
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2017

OR

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

Commission File Number: 001-38080

Biohaven Pharmaceutical Holding Company Ltd.

(Exact Name of Registrant as Specified in its Charter)

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

Not applicable
(I.R.S. Employer
Identification No.)

c/o Biohaven Pharmaceuticals, Inc.
234 Church Street, New Haven, Connecticut
(Address of principal executive offices)

06510
(Zip Code)

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

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a small reporting company)

Small reporting company

Emerging growth company

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

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

As of June 15, 2017, the registrant had 35,748,083 common shares, without par value per share, outstanding.



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PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

| | <u>March 31,</u> <u>2017</u> | <u>December 31,</u> <u>2016</u> |
|--|---------------------------------|------------------------------------|
| Assets | | |
| Current assets: | | |
| Cash | \$ 52,286 | \$ 23,565 |
| Restricted cash | — | 67 |
| Prepaid expenses and other current assets | 883 | 403 |
| Total current assets | <u>53,169</u> | <u>24,035</u> |
| Property and equipment, net | 43 | 26 |
| Deferred offering costs | 2,399 | 134 |
| Equity method investment (Note 5) | 4,511 | 2,753 |
| Restricted cash | 60 | 60 |
| Deferred tax assets | 9 | 9 |
| Total assets | <u>\$ 60,191</u> | <u>\$ 27,017</u> |
| Liabilities, Convertible Preferred Shares and Shareholders' Equity (Deficit) | | |
| Current liabilities: | | |
| Notes payable, net of discount | \$ 4,489 | \$ 4,216 |
| Accounts payable | 4,022 | 746 |
| Accrued expenses | 6,931 | 2,980 |
| Total current liabilities | <u>15,442</u> | <u>7,942</u> |
| Warrant liability | 1,234 | 780 |
| Derivative liability | 223 | 512 |
| Contingent equity liability | 22,313 | 18,938 |
| Notes payable to related parties | 602 | 595 |
| Other long-term liabilities | 19 | 13 |
| Total liabilities | <u>39,833</u> | <u>28,780</u> |
| Commitments and contingencies (Note 14) | | |
| Series A convertible preferred shares, no par value; 11,242,172 shares authorized as of March 31, 2017 and December 31, 2016; 9,358,560 and 4,948,369 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively; aggregate liquidation preference of \$86,951 and \$45,976 as of March 31, 2017 and December 31, 2016, respectively | 73,900 | 43,270 |
| Shareholders' equity (deficit): | | |
| Common shares, no par value; 38,000,000 shares authorized as of March 31, 2017 and December 31, 2016; 13,121,000 and 13,088,500 shares issued and outstanding as of March 31, 2017 and December 31, 2016, respectively | 20,296 | 19,944 |
| Additional paid-in capital | 20,371 | 10,479 |
| Accumulated deficit | (94,209) | (75,456) |
| Total shareholders' equity (deficit) | <u>(53,542)</u> | <u>(45,033)</u> |
| Total liabilities, convertible preferred shares and shareholders' equity (deficit) | <u>\$ 60,191</u> | <u>\$ 27,017</u> |

The accompanying notes are an integral part of these consolidated financial statements.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

(Unaudited)

| | <u>Three Months Ended March 31,</u> | |
|---|-------------------------------------|-------------------|
| | <u>2017</u> | <u>2016</u> |
| Operating expenses: | | |
| Research and development | \$ 10,740 | \$ 2,370 |
| General and administrative | 3,757 | 613 |
| Total operating expenses | <u>14,497</u> | <u>2,983</u> |
| Loss from operations | <u>(14,497)</u> | <u>(2,983)</u> |
| Other income (expense): | | |
| Interest expense | (305) | — |
| Change in fair value of warrant liability | (454) | — |
| Change in fair value of derivative liability | 289 | (3) |
| Change in fair value of contingent equity liability | (3,375) | — |
| Loss from equity method investment | (218) | — |
| Total other income (expense), net | <u>(4,063)</u> | <u>(3)</u> |
| Loss before provision for income taxes | <u>(18,560)</u> | <u>(2,986)</u> |
| Provision for income taxes | 193 | — |
| Net loss and comprehensive loss | <u>(18,753)</u> | <u>(2,986)</u> |
| Net loss attributable to non-controlling interests | — | 35 |
| Accretion of beneficial conversion feature on Series A preferred shares | (4,000) | — |
| Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd. | <u>\$ (22,753)</u> | <u>\$ (2,951)</u> |
| Net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.— | | |
| basic and diluted | <u>\$ (1.74)</u> | <u>\$ (0.25)</u> |
| Weighted average common shares outstanding—basic and diluted | <u>13,088,861</u> | <u>11,776,429</u> |

