loss and results in a corresponding adjustment to the carrying value of the investment on the combined 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 4 "Acquisitions" 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 and land, office and lab equipment, computer hardware and software, and furniture and fixtures.

NOTES TO COMBINED FINANCIAL STATEMENTS

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The fixed assets have the following useful lives:

Building	30 years
Computer hardware and software	3 - 5 years
Office and lab equipment	3 - 5 years
Furniture and fixtures	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*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 fair value of acquired intangible assets is primarily determined using an income-based approach referred to as the multi-period excess earnings method utilizing Level 3 fair value inputs. The market participant valuation assumes a global view considering all potential jurisdictions and indications based on discounted after-tax cash flow projections, risk adjusted for estimated probability of technical and regulatory success.

The Company evaluates IPR&D for impairment at least annually in the fourth quarter and 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 the acquisition of Kleo, the Company recorded intangible assets consisting of IPR&D assets of \$18,400, which included an oncology therapeutic candidate and a COVID-19 therapeutic candidate which have entered clinical trials, and goodwill of \$1,390. See Note 4 "Acquisitions" for additional details.

Impairment of Long-Lived Assets

The Company monitors its long-lived assets 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

NOTES TO COMBINED FINANCIAL STATEMENTS

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market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying values of other current assets, accounts payable, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

Leases

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 its real estate leases, which are accounted for as operating leases, the Company has elected the practical expedient to include both the lease and non-lease components as a single component. 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 non-current assets in the combined 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 of leasehold improvements from prepaid rent to operating right-of-use asset. As of December 31, 2021, the Company had restricted cash of \$250 and \$750 included in other current assets and other non-current assets, respectively, in the combined financial statements, which represent 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 8 "Commitments and Contingencies" for additional information on the real estate lease.

Segment Information

The Company manages its operations as a single segment, the development of therapies targeting neurological diseases, for the purposes of assessing performance and making operating decisions. In 2021 and 2020, materially all the Company's long-lived assets were held in the United States.

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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.

Non-Cash Share-Based Compensation

Certain of the Company's employees have historically participated in the Parent's share-based compensation plans. Share-based compensation expense has been allocated to the Company based on a combination of specific identification and a proportionate cost allocation method. The Company expenses all share-based payments to employees over the requisite service period based on the grant-date fair value of the awards.

Equity

The Business' equity on the combined balance sheets represents the historical investment by the Parent in the Business and is presented in net investment from Parent in lieu of stockholders' equity. The combined statement of changes in equity includes net cash transfers and other assets and liabilities between the Parent and the Business as well as the net losses after tax.

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 combined financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the combined 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.

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

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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 combined financial statements.

Recently Issued Accounting Pronouncements

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 combined financial statements. The effect will largely depend on the terms of written call options or financings issued or modified in the future.

3. Balance Sheet Components**Other Current Assets**

Other current assets consisted of the following:

	December 31,	
	2021	2020
Accrued income tax receivable	\$ 9,911	\$ —
Other	2,121	10
	<u>\$ 12,032</u>	<u>\$ 10</u>

Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2021	2020
Building and land	\$ 12,297	\$ 6,858
Computer hardware and software	1,200	420
Office and lab equipment	1,653	674
Furniture and fixtures	1,202	1,202
Construction in progress	—	130
	<u>\$ 16,352</u>	<u>\$ 9,284</u>
Accumulated depreciation	<u>(3,342)</u>	<u>(1,705)</u>
	<u>\$ 13,010</u>	<u>\$ 7,579</u>

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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 common shares of the Parent valued at approximately \$4,871. The Purchase and Sale Agreement closed and the Parent issued the shares in December 2021.

Depreciation expense was \$673 and \$72 for the years ended December 31, 2021 and 2020 respectively.

As of December 31, 2021 and 2020, computer software costs included in property and equipment were \$760 and \$0, respectively, net of accumulated amortization of \$211 and \$0, respectively. Depreciation and amortization expense for capitalized computer software costs was \$28 and \$0 for the years ended December 31, 2021 and 2020.

Other Non-current Assets

Other non-current assets consisted of the following:

	December 31,	
	2021	2020
Series A-2 Preferred Stock Investment	6,000	6,000
Operating lease right-of-use assets	5,222	5,981
Other	3,216	1,007
	<u>\$ 14,438</u>	<u>\$ 12,988</u>

In December 2020, the Company entered into a Series A-2 Preferred Stock Purchase Agreement with Artizan Biosciences Inc. ("Artizan"). Under the agreement, the Company paid Artizan 61,494 shares of the Parent's common 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 determined that 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. See Note 6 "License Agreements" for additional details on the Artizan Agreement.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2021	2020
Accrued employee compensation and benefits	\$ 9,538	\$ 7,054
Accrued clinical trial costs	24,051	11,840
Accrued Series A-2 Preferred Stock Investment	—	6,000
Other	3,571	2,225
	<u>\$ 37,160</u>	<u>\$ 27,119</u>

Contingently Redeemable Non-controlling Interest

In September 2020, the Company's Asia-Pacific Subsidiary, BioShin Limited ("BioShin"), 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.

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In November 2021, the Company, Biohaven Therapeutics Ltd. (“BTL”), Atlas Merger Sub and BioShin entered into an Agreement and Plan of Merger (the “BioShin Merger Agreement”). The BioShin Merger Agreement provided for the merger of Atlas Merger Sub with and into BioShin, with BioShin surviving the merger as a wholly owned indirect subsidiary of the Parent, in accordance with Section 233 of the Cayman Islands Companies Act. As a result of the satisfaction of the closing conditions described in the BioShin 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 BioShin Merger Agreement), was converted into the right to receive 0.080121 of the Parent’s common shares.

4. Acquisitions

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 Parent 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 its equity method investment of \$5,261 for the year ended December 31, 2021 as a result of remeasuring to fair value the existing equity interest in Kleo, which was included as Gain (loss) from equity method investment on the combined statements of operations and comprehensive loss.

In connection with the transaction, the Company 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. The goodwill is primarily attributable to the acquired workforce.

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.

5. Share-Based Compensation

The Parent has share-based compensation plans under which it may issue common shares or restricted common shares, or 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 Parent. The Parent also has an Employee Share Purchase Plan (the “ESPP”) which allows eligible employee who are participating in the plan to purchase shares of the Parent at a discount.

Share-based compensation has been allocated to the Company by using a combination of specific identification and a proportionate cost allocation method based on employee hours or directly identified operating expenses, depending on the employee’s function. The amounts presented are not necessarily indicative of future awards and do

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not necessarily reflect the costs that the Company would have incurred as an independent company for the periods presented.

Share-based compensation under the Parent's share-based compensation plans 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. Share-based compensation expense attributed to the Company by classification included within in the combined statements of operations and comprehensive loss was as follows:

	Year Ended December 31,	
	2021	2020
Research and development expenses	\$ 39,381	\$ 18,475
General and administrative expenses	26,258	11,025
	\$ 65,639	\$ 29,500

6. License Agreements

Yale Agreement

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 of the Parent and granted Yale the right to purchase up to 10% of the securities issued in specified future equity offerings by the Parent, in addition to the obligation to issue shares to prevent anti-dilution. The obligation to contingently issue equity to Yale was no longer outstanding as of December 31, 2018.

The Yale Agreement was amended and restated in May 2019. As amended, the Company agreed to pay Yale up to \$2,000 upon the achievement of specified regulatory milestones and annual royalty payments of a low single-digit percentage based on net sales of riluzole-based products from the licensed patents or from products based on troriluzole. Under the amended and restated agreement, the royalty rates are reduced as compared to the original agreement. In addition, under the amended and restated agreement, the Company may develop products based on riluzole or troriluzole. The amended and restated agreement retains a minimum annual royalty of up to \$1,000 per year, beginning after the first sale of product under the agreement. If the Company grants any sublicense rights under the Yale Agreement, it must pay Yale a low single-digit percentage of sublicense income that it receives.

In January 2021, the Company entered a worldwide, exclusive license agreement with Yale University for the development and commercialization of a novel Molecular Degradator of Extracellular Protein ("MoDE") platform (the "Yale MoDE Agreement"). Under the license agreement, the Company 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 shares of the Parent 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.

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

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 royalties in two tiers, with each tiered royalty in the range from 0-10% of net sales of products licensed under the agreement. 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 and 2020, the Company did not record any expense or make any milestone or royalty payments under the 2016 AstraZeneca Agreement.

NOTES TO COMBINED FINANCIAL STATEMENTS

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2018 AstraZeneca Agreement

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 sales-based milestones. In addition, the Company will pay AstraZeneca royalties in three tiers, with each tiered royalty in the range from 0-10% of net sales of specified approved products, subject to specified reductions.

In November 2021, the Company completed enrollment in a Phase 3 clinical trial of this product candidate, which is now referred to as verdiperstat, for the treatment of Amyotrophic Lateral Sclerosis (“ALS”). ALS is a progressive, life-threatening, and rare neuromuscular disease for which there are currently limited treatment options and no cure. 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 and 2020, 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, the Company 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, the Company issued 100,000 of the Parent’s common shares to FCCDC valued at \$5,646.

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 of the Parent’s 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, the Company 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 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.

NOTES TO COMBINED FINANCIAL STATEMENTS

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

The Company recorded \$1,746 and \$1,500 in research and development expense in the combined statements of operations related to the FCCDC Agreement during the years ended December 31, 2021 and 2020, respectively.