The accompanying notes are an integral part of these consolidated financial statements.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

CONSOLIDATED STATEMENT OF CONVERTIBLE PREFERRED SHARES AND SHAREHOLDERS' EQUITY (DEFICIT)

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

(Unaudited)

| | Series A Convertible Preferred Shares | | Common Shares | | Additional Paid-in Capital | Accumulated Deficit | Total Shareholders' Equity (Deficit) |
|---|---------------------------------------|------------------|-------------------|------------------|----------------------------|---------------------|--------------------------------------|
| | Shares | Amount | Shares | Amount | | | |
| Balances as of December 31, 2016 | 4,948,369 | \$ 43,270 | 13,088,500 | \$ 19,944 | \$ 10,479 | \$ (75,456) | \$ (45,033) |
| Issuance of Series A preferred shares, net offering costs of \$1,364 | 4,305,182 | 38,636 | — | — | — | — | — |
| Issuance of Series A preferred shares as payment of offering costs | 105,009 | — | — | — | — | — | — |
| Beneficial conversion feature on Series A preferred shares | — | (12,006) | — | — | 12,006 | — | 12,006 |
| Accretion of beneficial conversion feature on Series A preferred shares | — | 4,000 | — | — | (4,000) | — | (4,000) |
| Issuance of common shares as payment for equity investment (Note 5) | — | — | 32,500 | 352 | — | — | 352 |
| Share-based compensation expense | — | — | — | — | 1,886 | — | 1,886 |
| Net loss | — | — | — | — | — | (18,753) | (18,753) |
| Balances as of March 31, 2017 | <u>9,358,560</u> | <u>\$ 73,900</u> | <u>13,121,000</u> | <u>\$ 20,296</u> | <u>\$ 20,371</u> | <u>\$ (94,209)</u> | <u>\$ (53,542)</u> |

The accompanying notes are an integral part of these consolidated financial statements.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.
CONSOLIDATED STATEMENTS OF CASH FLOWS

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

(Unaudited)

| | Three Months Ended March 31, | |
|--|-------------------------------------|-----------------|
| | 2017 | 2016 |
| Cash flows from operating activities: | | |
| Net loss | \$ (18,753) | \$ (2,986) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Share-based compensation expense | 1,886 | 687 |
| Depreciation expense | 4 | 1 |
| Non-cash interest expense | 280 | — |
| Change in fair value of warrant liability | 454 | — |
| Change in fair value of derivative liability | (289) | 3 |
| Change in fair value of contingent equity liability | 3,375 | — |
| Loss from equity method investment | 218 | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | (480) | 125 |
| Accounts payable | 2,656 | 63 |
| Accrued expenses | 2,991 | 562 |
| Other long-term liabilities | 6 | — |
| Net cash used in operating activities | <u>(7,652)</u> | <u>(1,545)</u> |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (21) | — |
| Purchase of equity method investment | (1,624) | — |
| Decrease in restricted cash | 67 | — |
| Net cash used in investing activities | <u>(1,578)</u> | <u>—</u> |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common shares | — | 3,003 |
| Proceeds from issuance of Series A preferred shares | 40,000 | — |
| Payments of offering costs | (2,049) | (23) |
| Net cash provided by financing activities | <u>37,951</u> | <u>2,980</u> |
| Net increase in cash | <u>28,721</u> | <u>1,435</u> |
| Cash at beginning of period | 23,565 | 1,460 |
| Cash at end of period | <u>\$ 52,286</u> | <u>\$ 2,895</u> |
| Supplemental disclosure of cash flow information: | | |
| Cash paid for interest | \$ 25 | \$ — |
| Supplemental disclosure of non-cash investing and financing activities: | | |
| Deferred offering costs included in accounts payable and accrued expenses | \$ 1,515 | \$ — |
| Deferred Series A offering costs included in accrued expenses | \$ 65 | \$ — |
| Beneficial conversion feature on Series A preferred shares | \$ 12,006 | \$ — |
| Accretion of beneficial conversion feature on Series A preferred shares | \$ 4,000 | \$ — |
| Issuance of Series A preferred shares as payment of offering costs | \$ 1,242 | \$ — |
| Issuance of common shares as payment for equity investment | \$ 352 | \$ — |