UConn

In October 2018, the Company announced it had signed an exclusive, worldwide option and license agreement (the “UConn Agreement”) with the University of Connecticut (“UConn”) for the development and commercialization rights to UC1MT, a therapeutic antibody targeting extracellular metallothionein. Under this agreement, the Company has the option to acquire an exclusive, worldwide license to UC1MT and its underlying patents to develop and commercialize throughout the world in all human indications. If the Company chooses to exercise the option, it would be obligated to pay UConn upon the achievement of specified regulatory and commercial milestones, and royalties of a low single-digit percentage of net sales of licensed products sold by the Company, its affiliates or its sublicensees.

Artizan Agreement

In December 2020, BTL entered into an Option and License Agreement with Artizan Biosciences Inc. (the “2020 Artizan Agreement”). Pursuant to the 2020 Artizan Agreement, BTL acquired an option (“Biohaven Option”) to obtain a royalty-based license from Artizan to manufacture, use and commercialize certain products in the United States for the treatment of diseases, including, for example, inflammatory bowel disease and other gastrointestinal inflammatory disorders, e.g., Crohn’s disease. 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. BTL and Artizan have also formed a joint steering committee to oversee, review and coordinate the product development activities with regard to all products for which BTL 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 of the Parent’s common 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.

In June 2021, BTL entered into a Development and License Agreement with Artizan Biosciences Inc (the “2021 Artizan Agreement”). Pursuant to the 2021 Artizan Agreement, BTL acquired an exclusive, worldwide license under Artizan’s IgA-SEQ patented technology and know-how to develop, manufacture and commercialize certain of Artizan’s compounds for use in Parkinson’s Disease. Under the agreement, BTL is responsible for funding the development of the compounds, obtaining regulatory approvals, manufacturing the compounds and commercializing the compounds. BTL is also responsible for the prosecution, maintenance and enforcement of Artizan’s patents. BTL will pay Artizan development milestones of \$20,000 for the first licensed compound to achieve U.S. marketing authorization and \$10,000 for each subsequent U.S. approval. In addition, BTL will pay Artizan commercialization milestones totaling up to \$150,000 and royalties in the low to mid single digits. The 2021 Artizan Agreement terminates on a country-by-country basis on the later of 10 years from the first commercial sale of licensed product in such country or the expiration of Artizan’s patents in such country and can also be terminated if certain events occur, e.g., material breach or insolvency.

In June 2022, the Company entered into an Amendment to the Series A-2 Preferred Stock Purchase Agreement with Artizan. Under the Amendment, the Company made a cash payment of \$4,000 in exchange for 22,975,301 shares of series A-2 preferred stock of Artizan out of a total of 45,950,601 shares of series A-2 preferred stock of Artizan for a total raise of \$8,000 (the “A2 Extension Raise”). Along with the Amendment, the Company and Artizan executed a non-binding indication of interest (“Artizan Side Letter”) which describes terms under which BTL and Artizan would amend the 2020 Artizan Agreement to eliminate certain milestone payments required by us in exchange for limiting our option to the selection of the first (ARZC-001) licensed product. The Artizan Side Letter requires Artizan to commit at least 80% of the funds raised in the A-2 Extension Raise to a certain program and to raise \$35,000 of additional capital within a certain time.

NOTES TO COMBINED FINANCIAL STATEMENTS

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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 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 of the Parent 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 combined statement of operations and comprehensive loss. 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.

KU Leuven Agreement

In January 2022, the Company and Katholieke Universiteit Leuven (“KU Leuven”) entered into an Exclusive License and Research Collaboration Agreement (the “KU Leuven Agreement”) to develop and commercialize 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, the Company 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 is being evaluated in preclinical pain models and will be the first to advance towards Phase 1 studies. The Company 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 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 it 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

NOTES TO COMBINED FINANCIAL STATEMENTS

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

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.

7. Income Taxes

The income tax amounts in the combined financial statements have been calculated on a separate return method and are presented as if the Company’s operations were separate taxpayers in the respective jurisdiction. Therefore, tax expense, cash tax payments, and items of current and deferred taxes may not be reflective of the Company’s actual tax balances prior to or subsequent to the distribution.

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, the Company and all dividends, interest, rents, royalties, compensation and other amounts paid by the Company to persons who are not resident in the BVI and any capital gains realized with respect to any shares, debt obligations, or other securities of the Company by persons who are not resident in the BVI are exempt from all provisions of the Income Tax Ordinance in the BVI.

Parent has historically outsourced all of the research and clinical development for its programs under a master services agreement with Biohaven Pharmaceuticals, Inc. (“BPI”). As a result of providing services under this agreement, BPI was profitable during the years ended December 31, 2021 and 2020, and BPI is subject to taxation in the United States. As such, in each reporting period, the Biohaven Research Business tax provision includes the effects of consolidating the results of operations of BPI.

At December 31, 2021 and 2020, the Company continued to maintain a full valuation allowance against its net deferred tax assets, which are comprised primarily of research and development credit carryforwards and future stock based compensation deductions based on management’s assessment that it is more likely than not that the deferred tax assets will not be realized.

The Company recorded an income tax provision during the years ended December 31, 2021 and 2020 of \$1,366 and \$0, respectively, which primarily represents U.S. Federal and state taxes related to the Company’s profitable operations of BPI in the US.

Income (loss) before provision for income taxes consisted of the following:

	Year Ended December 31,	
	2021	2020
BVI	\$ (211,334)	\$ (123,468)
Foreign	(1,096)	4,800
Loss before provision for income taxes	\$ (212,430)	\$ (118,668)

NOTES TO COMBINED FINANCIAL STATEMENTS

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

The provision for income taxes consisted of the following:

	Year Ended December 31,	
	2021	2020
Current income tax provision:		
BVI	\$ —	\$ —
Foreign (U.S. federal and state)	1,366	—
Total current income tax provision	1,366	—
Deferred income tax provision (benefit):		
BVI	—	—
Foreign (U.S. federal and state)	—	—
Total deferred income tax provision (benefit)	—	—
Total provision for income taxes	\$ 1,366	\$ —

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
BVI statutory income tax rate	— %	— %
Foreign tax rate differential	— %	1.00 %
Tax Credits	(5.00)%	(6.00)%
Change in valuation allowance	7.00 %	9.00 %
Other	(1.00)%	(4.00)%
Effective income tax rate	1.00 %	— %

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

	December 31,	
	2021	2020
Deferred tax assets:		
Foreign net operating loss carryforwards	\$ 9,573	\$ —
Tax credits	26,590	20,577
Stock based compensation	18,246	11,023
Other	4,917	1,592
Total deferred tax assets	59,326	33,192
Valuation allowance	(54,224)	(32,970)
Net deferred tax assets	5,102	222
Deferred tax liabilities:		
Intangible assets and other	(5,102)	(222)
Total deferred tax liabilities	(5,102)	(222)
Net deferred tax assets	\$ —	\$ —

In January 2021, the Company completed the acquisition of Kleo and recorded a full valuation allowance against its Kleo deferred tax assets due to Kleo's cumulative loss history. The Company will continue to evaluate the need for a valuation allowance on all of its deferred tax assets until there is sufficient positive evidence to support the reversal of all or some portion of these allowances.

NOTES TO COMBINED FINANCIAL STATEMENTS

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As of December 31, 2021, and 2020, the Company had foreign net operating loss carryforwards of \$39,281, and, \$0, respectively. As of December 31, 2021 and 2020, the Company had federal and state research and development and orphan drug credits of \$26,590 and \$20,577, respectively, which begin to expire in 2030.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2021 and 2020 were due primarily to generation of excess tax credits and the acquisition of Kleo as follows:

	Year Ended December 31,	
	2021	2020
Valuation allowance as of beginning of year	\$ (32,970)	\$ (23,592)
Decreases recorded as benefit to income tax provision	—	—
Increases recorded to Purchase Accounting and Net Parent Investment	(6,449)	1,089
Increases recorded to income tax provision	(14,805)	(10,467)
Valuation allowance as of end of year	\$ (54,224)	\$ (32,970)

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 Ended December 31,	
	2021	2020
Beginning of period balance	\$ 2,700	\$ 1,800
Increase for tax positions taken during the current period	50	—
Increases recorded to Purchase Accounting and Net Parent Investment	1,050	900
Decreases for tax positions taken during a prior period	—	—
End of period balance	\$ 3,800	\$ 2,700

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.

BPI files income tax returns in the U.S. and certain state jurisdictions. BPI's U.S. federal and state income tax returns are subject to tax examinations for the tax year ended December 31, 2018 and subsequent years. The federal tax return for BPI is currently under audit by the IRS for the period ended December 31, 2019.

8. Commitments and Contingencies

The following agreements are either current Company agreements, or those the Parent expects to assign to the Company upon separation, accordingly, all considerations paid by the Parent in association with these agreements are recorded in the combined financial statements of the Company.

Lease Agreements

The Parent's leases primarily consist of office space that will be attributed to the Company in connection with the separation. The Company determines if an arrangement is a lease at inception. The lease term includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Real estate leases for facilities have an average remaining lease term of 5.75 years, for which none include the optional extension. The Company has made an accounting policy election not to record short-term leases (leases with an initial term of 12 months or less) on the balance sheet. The Company currently has two short-term leases with immaterial lease expense.

NOTES TO COMBINED FINANCIAL STATEMENTS

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

Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Operating lease assets and liabilities are recognized based on the present value of lease payments over the lease term. Since most of the Company's leases do not have a readily determinable implicit discount rate, the Company uses the Parent's incremental borrowing rate to calculate the present value of lease payments. The Company does not separate lease components (e.g., payments for rent, real estate taxes and insurance costs) from non-lease components (e.g., common-area maintenance costs) in the event that the agreement contains both. The Company includes both the lease and non-lease components for purposes of calculating the right-of-use asset and related lease liability (if the non-lease components are fixed). The allocated operating lease cost was \$264 in 2021 and \$0 in 2020.

Certain of the Company's lease agreements contain variable lease payments that are adjusted for actual operating expense true-ups compared with estimated amounts; however, these amounts are immaterial. The Company had no sublease income and there are no sale-leaseback transactions. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Supplemental balance sheet information related to operating leases is as follows:

	Year Ended December 31,	
	2021	2020
Assets		
Other non-current assets	\$ 5,222	\$ 5,981
Liabilities		
Other current liabilities	439	675
Other non-current liabilities	2,797	2,929
	<u>\$ 3,236</u>	<u>\$ 3,604</u>
Weighted-average remaining lease term (years)	5.75	6.75
Weighted-average discount rate	9.07 %	9.07 %

Maturities of operating lease liabilities are as follows:

2022	\$ 689
2023	703
2024	717
2025	731
2026	746
Thereafter	568
Total lease payments	<u>4,154</u>
Less: imputed interest	918
Total lease liabilities	<u>\$ 3,236</u>

Research Commitments

The Parent has entered into agreements with several CROs to provide services in connection with the Company's preclinical studies and clinical trials. Research Commitments entered into by the Parent and related to the Company are expected to transfer to the Company upon separation. As of December 31, 2021, the Company had no material noncancellable research commitments in excess of one year.

NOTES TO COMBINED FINANCIAL STATEMENTS

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Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company's amended and restated memorandum and articles of association also provide for indemnification of directors and officers in specific circumstances. To date, the Company has not incurred any material costs as a result of such indemnification provisions. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its combined financial statements as of December 31, 2021 or 2020.

License Agreements

The Parent entered into license agreements with various parties that are directly attributed to the Company under which it is obligated to make contingent and non-contingent payments (see Note 6). License agreements entered by the Parent and related to the Company are expected to transfer to the Company upon separation.

Sixth Street Financing Agreement

In August 2020, the Parent and Biohaven Pharmaceuticals, Inc., (together with the Parent 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 Borrowers (the "Sixth Street Financing Agreement"). The Sixth Street Financing Agreement, as amended, provides for term loans in an aggregate principal amount up to \$750,000, plus any capitalized interest paid in kind (the "Sixth Street Financing Agreement") and is accounted for as third-party, long-term debt by the Parent.

The Company is a co-obligor, jointly and severally with the Parent on its third-party long-term debt obligation under the Sixth Street Financing Agreement. The Parent's third-party debt and related interest expense are not reflected in the combined financial statements because the Company has not agreed to pay a specified amount of the borrowings on the basis of its arrangement with the Parent, nor is the Company expected to pay any portion of the Parent's third-party debt, and the borrowings are not specifically identifiable to SpinCo. Pursuant to the terms of the Merger Agreement, at closing of the Merger, Pfizer will pay off or cause to be paid off the applicable payoff amount on behalf of the Parent.

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.

9. Related Party Transactions

The Company has not historically operated as a standalone business and the combined financial statements are derived from the consolidated financial statements and accounting records of the Parent. The following disclosure summarizes activity between the Company and the Parent, including the affiliates of the Parent that are not part of the planned spin-off.

NOTES TO COMBINED FINANCIAL STATEMENTS

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Cost Allocations

The combined financial statements reflect allocations of certain expenses from the financial statements of the Parent, including research and development expenses and general and administrative expenses. These allocations include, but are not limited to, executive management, employee compensation and benefits, facilities and operations, information technology, business development, financial services (such as accounting, audit, and tax), legal, insurance, and share-based compensation. Some of these services are expected to continue to be provided to the Parent on a temporary basis following the Distribution under a transition services agreement. See Note 2 for discussion of these costs and the methodology used to allocate them.

These allocations to SpinCo are reflected in the combined statement of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2021	2020
Research and development	\$ 70,929	\$ 33,482
General and administrative	33,928	14,646
Total	\$ 104,857	\$ 48,128

Management believes these cost allocations are a reasonable reflection of services provided to, of the benefit derived by, the Company during the periods presented. The allocations may not, however, be indicative of the actual expenses that would have been incurred had the Company operated as a standalone public company. Actual costs that may have been incurred if the Company had been a standalone public company would depend on a number of factors, including the chosen organizational structure, whether functions were outsourced or performed by Company employees, and strategic decisions made in areas such as research and development, information technology and infrastructure.

Share-Based Compensation

As discussed in Note 5, Share-based compensation, SpinCo employees participate in the Parent's share-based compensation plans, the costs of which have been allocated to SpinCo and recorded in research and development and general and administrative expenses in the combined statements of operations and comprehensive loss.

NOTES TO COMBINED FINANCIAL STATEMENTS

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

Net Transfers From Parent

Net transfers from Parent represent the net effect of transactions between SpinCo and the Parent. The components of net transfers from Parent are as follows:

	Year Ended December 31,	
	2021	2020
General financing activities	\$ 98,834	\$ 73,614
Corporate cost allocations, excluding share-based compensation	39,218	18,628
Net transfers from Parent as reflected in the Combined Statement of Cash Flows	138,052	92,242
Share-based compensation	65,639	29,500
Issuance of Parent common shares as payment for business acquisition	10,673	—
Issuance of Parent common shares as payment for license and consulting agreements	7,929	—
Issuance of Parent common shares as payment for building purchase	4,871	—
Issuance of Parent common shares as payment for Artizan investment	6,000	—
Other non-cash adjustments	(1,458)	(744)
Net transfers from Parent as reflected in the Combined Statement of Changes in Equity	\$ 231,706	\$ 120,998

Related Party Agreements*License Agreement with Yale*

On September 30, 2013, the Company entered into the Yale Agreement with Yale (see Note 6). 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 6 for detail). Under the license agreement, the Company 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 of the Parent 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 years ended December 31, 2021 and 2020, excluding the development milestone payment noted above, the Company recorded \$458 and \$138 in research and development expense related to the Yale MoDE Agreement and Yale Agreement (the "Yale Agreements"). As of December 31, 2021 and 2020, the Company owed no amounts to Yale.

10. Subsequent Events

Management has evaluated subsequent events through July 1, 2022, the date on which these combined financial statements were available to be issued.

Kv7 Platform Acquisition

In April 2022, the Company closed the acquisition from Knopp Biosciences LLC ("Knopp") of Channel Biosciences, LLC ("Channel"), a wholly owned subsidiary of Knopp owning the assets of Knopp's Kv7 channel targeting platform (the "Transaction"), pursuant to a Membership Interest Purchase Agreement (the "Purchase Agreement"), dated February 24, 2022.

NOTES TO COMBINED FINANCIAL STATEMENTS

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In consideration for the Transaction, on April 4, 2022, the Company made an upfront payment comprised of \$35,000 in cash and 493,254 common shares of the Parent, valued at approximately \$58,750, issued through a private placement. The Company has also agreed to pay additional success-based 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. 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 tens digits for the pipeline programs.

The Company expects to account for this purchase as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset, in-process research and development ("IPR&D"). The IPR&D asset has no alternative future use and relates to intellectual property rights related to the Kv7 platform lead, now BHV-7000.

Real Estate Leases

In May 2022, the Company entered into a sublease for office space in Dublin, Ireland to replace an existing license agreement for separate office space. The lease commenced in May 2022 and the lease has a lease term of 59 full calendar months, with no contractual option to extend at the end of the lease term. Upon commencement, the Company's base rent per quarter will be €100 to be paid in advance, with no open market rent review until termination of the lease. The Company will also be responsible for its proportionate share of operating costs, including, but not limited to, real estate taxes, common area maintenance, and utilities.

In June 2022, the Company entered into a lease agreement for office space in West Palm Beach, Florida to support its operations, which will be attributed to the Company in connection with the separation. The Company expects to take occupancy of the premises in late 2024, following substantial completion of the tenant improvements. The lease term will commence on the date the Company takes occupancy of the premises and continue for 120 full calendar months, with an option to extend for two additional periods of 60 months each. Upon commencement, the Company's base rent per month will be \$105 to be paid in advance, with annual base rent increases of 3.00%. In addition, there is a rent abatement period for the first three full calendar months of the lease term. The Company will also be responsible for its proportionate share of operating costs, including, but not limited to, real estate taxes, common area maintenance, and utilities.

BIOHAVEN LTD.
(A BUSINESS OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.)

CONDENSED COMBINED BALANCE SHEETS

(Amounts in thousands)

	June 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash	\$ 23,209	\$ 76,057
Prepaid expenses	14,469	6,734
Other current assets	9,073	12,032
Total current assets	46,751	94,823
Property and equipment, net	13,397	13,010
Intangible assets	18,400	18,400
Goodwill	1,390	1,390
Other non-current assets	18,282	14,438
Total assets	<u>\$ 98,220</u>	<u>\$ 142,061</u>
Liabilities and Equity		
Current liabilities:		
Accounts payable	\$ 6,377	\$ 4,775
Accrued expenses and other current liabilities	59,473	37,160
Total current liabilities	65,850	41,935
Other non-current liabilities	7,372	5,435
Total liabilities	73,222	47,370
Commitments and contingencies (Note 8)		
Contingently redeemable non-controlling interests	—	60,000
Equity:		
Net investment from Parent	24,998	34,691
Total equity	24,998	34,691
Total liabilities and equity	<u>\$ 98,220</u>	<u>\$ 142,061</u>

The accompanying notes are an integral part of these combined financial statements.