The accompanying notes are an integral part of these consolidated financial statements.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

1. Nature of the Business and Basis of Presentation

Biohaven Pharmaceutical Holding Company Ltd. (the “Company”) was incorporated in Tortola, British Virgin Islands in September 2013. The Company is a clinical-stage biopharmaceutical company with a portfolio of innovative, late-stage product candidates targeting neurologic diseases, including rare disorders. The Company’s product candidates are small molecules based on two distinct mechanistic platforms—calcitonin gene-related peptide (“CGRP”) receptor antagonists and glutamate modulators—which the Company believes have the potential to significantly alter existing treatment approaches across a diverse set of neurological indications with high unmet need in both large markets and orphan indications. The most advanced product candidate from the Company’s CGRP receptor antagonist platform is rimegepant, which the Company is developing for the acute treatment of migraine and for which it intends to initiate two Phase 3 clinical trials in the second half of 2017. The most advanced product candidate from the Company’s glutamate modulation platform is trigriluzole, which the Company is developing for the treatment of ataxias with an initial focus on spinocerebellar ataxia (“SCA”). The Company has received both orphan drug designation and fast track designation from the U.S. Food and Drug Administration (“FDA”) for trigriluzole in SCA, and the Company began a Phase 2/3 clinical trial in SCA in December 2016. The Company’s second most advanced product candidate from its glutamate modulation platform is BHV-0223, which the Company is developing for the treatment of amyotrophic lateral sclerosis (“ALS”), a neurodegenerative disease that affects nerve cells in the brain and spinal cord. The Company has received orphan drug designation from the FDA for BHV-0223 in ALS.

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 require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting 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.

The Company has historically outsourced all of the research and clinical development for its programs under a master services agreement (the “MSA”) with Biohaven Pharmaceuticals, Inc. (“BPI”). BPI was incorporated in the state of Delaware in July 2013. The three founders of BPI, each of whom beneficially owned one-third of the equity of BPI prior to the Company’s acquisition of BPI on December 31, 2016 (see Note 15), are shareholders of the Company and also serve as the Company’s Chairman of the board of directors, Chief Executive Officer, and Chief Medical Officer, respectively (see Note 15). BPI is a contract research organization (“CRO”) whose only customer is the Company. Since its incorporation, substantially all of the operations of BPI have been performed in service to the Company under the terms of the MSA, and substantially all of the funding for the operations of BPI was provided by the Company. The Company has determined that (i) it has the authority to direct the activities of BPI that most significantly impact the economics of the entity and (ii) the equity at risk in BPI is insufficient to finance its operations. As a result, the Company is deemed to have had a variable interest in BPI, and BPI is deemed to be a variable interest entity (“VIE”) of which the Company is the primary beneficiary. Accordingly, since the date of the Company’s incorporation in September 2013, the Company has consolidated the results of BPI. Upon original consolidation, the Company applied purchase accounting by recording the fair values of BPI’s assets acquired and liabilities assumed, which were determined to be zero because BPI had not yet commenced any operations. For the three months ended March 2016, 100% of the equity in BPI was reflected as a net loss attributable to non-

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

controlling interest on the consolidated statement of operations and comprehensive loss. On December 31, 2016, the Company acquired 100% of the issued and outstanding shares of BPI (see Note 16), and as a result, for periods subsequent to the acquisition, the Company no longer reports any non-controlling interest related to BPI.