BIOHAVEN LTD.
(A BUSINESS OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.)
CONDENSED COMBINED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2022	2021
Operating expenses:		
Research and development	\$ 247,183	\$ 92,695
General and administrative	39,700	19,830
Total operating expenses	286,883	112,525
Loss from operations	(286,883)	(112,525)
Other (expense) income:		
Gain from equity method investment	—	5,261
Other expense, net	(71)	(240)
Total other (expense) income, net	(71)	5,021
Loss before provision for income taxes	(286,954)	(107,504)
Provision for income taxes	13,365	41
Net loss and comprehensive loss	\$ (300,319)	\$ (107,545)

The accompanying notes are an integral part of these combined financial statements.

BIOHAVEN LTD.
(A BUSINESS OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.)
CONDENSED COMBINED STATEMENTS OF CHANGES IN EQUITY
(Amounts in thousands)
(Unaudited)

	Net Investment from Parent
Balance as of December 31, 2021	\$ 34,691
Net loss	(300,319)
Net transfers from Parent	290,626
Balance as of June 30, 2022	\$ 24,998

	Net Investment from Parent
Balance as of December 31, 2020	\$ 16,781
Net loss	(107,545)
Net transfers from Parent	132,896
Balance as of June 30, 2021	\$ 42,132

BIOHAVEN LTD.
(A BUSINESS OF BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.)

CONDENSED COMBINED STATEMENTS OF CASH FLOWS

(Amounts in thousands)

(Unaudited)

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (300,318)	\$ (107,545)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	60,930	37,278
Acquisition of IPR&D asset	93,747	—
Depreciation and amortization	665	482
Issuance of Parent common shares as payment for license and consulting agreements	1,779	4,243
(Gain) from equity method investment	—	(5,261)
Other non-cash items	—	(1,951)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,026)	(2,557)
Other non-current assets	(4,350)	(170)
Accounts payable	1,602	5,581
Accrued expenses and other current liabilities	22,312	(559)
Other non-current liabilities	1,937	1,406
Net cash used in operating activities	(126,722)	(69,053)
Cash flows from investing activities:		
Purchases of property and equipment	(1,250)	(706)
Payment for IPR&D asset acquisition	(35,000)	—
Cash acquired in business acquisition	—	1,882
Net cash (used in) provided by investing activities	(36,250)	1,176
Cash flows from financing activities:		
Net transfers from Parent	109,874	75,396
Other	—	395
Net cash provided by financing activities	109,874	75,791
Net (decrease) increase in cash and restricted cash	(53,098)	7,914
Cash and restricted cash at beginning of period	77,057	83,506
Cash and restricted cash at end of period	<u>\$ 23,959</u>	<u>\$ 91,420</u>

The accompanying notes are an integral part of these combined financial statements.

NOTES TO CONDENSED COMBINED FINANCIAL STATEMENTS

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

1. Nature of the Business and Basis of Presentation

On May 9, 2022, Biohaven Pharmaceutical Holding Company Ltd. (“Biohaven” or the “Parent”), Pfizer Inc. (“Pfizer”) and a wholly owned subsidiary of Pfizer (“Merger Sub”), entered into an Agreement and Plan of Merger (the “Merger Agreement”), which provides for the acquisition by Pfizer of the Parent through the merger of Merger Sub with and into the Parent (the “Merger”). In connection with the Merger Agreement, the Parent and Biohaven Ltd. (“SpinCo” or “the Company”) entered into a Separation and Distribution Agreement, dated as of May 9, 2022 (the “Distribution Agreement”). In connection with the Distribution Agreement, the Board of Directors of the Parent approved and directed the Parent’s management to effect the spin-off of the business, operations, and activities that are not the CGRP Business (as defined below), including the Kv7 ion channel activators, glutamate modulation, MPO inhibition and myostatin inhibition platforms, preclinical product candidates, and certain corporate infrastructure currently owned by the Parent, or collectively the “Biohaven Research Business”.

To implement the spin-off, the Parent expects to transfer the related license agreements, intellectual property and corporate infrastructure, including certain non-commercial employee agreements, share based awards and other corporate agreements (the “Business”) to Biohaven Ltd, through a series of internal restructuring transactions, which we refer to as the pre-closing reorganization. Descriptions of historical business activities in these Notes to Condensed Combined Financial Statements are presented as if these transfers had already occurred, and the Parent’s activities related to such assets and liabilities had been performed by the Company.

To effect the spin-off, each of the Parent’s shareholders will receive one of our common shares for every two common shares of the Parent held prior to the spin-off. Upon completion of the spin-off, the Company will be a stand-alone, publicly traded company focused on the development of its Kv7 ion channel activator, glutamate modulation, MPO inhibition and myostatin inhibition platforms, which it believes have the potential to alter existing treatment approaches across a diverse set of neurological indications with high unmet need in both large markets and orphan indications.

The spin-off would generally result in (a) the Company directly or indirectly owning, assuming, or retaining certain assets and liabilities of the Parent and its subsidiaries related to the Parent’s pipeline assets and businesses and (b) the Parent directly or indirectly owning, assuming, or retaining all other assets and liabilities, including those associated with the Parent’s platform for the research, development, manufacture and commercialization of calcitonin gene-related receptor antagonists, including rimegepant, zavegepant and the Heptares Therapeutics Limited preclinical CGRP portfolio and related assets (the “CGRP Business”).

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts may require additional capital, additional personnel and infrastructure, and further regulatory and other capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Upon formation and to date, Biohaven Ltd. has had nominal assets, and no liabilities or results of operations and has 100 common shares of no par value outstanding.

Basis of Presentation

The accompanying condensed combined financial statements present, on a historical basis, the combined assets, liabilities, expenses and cash flows directly attributable to the Business which have been prepared from the Parent’s combined financial statements and accounting records and are presented on a stand-alone basis as if the operations have been conducted independently from the Parent. Historically, separate financial statements have not been prepared for the Company and it has not operated as a standalone business from the Parent.

NOTES TO CONDENSED COMBINED FINANCIAL STATEMENTS**(Amounts in thousands, except share and per share amounts)**

The condensed combined financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and pursuant to the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”).

The condensed combined financial statements of operations and comprehensive loss include all costs directly related to the Business, including costs for facilities, functions and services utilized by the Company. The condensed combined statements of operations and comprehensive loss also include allocations for various expenses related to the Parent’s corporate functions, including research and development, human resources, information technology, facilities, tax, shared services, accounting, finance and legal. These expenses were allocated on the basis of direct usage or benefit when specifically identifiable, with the remainder allocated on a proportional cost allocation method primarily based on employee labor hours or direct expenses. Management believes the assumptions underlying the condensed combined financial statements, including the expense methodology and resulting allocation, are reasonable for all periods presented. However, the allocations may not include all of the actual expenses that would have been incurred by the Company and may not reflect its combined results of operations, financial position and cash flows had it been a standalone company during the periods presented. It is not practicable to estimate actual costs that would have been incurred had the Company been a standalone company and operated as an unaffiliated entity during the periods presented. Actual costs that might have been incurred had the Company been a standalone company would depend on a number of factors, including the organizational structure, what corporate functions the Company might have performed directly or outsourced and strategic decisions the Company might have made in areas such as executive management, legal and other professional services, and certain corporate overhead functions.

The income tax amounts in the condensed combined financial statements have been calculated on a separate return method and are presented as if the Company’s operations were separate taxpayers in the respective jurisdiction. Therefore, tax expense, cash tax payments, and items of current and deferred taxes may not be reflective of the Company’s actual tax balances prior to or subsequent to the distribution.

In connection with the separation, the Company and Biohaven expect to enter into a transition services agreement whereby the Company will provide certain transition services to Biohaven and Biohaven will provide certain transition services to the Company. The Company expects to continue to incur certain costs to establish itself as a standalone public company, as well as ongoing additional costs associated with operating as an independent, publicly traded company.

The condensed combined balance sheets include assets and liabilities that have been determined to be specifically identifiable or otherwise attributable to the Company, including certain assets that were historically held at the corporate level in the Parent. All intracompany transactions within the Company have been eliminated. All intercompany transactions between the Company and the Parent are considered to be effectively settled in the condensed combined financial statements at the time the transactions are recorded. The total net effect of these intercompany transactions considered to be settled is reflected in the condensed combined statement of cash flows within financing activities and in the condensed combined balance sheets as “Net investment from Parent.” See Note 9, Related Party Transactions for additional information regarding related party transactions.

Our equity balance in these condensed combined financial statements represents the excess of total assets over liabilities. Net investment from Parent is primarily impacted by contributions from Parent which are the result of net funding provided by or distributed to Parent.

Cash on the condensed combined balance sheets represents cash balances from the standalone entities established to operate the Business and that will be contributed to the Company in connection with the spin-off. The Company is a co-obligor, jointly and severally with the Parent on Biohaven’s third-party long-term debt obligations with Sixth Street Specialty Lending, Inc. Biohaven’s third-party long-term debt and related interest expense are not reflected in the condensed combined financial statements because the Company has not agreed to pay a specified amount of the borrowings on the basis of its arrangement with the Parent, nor is the Company expected to pay any portion of the Parent’s third-party debt, and the borrowings are not specifically identifiable to SpinCo. See Note 8, Commitments and Contingencies for additional information regarding debt.

NOTES TO CONDENSED COMBINED FINANCIAL STATEMENTS

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

Going Concern

In accordance with Accounting Standards Codification (“ASC”) 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the condensed combined financial statements are issued.

Through August 10, 2022, the Company has funded its operations primarily with proceeds from Biohaven Pharmaceutical Holding Co. Ltd., its Parent, and the Company expects the Parent to continue to fund its cash needs through the date of Distribution. The Company has incurred recurring losses since its inception, including net losses of \$300,319 and \$107,545 during the six months ended June 30, 2022 and 2021, respectively. The Company expects to continue to generate operating losses for the foreseeable future. As of August 10, 2022, the issuance date of these condensed combined financial statements, the Company expects that its continued funding from Parent will be sufficient to fund operating expenses, financial commitments and other cash requirements for at least one year after the issuance date of these financial statements. Following the Distribution, the Company’s viability will be dependent on its ability to raise additional capital to finance its operations.

To execute its business plans, the Company will require funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales, if ever, it expects to finance its operations through the sale of public or private equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company’s shareholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

2. Summary of Significant Accounting Policies

Our significant accounting policies used in preparation of these combined financial statements for the six months ended June 30, 2022 and 2021 are described in Note 2 to the combined financial statements for the year ended December 31, 2021. Updates to our accounting policies, including impacts from the adoption of new accounting standards, are discussed below in this Note 2.

Unaudited Interim Condensed Combined Financial Information

The accompanying unaudited condensed combined financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information. The accompanying unaudited condensed combined financial statements do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete combined financial statements. The accompanying year-end condensed combined balance sheet was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. The unaudited interim condensed combined financial statements have been prepared on the same basis as the audited annual combined financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company’s financial position as of June 30, 2022 and the results of its operations for the six months ended June 30, 2022 and 2021 and its cash flows for the six months ended June 30, 2022 and 2021. The results for the six months ended June 30, 2022 are not necessarily indicative of results to be expected for the year ending December 31, 2022, any other interim periods or any future year or period.

NOTES TO CONDENSED COMBINED FINANCIAL STATEMENTS

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

Use of Estimates

The preparation of condensed combined 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 combined financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed combined financial statements include, but are not limited to, the valuation of intangible assets, determining the allocations of costs and expenses from the Parent and the accrual for research and development expenses. 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.

Intangible Assets***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 asset is classified as a definite-lived intangible and 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.

If we acquire an asset or group of assets that do not meet the definition of a business under applicable accounting standards, the acquired IPR&D is expensed on its acquisition date, unless it has an alternative future use. Future costs to develop these assets are recorded to research and development expense as they are incurred.

Recently Adopted Accounting Pronouncements

Effective January 1, 2022 the Company adopted 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 has been applied prospectively and did not have a material effect on the combined financial statements of the Company.

Recently Issued Accounting Pronouncements

In June 2022 the FASB issued ASU No. 2022-03, Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions, to clarify the guidance in Topic 820

BIOHAVEN LTD.

NOTES TO CONDENSED COMBINED FINANCIAL STATEMENTS

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

when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security. The ASU also introduced new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value in accordance with Topic 820. The amendments in ASU 2022-03 are effective for fiscal years beginning after December 15, 2023. The Company is currently evaluating the effects of ASU 2022-03 on its combined financial statements.

3. Balance Sheet Components

Restricted Cash

Restricted cash primarily consists of collateral held by a bank for a letter of credit (“LOC”) issued in connection with the leased office space in Yardley, Pennsylvania. See Note 8 “Commitments and Contingencies” for additional information on the real estate lease. The following represents a reconciliation of cash in the condensed combined balance sheets to total cash and restricted cash as of June 30, 2022 and June 31, 2021, respectively, in the condensed combined statements of cash flows:

	June 30, 2022	June 30, 2021
Cash	\$ 23,209	\$ 90,420
Restricted cash (included in other current assets)	—	250
Restricted cash (included in other non-current assets)	750	750
Total cash and restricted cash at the end of the period in the condensed combined statement of cash flows	<u>\$ 23,959</u>	<u>\$ 91,420</u>

Other Current Assets

Other current assets consisted of the following:

	June 30, 2022	December 31, 2021
Accrued income tax receivable	8,097	\$ 9,911
Other	976	2,121
	<u>\$ 9,073</u>	<u>\$ 12,032</u>

Property and Equipment, Net

Property and equipment, net consisted of the following:

	June 30, 2022	December 31, 2021
Building and land	\$ 12,297	\$ 12,297
Computer hardware and software	1,200	1,200
Office and lab equipment	2,904	1,653
Furniture and fixtures	1,202	1,202
	<u>\$ 17,602</u>	<u>\$ 16,352</u>
Accumulated depreciation	(4,205)	(3,342)
	<u>\$ 13,397</u>	<u>\$ 13,010</u>

Depreciation expense was \$488 for the six months ended June 30, 2022 and \$329 for the six months ended June 30, 2021.

BIOHAVEN LTD.

NOTES TO CONDENSED COMBINED FINANCIAL STATEMENTS

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

As of June 30, 2022 and December 31, 2021, computer software costs included in property and equipment were \$760 and \$760, respectively, net of accumulated amortization of \$338 and \$211, respectively. Depreciation and amortization expense for capitalized computer software costs not material for the six months ended June 30, 2022 or 2021.

Other Non-current Assets

Other non-current assets consisted of the following:

	June 30, 2022	December 31, 2021
Series A-2 Preferred Stock Investment	\$ 10,000	\$ 6,000
Operating lease right-of-use assets	7,262	5,222
Other	1,020	3,216
	<u>\$ 18,282</u>	<u>\$ 14,438</u>

In December 2020, the Company entered into a Series A-2 Preferred Stock Purchase Agreement with Artizan Biosciences Inc. (“Artizan”). Under the agreement, the Company paid Artizan 61,494 shares of the Parent’s common 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. In June 2022, the Company entered into an Amendment to the Series A-2 Preferred Stock Purchase Agreement with Artizan. Under the Amendment, the Company made a cash payment of \$4,000 in exchange for 22,975,301 additional shares of series A-2 preferred stock of Artizan. The Company determined that 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. See Note 6 “License Agreements” for additional details on the Artizan Agreement.

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2022	December 31, 2021
Accrued development milestones	\$ 25,000	\$ —
Accrued employee compensation and benefits	5,178	9,538
Accrued clinical trial costs	22,015	24,051
Other	7,280	3,571
	<u>\$ 59,473</u>	<u>\$ 37,160</u>

Contingently Redeemable Non-controlling Interest

In September 2020, the Company’s Asia-Pacific Subsidiary, BioShin Limited (“BioShin”), 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 November 2021, the Company, Biohaven Therapeutics Ltd. (“BTL”), Atlas Merger Sub and BioShin entered into an Agreement and Plan of Merger (the “BioShin Merger Agreement”). The BioShin Merger Agreement

NOTES TO CONDENSED COMBINED FINANCIAL STATEMENTS

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

provided for the merger of Atlas Merger Sub with and into BioShin, with BioShin surviving the merger as a wholly owned indirect subsidiary of the Parent, in accordance with Section 233 of the Cayman Islands Companies Act. As a result of the satisfaction of the closing conditions described in the BioShin 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 BioShin Merger Agreement), was converted into the right to receive 0.080121 of the Parent's common shares and was removed from mezzanine equity. No Series A convertible preferred shares of BioShin were outstanding following the closing.

4. Acquisitions

Acquisition of Kleo Pharmaceuticals, Inc.

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 Parent 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 its equity method investment of \$5,261 for the year ended December 31, 2021 as a result of remeasuring to fair value the existing equity interest in Kleo, which was included as Gain (loss) from equity method investment on the condensed combined statements of operations and comprehensive loss.

In connection with the transaction, the Company 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. The goodwill is primarily attributable to the acquired workforce.

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.

Kv7 Platform Acquisition

In April 2022, the Company closed the acquisition from Knopp Biosciences LLC ("Knopp") of Channel Biosciences, LLC ("Channel"), a wholly owned subsidiary of Knopp owning the assets of Knopp's Kv7 channel targeting platform (the "Kv7 Platform Acquisition"), pursuant to a Membership Interest Purchase Agreement (the "Purchase Agreement"), dated February 24, 2022.

In consideration for the Kv7 Platform Acquisition, on April 4, 2022, the Company made an upfront payment comprised of \$35,000 in cash and 493,254 common shares of the Parent, valued at approximately \$58,747, issued through a private placement. The Company has also agreed to pay additional success-based payments comprised of

NOTES TO CONDENSED COMBINED FINANCIAL STATEMENTS

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

(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. 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 tens digits for the pipeline programs.

The Company accounted for this purchase as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset, in-process research and development (“IPR&D”). The IPR&D asset has no alternative future use and relates to intellectual property rights related to the Kv7 platform lead, now BHV-7000. There was no material value assigned to any other assets acquired in the acquisition. As such, during the second quarter of 2022, the Company recorded a charge to R&D expense in the accompanying condensed combined statements of operations and comprehensive loss of \$93,747.

In the second quarter of 2022, the Company recorded a liability for a \$25,000 regulatory milestone payment which became due to Knopp in June 2022. The milestone payment was recorded as R&D expense in the accompanying condensed combined statements of operations and comprehensive loss during the six months ended June 30, 2022.

Excluding the milestone payment noted above, the Company has not recorded any of the possible contingent consideration payments to Knopp as a liability in the accompanying condensed combined balance sheet as none of the future events which would trigger a milestone payment were considered probable of occurring at June 30, 2022.

5. Share-Based Compensation

The Parent has share-based compensation plans under which it may issue common shares or restricted common shares, or 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 Parent. The Parent also has an Employee Share Purchase Plan (the “ESPP”) which allows eligible employee who are participating in the plan to purchase shares of the Parent at a discount.