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and include the accounts of the Company and its subsidiaries after elimination of all significant intercompany accounts and transactions.

Stock Split

In October 2016, the Company effected a 500-for-one stock split of its issued and outstanding common shares. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split.

Initial Public Offering

On May 3, 2017, the Company’s registration statement on Form S-1 relating to its initial public offering of its common shares (the “IPO”) was declared effective by the Securities and Exchange Commission (“SEC”). The IPO closed on May 9, 2017 and the Company issued and sold 9,900,000 common shares at a public offering price of \$17.00 per share (see note 17) for net proceeds of \$152,889 after deducting underwriting discounts and commissions of \$11,781 and other offering expenses of approximately \$3,630. Upon the closing of the IPO, all convertible preferred shares then outstanding converted into an aggregate of 9,358,560 common shares. In addition, on May 9, 2017, the underwriters of the IPO fully exercised their option to purchase additional shares, and on May 11, 2017, the Company issued and sold 1,485,000 additional common shares for additional net proceeds of \$23,478 after deducting underwriting discounts and commissions of \$1,767. Thus, the aggregate net proceeds to the Company from the IPO, after deducting underwriting discounts and commissions and other offering costs, were \$176,367.

In connection with the completion of its IPO, the Company issued an additional aggregate of 1,883,523 common shares to BMS and AstraZeneca in satisfaction of obligations to contingently issue equity securities pursuant to the license agreements (see Note 12) for no additional consideration.

Also in connection with the completion of its IPO in May 2017, the Company amended its memorandum and articles of association to authorize the issuance of up to 200,000,000 no par value common shares and 10,000,000 no par value undesignated preferred shares.

Going Concern

In accordance with Accounting Standards Update (“ASU”) 2014-15, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40), management must evaluate whether there are conditions or 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 financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved before the date that the financial statements are issued.

Through March 31, 2017, the Company has funded its operations primarily with proceeds from sales of preferred and common shares and borrowings under a credit agreement. The Company has incurred recurring losses since its inception, including net losses of \$18,753 and \$2,986 during the three months ended March 31, 2017 and 2016, respectively. In addition, as of March 31, 2017, the Company had an accumulated deficit of \$94,209. The Company expects to continue to generate operating losses for the foreseeable future. As of June 16, 2017, the issuance date of these consolidated financial statements, the Company expects that its cash of \$52,286 as of March 31, 2017, together with the \$176,367 of net cash proceeds received from the Company’s IPO, will be

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

sufficient to fund its operating expenses, capital expenditure requirements and debt service payments for at least 15 months from the date of issuance of these consolidated financial statements, and as a result, there is not substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

To execute its business plans, the Company will need substantial 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.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of income and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the accrual for research and development expenses and the valuation of common shares, stock options, warrants, derivative instruments and contingent equity instruments. 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.

Unaudited Interim Consolidated Financial Information

The accompanying consolidated balance sheet as of March 31, 2017, the consolidated statements of operations and comprehensive loss and of cash flows for the three months ended March 31, 2017 and 2016, and the consolidated statement of convertible preferred shares and shareholders' equity (deficit) as of March 31, 2017 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated 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 March 31, 2017 and the results of its operations and its cash flows for the three months ended March 31, 2017 and 2016. The financial data and other information disclosed in these consolidated notes related to the three months ended March 31, 2017 and 2016 are unaudited. The results for the three months ended March 31, 2017 are not necessarily indicative of results to be expected for the year ending December 31, 2017, any other interim periods or any future year or period.