Share-based compensation has been allocated to the Company by using a combination of specific identification and a proportionate cost allocation method based on employee hours or directly identified operating expenses, depending on the employee’s function. The amounts presented are not necessarily indicative of future awards and do not necessarily reflect the costs that the Company would have incurred as an independent company for the periods presented.

Share-based compensation under the Parent’s share-based compensation plans 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. Share-based compensation expense attributed to the Company by classification included within in the condensed combined statements of operations and comprehensive loss was as follows:

	Six Months Ended June 30,	
	2022	2021
Research and development expenses	\$ 37,254	\$ 21,899
General and administrative expenses	23,676	15,379
	<u>\$ 60,930</u>	<u>\$ 37,278</u>

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6. License Agreements***Yale Agreement***

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 of the Parent and granted Yale the right to purchase up to 10% of the securities issued in specified future equity offerings by the Parent, in addition to the obligation to issue shares to prevent anti-dilution. The obligation to contingently issue equity to Yale was no longer outstanding as of December 31, 2018.

The Yale Agreement was amended and restated in May 2019. As amended, the Company agreed to pay Yale up to \$2,000 upon the achievement of specified regulatory milestones and annual royalty payments of a low single-digit percentage based on net sales of riluzole-based products from the licensed patents or from products based on troriluzole. Under the amended and restated agreement, the royalty rates are reduced as compared to the original agreement. In addition, under the amended and restated agreement, the Company may develop products based on riluzole or troriluzole. The amended and restated agreement retains a minimum annual royalty of up to \$1,000 per year, beginning after the first sale of product under the agreement. If the Company grants any sublicense rights under the Yale Agreement, it must pay Yale a low single-digit percentage of sublicense income that it receives.

For the six months ended June 30, 2022 and 2021, the Company did not record any material expense or make any milestone or royalty payments under the Yale Agreement.

In January 2021, the Company entered a worldwide, exclusive license agreement with Yale University for the development and commercialization of a novel Molecular Degradator of Extracellular Protein (“MoDE”) platform (the “Yale MoDE Agreement”). Under the license agreement, the Company 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 shares of the Parent 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. Under the Yale MoDE Agreement, the Company entered into a sponsored research agreement (the “Yale MoDE SRA”) which included funding of up to \$4,000 over the life of the agreement.

Excluding the upfront payments above, the Company recorded research and development expense related to the Yale MoDE Agreement of \$2,000 and \$150 for the six months ended June 30, 2022 and 2021, respectively. For the six months ended June 30, 2022 and 2021, the Company did not make any milestone or royalty payments under 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

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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 six months ended June 30, 2022 and 2021, the Company did not record any expense or make any milestone or royalty payments under the ALS Biopharma Agreement.

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 royalties in two tiers, with each tiered royalty in the range from 0-10% of net sales of products licensed under the agreement. 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 six months ended June 30, 2022 and 2021, the Company did not record any expense or make any milestone or royalty payments under the 2016 AstraZeneca Agreement.

2018 AstraZeneca Agreement

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 sales-based milestones. In addition, the Company will pay AstraZeneca royalties in three tiers, with each tiered royalty in the range from 0-10% of net sales of specified approved products, subject to specified reductions.

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In November 2021, the Company completed enrollment in a Phase 3 clinical trial of this product candidate, which is now referred to as verdiperstat, for the treatment of Amyotrophic Lateral Sclerosis (“ALS”). ALS is a progressive, life-threatening, and rare neuromuscular disease for which there are currently limited treatment options and no cure. 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 six months ended June 30, 2022 and 2021, 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, the Company 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, the Company issued 100,000 of the Parent’s common shares to FCCDC valued at \$5,646.

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 of the Parent’s common shares, at a strike price of \$56.46 per share, subject to vesting upon achievement of certain milestones in development of TDP-43.

In connection with the FCCDC Agreement, the Company 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 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 did not record any material research and development expense or make any milestone payments related to the FCCDC Agreement in the combined statements of operations and comprehensive loss during the six months ended June 30, 2022 and 2021.

UConn

In October 2018, the Company announced it had signed an exclusive, worldwide option and license agreement (the “UConn Agreement”) with the University of Connecticut (“UConn”) for the development and commercialization rights to UC1MT, a therapeutic antibody targeting extracellular metallothionein. Under this agreement, the Company has the option to acquire an exclusive, worldwide license to UC1MT and its underlying patents to develop and commercialize throughout the world in all human indications. If the Company chooses to exercise the option, it would be obligated to pay UConn upon the achievement of specified regulatory and

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commercial milestones, and royalties of a low single-digit percentage of net sales of licensed products sold by the Company, its affiliates or its sublicensees.

For the six months ended June 30, 2022 and 2021, the Company did not record any research and development expense or make any milestone payments related to the UConn Agreement.

Artizan Agreement

In December 2020, BTL entered into an Option and License Agreement with Artizan Biosciences Inc (the “2020 Artizan Agreement”). Pursuant to the 2020 Artizan Agreement, BTL acquired an option (“Biohaven Option”) to obtain a royalty-based license from Artizan to manufacture, use and commercialize certain products in the United States for the treatment of diseases, including, for example, inflammatory bowel disease and other gastrointestinal inflammatory disorders, e.g., Crohn’s disease. 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. BTL and Artizan have also formed a joint steering committee to oversee, review and coordinate the product development activities with regard to all products for which BTL 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 of the Parent’s common 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.

In June 2021, BTL entered into a Development and License Agreement with Artizan Biosciences Inc (the “2021 Artizan Agreement”). Pursuant to the 2021 Artizan Agreement, BTL acquired an exclusive, worldwide license under Artizan’s IgA-SEQ patented technology and know-how to develop, manufacture and commercialize certain of Artizan’s compounds for use in Parkinson’s Disease. Under the agreement, BTL is responsible for funding the development of the compounds, obtaining regulatory approvals, manufacturing the compounds and commercializing the compounds. BTL is also responsible for the prosecution, maintenance and enforcement of Artizan’s patents. BTL will pay Artizan development milestones of \$20,000 for the first licensed compound to achieve U.S. marketing authorization and \$10,000 for each subsequent U.S. approval. In addition, BTL will pay Artizan commercialization milestones totaling up to \$150,000 and royalties in the low to mid single digits. The 2021 Artizan Agreement terminates on a country-by-country basis on the later of 10 years from the first commercial sale of licensed product in such country or the expiration of Artizan’s patents in such country and can also be terminated if certain events occur, e.g., material breach or insolvency.

In June 2022, the Company entered into an Amendment to the Series A-2 Preferred Stock Purchase Agreement with Artizan. Under the Amendment, the Company made a cash payment of \$4,000 in exchange for 22,975,301 shares of series A-2 preferred stock of Artizan out of a total of 45,950,601 shares of series A-2 preferred stock of Artizan for a total raise of \$8,000 (the “A2 Extension Raise”). Along with the Amendment, the Company and Artizan executed a non-binding indication of interest (“Artizan Side Letter”) which describes terms under which BTL and Artizan would amend the 2020 Artizan Agreement to eliminate certain milestone payments required by us in exchange for limiting our option to the selection of the first (ARZC-001) licensed product. The Artizan Side Letter requires Artizan to commit at least 80% of the funds raised in the A-2 Extension Raise to a certain program and to raise \$35,000 of additional capital within a certain time.

For the six months ended June 30, 2022 and 2021, excluding the upfront payments above, 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

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(including the technology licensed under the 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 of the Parent 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 six months ended June 30, 2022 and 2021, excluding the upfront payments above, 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 combined statement of operations and comprehensive loss. 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 six months ended June 30, 2022 and 2021, the Company did not record any material research and development expense related to the Reliant Agreement.

KU Leuven Agreement

In January 2022, the Company and Katholieke Universiteit Leuven ("KU Leuven") entered into an Exclusive License and Research Collaboration Agreement (the "KU Leuven Agreement") to develop and commercialize 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, the Company 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 is being evaluated in preclinical pain models and will be the first to advance towards Phase 1 studies. The Company 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 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.

Excluding the upfront payments discussed above, the Company recorded \$397 in research and development expense related to the KU Leuven Agreement during the six months ended June 30, 2022. The Company did not record any research and development expense relating to the KU Leuven Agreement during the six months ended June 30, 2021.

Taldefgrobep Alfa License Agreement

In February 2022, following the transfer of intellectual property the Company announced that it 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

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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.

For the six months ended June 30, 2022 and 2021, the Company did not record any material expense or make any milestone or royalty payments under the Taldefgrobep Alfa License Agreement.

7. Income Taxes

The following table provides a comparative summary of the Company's income tax provision and effective income tax rate for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,	
	2022	2021
Income tax provision	\$ 13,365	\$ 41
Effective income tax rate	4.66 %	0.04 %

The Company recorded an income tax provision of \$13,365 for the six months ended June 30, 2022 compared to a provision for income taxes of \$41 for the six months ended June 30, 2021. The increase in income tax expense for the six months ended June 30, 2022 as compared to 2021 was primarily attributable to the mandatory capitalization of R&D expenses effective January 1, 2022 under the Tax Cuts and Jobs Act, offset by an increased benefit to the Company's foreign derived intangible income deduction.

8. Commitments and Contingencies

The following agreements are either current Company agreements, or those the Parent expects to assign to the Company upon separation, accordingly, all considerations paid by the Parent in association with these agreements are recorded in the combined financial statements of the Company.

Lease Agreements

The Parent's leases primarily consist of office space that will be attributed to the Company in connection with the separation. The Company determines if an arrangement is a lease at inception. The lease term includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Real estate leases for facilities have an average remaining lease term of 4.66 years as of June 30, 2022, for which none include the optional extension. The Company has made an accounting policy election not to record short-term leases (leases with an initial term of 12 months or less) on the balance sheet. The Company currently has two short-term leases with immaterial lease expense.

Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Operating lease assets and liabilities are recognized based on the present value of lease payments over the lease term. Since most of the Company's leases do not have a readily determinable implicit discount rate, the Company uses the Parent's incremental borrowing rate to calculate the present value of lease payments. The Company does not separate lease components (e.g., payments for rent, real estate taxes and insurance costs) from non-lease components (e.g., common-area maintenance costs) in the event that the agreement contains both. The Company includes both the lease and non-lease components for purposes of calculating the right-of-use asset and related lease liability (if the non-lease components are fixed). The allocated operating lease cost was \$220 and \$153 for the six months ended June 30, 2022 and 2021, respectively.

Certain of the Company's lease agreements contain variable lease payments that are adjusted for actual operating expense true-ups compared with estimated amounts; however, these amounts are immaterial. The Company had no sublease income and there are no sale-leaseback transactions. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

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Supplemental cash flow information related to leases is as follows:

	June 30,	
	2022	2021
Right-of-use assets obtained in exchange for new operating lease liabilities	\$ 2,633	\$ —

No right-of-use assets were obtained in exchange for new operating lease liabilities during the six months ended June 30, 2021. Operating cash flows paid for operating leases were immaterial for the six months ended June 30, 2022 and 2021.

Supplemental balance sheet information related to operating leases is as follows:

	June 30,		December 31,	
	2022		2021	
Assets				
Other non-current assets	\$	7,262	\$	5,222
Liabilities				
Other current liabilities		1,105		439
Other non-current liabilities		4,352		2,797
	\$	5,457	\$	3,236
Weighted-average remaining lease term (years)		4.66		5.75
Weighted-average discount rate		9.47 %		9.07 %

Maturities of operating lease liabilities are as follows:

2022 (remaining sixth months)	\$ 756
2023	1,526
2024	1,476
2025	1,132
2026	1,147
Thereafter	669
Total lease payments	6,706
Less: imputed interest	(1,249)
Total lease liabilities	\$ 5,457

Research Commitments

The Parent has entered into agreements with several CROs to provide services in connection with the Company's preclinical studies and clinical trials. Research Commitments entered into by the Parent and related to the Company are expected to transfer to the Company upon separation. As of June 30, 2022, the Company had remaining maximum research commitments of approximately \$21,400, which are variable based on number of trial participants, and contingent upon the achievement of certain milestones of the clinical trials covered under the agreements. If all related milestones are achieved, the Company expects these amounts to be paid over the next five years.

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,

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losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company's amended and restated memorandum and articles of association also provide for indemnification of directors and officers in specific circumstances. To date, the Company has not incurred any material costs as a result of such indemnification provisions. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its combined financial statements as of June 30, 2022 or December 31, 2021.

License Agreements

The Parent entered into license agreements with various parties that are directly attributed to the Company under which it is obligated to make contingent and non-contingent payments (see Note 6). License agreements entered by the Parent and related to the Company are expected to transfer to the Company upon separation.

Sixth Street Financing Agreement

In August 2020, the Parent and Biohaven Pharmaceuticals, Inc., (together with the Parent 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 Borrowers (the "Sixth Street Financing Agreement"). The Sixth Street Financing Agreement, as amended, provides for term loans in an aggregate principal amount up to \$750,000, plus any capitalized interest paid in kind (the "Sixth Street Financing Agreement") and is accounted for as third-party, long-term debt by the Parent.

The Company is a co-obligor, jointly and severally with the Parent on its third-party long-term debt obligation under the Sixth Street Financing Agreement. The Parent's third-party debt and related interest expense are not reflected in the combined financial statements because the Company has not agreed to pay a specified amount of the borrowings on the basis of its arrangement with the Parent, nor is the Company expected to pay any portion of the Parent's third-party debt, and the borrowings are not specifically identifiable to SpinCo. Pursuant to the terms of the Merger Agreement, at closing of the Merger, Pfizer will pay off or cause to be paid off the applicable payoff amount on behalf of the Parent.

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 June 30, 2022, there were no matters which would have a material impact on the Company's financial results.

9. Related Party Transactions

The Company has not historically operated as a standalone business and the combined financial statements are derived from the consolidated financial statements and accounting records of the Parent. The following disclosure summarizes activity between the Company and the Parent, including the affiliates of the Parent that are not part of the planned spin-off.

Cost Allocations

The combined financial statements reflect allocations of certain expenses from the financial statements of the Parent, including research and development expenses and general and administrative expenses. These allocations include, but are not limited to, executive management, employee compensation and benefits, facilities and operations, information technology, business development, financial services (such as accounting, audit, and tax),

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legal, insurance, and share-based compensation. Some of these services are expected to continue to be provided to the Parent on a temporary basis following the Distribution under a transition services agreement. See Note 2 for discussion of these costs and the methodology used to allocate them.

These allocations to SpinCo are reflected in the combined statement of operations and comprehensive loss as follows:

	Six Months Ended June 30,	
	2022	2021
Research and development	\$ 61,724	\$ 34,674
General and administrative	33,377	18,778
Total	\$ 95,101	\$ 53,452

Management believes these cost allocations are a reasonable reflection of services provided to, of the benefit derived by, the Company during the periods presented. The allocations may not, however, be indicative of the actual expenses that would have been incurred had the Company operated as a standalone public company. Actual costs that may have been incurred if the Company had been a standalone public company would depend on a number of factors, including the chosen organizational structure, whether functions were outsourced or performed by Company employees, and strategic decisions made in areas such as research and development, information technology and infrastructure.

Share-Based Compensation

As discussed in Note 5, Share-based compensation, SpinCo employees participate in the Parent's share-based compensation plans, the costs of which have been allocated to SpinCo and recorded in research and development and general and administrative expenses in the condensed combined statements of operations and comprehensive loss.

Net Transfers From Parent

Net transfers from Parent represent the net effect of transactions between SpinCo and the Parent. The components of net transfers from Parent are as follows:

	Six Months Ended June 30,	
	2022	2021
General financing activities	\$ 75,703	\$ 59,222
Corporate cost allocations, excluding share-based compensation	34,171	16,174
Net transfers from Parent as reflected in the Combined Statement of Cash Flows	109,874	75,396
Share-based compensation	60,930	37,278
Issuance of Parent common shares to repurchase non-controlling interest in a subsidiary	60,000	—
Issuance of Parent common shares as payment for IPR&D asset acquisition	58,747	—
Issuance of Parent common shares as payment for business acquisition	—	10,673
Issuance of Parent common shares as payment for Artizan investment	—	6,000
Issuance of Parent common shares as payment for license and consulting agreements	1,779	4,243
Other non-cash adjustments	(704)	(694)
Net transfers from Parent as reflected in the Combined Statement of Changes in Equity	\$ 290,626	\$ 132,896

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

Related Party Agreements

License Agreement with Yale

On September 30, 2013, the Company entered into the Yale Agreement with Yale (see Note 6). 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 6 for detail). Under the license agreement, the Company 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 of the Parent valued at approximately \$1,000.

For the six months ended June 30, 2022 and 2021, the Company recorded \$2,000 and \$150 in research and development expense related to the Yale MoDE Agreement and Yale Agreement (the "Yale Agreements"). As of June 30, 2022, the Company owed \$2,000 to Yale, which is related to the Yale MoDE SRA.

20,000,000 Shares

biohaven

Common Shares

PROSPECTUS

J.P. Morgan

PART II

Information Not Required in Prospectus

Item 13. Other Expenses of Issuance and Distribution

The following is an estimate of the expenses (all of which are to be paid by us) that we may incur in connection with the securities being registered hereby. All amounts are estimates except for the Securities and Exchange Commission (the "SEC") registration fee.

Item	Amount to be paid
SEC registration fee	\$31,429
FINRA filing fee	43,280
NYSE supplemental listing fee	110,400
Legal fees and expenses	500,000
Accounting fees and expenses	75,000
Transfer Agent	5,000
Miscellaneous expenses	234,891
Total	<u>\$1,000,000</u>

Item 14. Indemnification of Directors and Officers

British Virgin Islands law does not limit the extent to which a company's memorandum and articles of association may provide for indemnification of officers and directors, except to the extent any such provision may be held by the BVI High Court to be contrary to public policy (e.g., for purporting to provide indemnification against the consequences of committing a crime). An indemnity will be void and of no effect and will not apply to a person unless the person acted honestly and in good faith and in what he believed to be in the best interests of the company and, in the case of criminal proceedings, the person had no reasonable cause to believe that his conduct was unlawful. Our Amended Memorandum and Articles of Association permit indemnification of officers and directors for losses, damages, costs and expenses incurred in their capacities as such unless such losses or damages arise from dishonesty or fraud of such directors or officers. This standard of conduct is generally the same as permitted under the Delaware General Corporation Law for a Delaware corporation. In addition, we have entered into indemnification agreements with our directors and executive officers that provide such persons with additional indemnification beyond that provided in our Amended Memorandum and Articles of Association.