Restricted Cash

As of December 31, 2016, current restricted cash consisted of \$67 of cash received from investors as an advance payment for their participation in the second closing of the Company's sale of Series A preferred shares. The Company closed the second and final tranche of its Series A preferred financing in February 2017. As a result, there was no current restricted cash as of March 31, 2017. As of March 31, 2017 and December 31, 2016, the Company's non-current restricted cash consisted of a \$60 certificate of deposit held as a security deposit in connection with the Company's corporate credit card.

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such equity financings are consummated. After consummation of the equity financing, these costs are recorded in shareholders' equity (deficit) as a reduction of proceeds generated as a result of the offering. Should the planned equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. As of March 31, 2017 and December 31, 2016, the Company recorded deferred offering costs relating to its IPO of \$2,399 and \$134, respectively. The Company's IPO was completed in May 2017 and these costs were recorded as a reduction to shareholders' equity.

Equity Method Investments

Investments in non-public companies in which the Company owns less than a 50% equity interest and where it exercises significant influence over the operating and financial policies of the investee are accounted for using the equity method of accounting. The Company's proportionate share of the net income or loss of the equity method investment is included in other income (expense), net in the consolidated statement of operations and comprehensive loss and results in a corresponding adjustment to the carrying value of the investment on the consolidated balance sheet. Dividends received reduce the carrying value of the investment. The Company periodically reviews the carrying value of its investment to determine if there has been an other-than-temporary decline in carrying value. A variety of factors are considered when determining if a decline in carrying value is other than temporary, including, among other factors, the financial condition and business prospects of the investee as well as the Company's intent with regard to the investment.

Fair Value Measurements

Certain assets of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1— Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's warrant liability, derivative liability and contingent equity liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of other current assets, accounts payable, accrued expenses and notes payable under a credit agreement approximate their fair values due to the short-term nature of these assets and liabilities.

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, share-based compensation and benefits, facilities costs, depreciation, third-party license fees, and external costs of outside vendors engaged to conduct clinical development activities and clinical trials as well as to manufacture clinical trial materials. Non-

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

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.

Research Contract Costs and Accruals

The Company has entered into various research and development-related contracts with companies both inside and outside of the United States. These agreements are cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant 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.

Share-Based Compensation

The Company measures stock options granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards, over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. Generally, the Company issues stock options with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company has not issued any stock options with performance-based vesting conditions.

For share-based awards granted to consultants and non-employees, compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common shares and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies share-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. Prior to May 2017, the Company was a private company and, accordingly, lacks company-specific historical and implied volatility information for its shares. Therefore, it estimates its expected share price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common shares and does not expect to pay any cash dividends in the foreseeable future.

Warrant Liability

In connection with entering into a credit agreement (see Note 7), the Company agreed to issue warrants to purchase common shares to two of the Company's directors in connection with a guarantee of its obligations under the agreement (see Note 7). The Company classifies the warrants as a liability on its consolidated balance sheet because each warrant represents a freestanding financial instrument that is not indexed to the Company's own shares. The warrant liability was initially recorded at fair value upon entering into the credit agreement and is subsequently remeasured to fair

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value at each reporting date. Changes in the fair value of the warrant liability are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. Changes in the fair value of the warrant liability will continue to be recognized until the warrants are exercised, expire or qualify for equity classification.

Derivative Liability

The Company's license agreement with Yale University ("Yale") (see Note 12) provides for a change-of-control payment to Yale upon the occurrence of a change-of-control event, as defined in the agreement, including an IPO. The Company classifies the change-of-control payment obligation as a liability on its consolidated balance sheet because it represents a contingent obligation to pay a variable amount of cash that may be based, in part, on the value of the Company's own shares. The derivative liability was initially recorded at fair value upon entering into the license agreement and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the derivative liability are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss.

In April 2017, the agreement with Yale was amended such that if the change-of-control event is an IPO, the change-of-control payment shall be due to Yale on the first trading day when Yale is free to sell its equity interest in the Company and the change-of-control fee shall be reduced by the dollar value of Yale's equity interest in the Company on the first trading day when Yale is free to sell its equity interest in the Company. Yale's equity interest in the Company is subject to a lock-up agreement, which generally restricts Yale's shares from being traded until October 31, 2017 and accordingly, the amount due to Yale in connection with the change-of-control provision of the agreement, if any, will be determined upon expiration of the lock-up period. The Company will continue to remeasure the derivative liability to fair value at each reporting date and will recognize changes in the fair value of the derivative liability until the expiration of the lock-up agreement in October 2017 (see Note 17).

Contingent Equity Liability

The Company's license agreements with AstraZeneca and BMS (see Note 12) require the Company to issue shares of capital stock upon the occurrence of specified financing or change-of-control events or development milestones, as defined in the agreements. In each agreement, the class and number of shares to be issued upon a triggering event were not known upon entering into the license agreements; however, the dollar amount of the shares to be issued upon a triggering event is fixed. The Company classifies these contingent obligations to issue shares as a liability on its consolidated balance sheet because each represents an obligation to issue a variable number of shares for a fixed dollar amount. Each contingent equity liability was initially recorded at fair value upon entering into each respective agreement and is subsequently remeasured to fair value at each reporting date. Changes in the fair values of the contingent equity liabilities are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. Changes in the fair value of the contingent equity liabilities will continue to be recognized until the occurrence of a respective triggering event. In May 2017, upon closing of the IPO, the conditions for issuing shares to BMS and AstraZeneca under the terms of the respective license agreements were satisfied, and accordingly, the Company issued 1,345,374 and 538,149 common shares, respectively, to BMS and AstraZeneca. The contingent equity liabilities were remeasured to fair value in the aggregate amount of \$32,020 immediately prior to the completion of the IPO, and upon issuance of the common shares, the contingent equity liabilities were reclassified to shareholders' equity (see Note 17).

Net Loss per Share Attributable to Common Shareholders of Biohaven Pharmaceutical Holding Company Ltd.

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common shareholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. Net income (loss) per share attributable to common shareholders is calculated based on net income (loss) attributable to Biohaven Pharmaceutical Holding Company Ltd. and excludes net income (loss) attributable to non-controlling interests for relevant periods.

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Basic net income (loss) per share attributable to common shareholders is computed by dividing the net income (loss) attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) attributable to common shareholders is computed by adjusting net income (loss) attributable to common shareholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common shareholders is computed by dividing the diluted net income (loss) attributable to common shareholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding options, warrants to purchase common shares, convertible preferred shares and contingently issuable equity are considered potential dilutive common shares.

The Company's convertible preferred shares contractually entitle the holders of such shares to participate in dividends but contractually do not require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders is the same as basic net loss per share attributable to common shareholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Recently Issued Accounting Pronouncements

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805) — Clarifying the Definition of a Business* ("ASU 2017-01"). ASU 2017-01 finalizes previous proposals regarding shareholder concerns that the definition of a business is applied too broadly. The guidance assists entities with evaluating whether transactions should be accounted for as acquisitions of assets or of businesses. The amendments are effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company is currently evaluating the impact that the adoption of ASU 2017-01 will have on its consolidated financial statements.

In October 2016, the FASB issued ASU No. 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfer of Assets Other than Inventory* ("ASU 2016-16"), which requires the recognition of the income tax consequences of an intra-entity transfer of an asset, other than inventory, when the transfer occurs. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2016-16 will have on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2016-15 will have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. ASU 2016-02 (Accounting Standards Codification ("ASC") Topic 842) supersedes the previous leases standard, ASC 840, *Leases*. The standard is effective for public entities for annual periods beginning after December 15, 2018 and for interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09"), which supersedes existing revenue recognition guidance under GAAP. The standard's core