Further, we have entered into indemnification agreements with each of our directors and executive officers that may be broader than the specific indemnification provisions contained under British Virgin Islands law. These indemnification agreements require us, among other things, to indemnify our directors and executive officers against liabilities that may arise by reason of their status or service. These indemnification agreements also require us to advance all expenses incurred by the directors and executive officers in investigating or defending any such action, suit, or proceeding. We believe that these agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

The limitation of liability and indemnification provisions that are included in our Amended Memorandum and Articles of Association and in indemnification agreements that we entered into with our directors and executive officers may discourage shareholders from bringing a lawsuit against our directors and executive officers for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against our directors and executive officers, even though an action, if successful, might benefit us and other shareholders. Further, a shareholder's investment may be harmed to the extent that we pay the costs of settlement and damage awards against directors and executive officers as required by these indemnification provisions. At present, we are not aware of any pending litigation or proceeding involving any person who is or was one of our directors, officers, employees or other agents or is or was serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

We have obtained insurance policies under which, subject to the limitations of the policies, coverage is provided to our directors and executive officers against loss arising from claims made by reason of breach of fiduciary duty or other wrongful acts as a director or executive officer, including claims relating to public securities matters, and to us with respect to payments that may be made by us to these directors and executive officers pursuant to our indemnification obligations or otherwise as a matter of law.

Item 15. Recent Sales of Unregistered Securities

In the three years preceding the filing of this Registration Statement, we have not issued securities that were not registered under the Securities Act.

Item 16. Exhibits and Financial Statement Schedules

Exhibit No.	Description
1.1	<u>Form of Underwriting Agreement.*</u>
2.1	<u>Separation and Distribution Agreement, dated as of May 9, 2022, by and among Pfizer Inc., Bulldog (BVI) Ltd. and Biohaven Pharmaceutical Holding Company Ltd. (incorporated by reference to Exhibit 2.1 to Company's Registration Statement on Form 10 filed on September 20, 2022).</u>
2.2	<u>Agreement and Plan of Merger, dated as of May 9, 2022, by and among Pfizer Inc., Bulldog (BVI) Ltd. and Biohaven Pharmaceutical Holding Company Ltd. (incorporated by reference to Exhibit 2.2 to Company's Registration Statement on Form 10 filed on September 20, 2022).</u>
2.3	<u>Membership Interest Purchase Agreement, dated as of February 24, 2022, by and among Biohaven Therapeutics LTD., Knopp Biosciences LLC, Channel Biosciences, LLC and Biohaven Pharmaceutical Holding Company Ltd., solely for the purpose of Section 9.14 (incorporated by reference to Exhibit 2.3 to Company's Registration Statement on Form 10 filed on September 20, 2022).</u>
3.1	<u>Amended Memorandum and Articles of Association (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on October 3, 2022).</u>
5.1	<u>Opinion of Maples and Calder.*</u>
10.1	<u>Amended and Restated Agreement, by and between the Registrant and Yale University, dated as of May 6, 2019 (incorporated by reference to Exhibit 10.1 to Company's Registration Statement on Form 10 filed on September 20, 2022).</u>
10.2	<u>License Agreement, by and between the Registrant and AstraZeneca AB, dated as of September 4, 2018 (incorporated by reference to Exhibit 10.2 to Company's Registration Statement on Form 10 filed on September 20, 2022).</u>
10.3	<u>License Agreement between Biohaven Therapeutics LTD. and Bristol-Myers Squibb Company, dated as of December 23, 2021 (incorporated by reference to Exhibit 10.3 to Company's Registration Statement on Form 10 filed on September 20, 2022).</u>
10.4	<u>ALS Biopharma Agreement, by and among the registrant, ALS Biopharma, LLC and Fox Chase Chemical Diversity Center Inc., dated as of August 10, 2015 (incorporated by reference to Exhibit 10.4 to Company's Registration Statement on Form 10 filed on September 20, 2022).</u>
10.5	<u>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 10.5 to Company's Registration Statement on Form 10 filed on September 20, 2022).</u>
10.6	<u>Employment Agreement dated May 9, 2017 by and between Biohaven Pharmaceuticals, Inc. and Vlad Coric (incorporated by reference to Exhibit 10.6 to Company's Registration Statement on Form 10 filed on September 20, 2022).#</u>
10.7	<u>Employment Agreement, dated December 8, 2021, between Biohaven Pharmaceuticals, Inc. and Matthew Buten (incorporated by reference to Exhibit 10.7 to Company's Registration Statement on Form 10 filed on September 20, 2022).#</u>
10.8	<u>Offer Letter dated February 21, 2017 by and between Biohaven Pharmaceuticals, Inc. and Elyse Stock (incorporated by reference to Exhibit 10.8 to Company's Registration Statement on Form 10 filed on September 20, 2022).#</u>

10.9	Employment Agreement dated February 1, 2014 by and between Biohaven Pharmaceuticals, Inc. and Kimberly A. Gentile (incorporated by reference to Exhibit 10.9 to Company's Registration Statement on Form 10 filed on September 20, 2022).#
10.10	Employment Agreement, dated March 29, 2016, between Biohaven Pharmaceutical Holding Company Ltd. and John Tilton (incorporated by reference to Exhibit 10.10 to Company's Registration Statement on Form 10 filed on September 20, 2022).#
10.11	2022 Equity Incentive Plan (incorporated by reference to Exhibit 4.2 to Company's Registration Statement on Form S-8 filed on October 11, 2022).#
10.12	Form of Restricted Share Unit Grant Notice and Restricted Share Unit Award Agreement under 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.12 to Company's Registration Statement on Form 10 filed on September 20, 2022).#
10.13	Form of Share Option Grant Notice and Share Option Agreement under 2022 Equity Incentive Plan (incorporated by reference to Exhibit 10.13 to Company's Registration Statement on Form 10 filed on September 20, 2022).#
10.14	Legacy Equity Award Settlement Plan (incorporated by reference to Exhibit 4.4 to Company's Registration Statement on Form S-8 filed on October 11, 2022).#
10.15	2022 Employee Share Purchase Plan (incorporated by reference to Exhibit 4.3 to Company's Registration Statement on Form S-8 filed on October 11, 2022).#
10.16	Form of Employment Agreement by and between Biohaven Ltd. and Vladimir Coric (incorporated by reference to Exhibit 10.16 to Company's Registration Statement on Form 10 filed on September 20, 2022).#
10.17	Form of Employment Agreement by and between Biohaven Ltd. and Matthew Buten (incorporated by reference to Exhibit 10.17 to Company's Registration Statement on Form 10 filed on September 20, 2022).#
21.1	List of Subsidiaries. (incorporated by reference to Exhibit 21.1 to the Company's Registration Statement on Form 10 filed on September 20, 2022).
23.1	Consent of Ernst & Young LLP.
23.2	Consent of Maples and Calder (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page of this Registration Statement).*
107	Calculation of Filing Fee Table.

Indicates management contract or compensatory plan.

* Previously filed

Item 17. Undertakings

- (a) The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.
- (b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.
- (c) The undersigned Registrant hereby undertakes that:
- (1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and

contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

- (2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Amendment No. 1 to the Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of New Haven, Connecticut, on the 20th day of October, 2022.

BIOHAVEN LTD.

By: /s/ Vlad Coric
Name: Vlad Coric
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No.1 to the Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Vlad Coric</u> Vlad Coric	Chief Executive Officer and Director (Principal Executive Officer)	October 20, 2022
* <u>Matthew Buten</u>	Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	October 20, 2022
* <u>Gregory Bailey</u>	Director	October 20, 2022
* <u>Irina Antonijevic</u>	Director	October 20, 2022
* <u>John W. Childs</u>	Director	October 20, 2022
* <u>Julia Gregory</u>	Director	October 20, 2022
* <u>Kishan Mehta</u>	Director	October 20, 2022
* <u>Michael Heffernan</u>	Director	October 20, 2022
* <u>Robert Hugin</u>	Director	October 20, 2022

*By: /s/ Vlad Coric
Vlad Coric
Attorney-in-Fact

AUTHORIZED REPRESENTATIVE

Pursuant to the United States Securities Act of 1933, as amended, the Authorized Representative has signed this Amendment No.1 to the Registration Statement solely in its capacity as the duly authorized representative of Biohaven Ltd. in the United States, in the New Haven, Connecticut on October 20, 2022.

BIOHAVEN LTD.

By: /s/ Vlad Coric
Name: Vlad Coric
Title: Authorized Representative in the United States
Biohaven Pharmaceuticals, Inc.

Calculation of Filing Fee Tables

FORM S-1
(Form Type)

Biohaven Ltd.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price ⁽¹⁾⁽²⁾	Fee Rate	Amount of Registration Fee ⁽³⁾
Newly Registered Securities								
Fees to be Paid	Equity	Common Shares, no par value	457(o)	—	—	\$285,200,000	0.0001102	\$31,429.04
Fees Previously Paid	—	—	—	—	—	—	—	\$26,233.11
Carry Forward Securities								
Carry Forward Securities	—	—	—	—	—	—	—	—
Total Offering Amounts						\$285,200,000		\$31,429.04
Total Fees Previously Paid								\$26,233.11
Total Fee Offsets								—
Net Fee Due								\$5,195.93

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(2) Includes the offering price of shares that the underwriters may purchase pursuant to an option to purchase additional shares.
(3) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

Consent of Independent Registered Public Accounting Firm

We consent to the reference to our firm under the caption "Experts" and to the use of our report dated July 1, 2022, in Amendment No. 1 to the Registration Statement (Form S-1 No. 333-267928) and related Prospectus of Biohaven Ltd. for the registration of 20,000,000 common shares.

/s/ Ernst & Young LLP

Hartford, Connecticut

October 20, 2022