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principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The standard defines a five-step process to achieve this principle, and will require companies to use more judgment and make more estimates than under the current guidance. The Company expects that these judgments and estimates will include identifying performance obligations in the customer contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts. In August 2015, the FASB issued ASU 2015-14, *Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date*, which delays the effective date of ASU 2014-09 such that the standard is effective for public entities for annual periods beginning after December 15, 2017 and for interim periods within those fiscal years. Early adoption of the standard is permitted for annual periods beginning after December 15, 2016. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations* (“ASU 2016-08”), which further clarifies the implementation guidance on principal versus agent considerations in ASU 2014-09. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, clarifying the implementation guidance on identifying performance obligations and licensing. Specifically, the amendments in this update reduce the cost and complexity of identifying promised goods or services and improve the guidance for determining whether promises are separately identifiable. The amendments in this update also provide implementation guidance on determining whether an entity’s promise to grant a license provides a customer with either a right to use the entity’s intellectual property (which is satisfied at a point in time) or a right to access the entity’s intellectual property (which is satisfied over time). In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients* (“ASU 2016-12”), which clarifies the objective of the collectability criterion, presentation of taxes collected from customers, non-cash consideration, contract modifications at transition, completed contracts at transition and how guidance in ASU 2014-09 is retrospectively applied. ASU 2016-08, ASU 2016-10 and ASU 2016-12 have the same effective dates and transition requirements as ASU 2014-09. The Company is currently evaluating the impact that the adoption that these standards will have on its consolidated financial statements, if and when it generates revenue.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company’s financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

| | Fair Value Measurements as of March 31, 2017 Using: | | | |
|-----------------------------|--|-------------|------------------|------------------|
| | Level 1 | Level 2 | Level 3 | Total |
| Liabilities: | | | | |
| Warrant liability | \$ — | \$ — | \$ 1,234 | \$ 1,234 |
| Derivative liability | — | — | 223 | 223 |
| Contingent equity liability | — | — | 22,313 | 22,313 |
| | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 23,770</u> | <u>\$ 23,770</u> |

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| | Fair Value Measurements as of December 31, 2016 Using: | | | |
|-----------------------------|---|-------------|------------------|------------------|
| | Level 1 | Level 2 | Level 3 | Total |
| Liabilities: | | | | |
| Warrant liability | \$ — | \$ — | \$ 780 | \$ 780 |
| Derivative liability | — | — | 512 | 512 |
| Contingent equity liability | — | — | 18,938 | 18,938 |
| | <u>\$ —</u> | <u>\$ —</u> | <u>\$ 20,230</u> | <u>\$ 20,230</u> |

During the periods ended March 31, 2017 and December 31, 2016 there were no transfers between Level 1, Level 2 and Level 3.

Valuation of Warrant Liability

The warrant liability in the table above is composed of the fair value of warrants to purchase common shares that the Company agreed to issue to two of its directors in connection with a guarantee of its obligations under a credit agreement (see Note 7). The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company utilized a Monte Carlo simulation, which is a statistical method used to generate a defined number of share price paths to develop a reasonable estimate of the range of the future expected share prices, to value the warrant liability. The Monte Carlo simulation incorporated assumptions and estimates to value the warrant liability. Estimates and assumptions impacting the fair value measurement included the estimated probability of adjusting the exercise price of the warrants, the number of shares for which the warrants will be exercisable, the fair value per share of the underlying common shares issuable upon exercise of the warrants, the remaining contractual term of the warrants, the risk-free interest rate, the expected dividend yield, and the expected volatility of the price of the underlying common shares. The Company estimated the fair value per share of its common shares by taking into consideration the most recent arm's length sale of its common shares or third-party valuation of its common shares as well as additional factors that the Company deemed relevant. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its shares. Therefore, it estimated its expected share volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company estimated a 0% expected dividend yield based on the fact that the Company has never paid or declared dividends and does not intend to do so in the foreseeable future.

Valuation of Derivative Liability

The fair value of the derivative liability recognized in connection with the Company's license agreement with Yale (see Note 12) was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the derivative liability was determined using the probability-weighted expected return method ("PWERM"), which considered as inputs the type and probability of occurrence of a change-of-control event, the amount of the payment, the expected timing of a change-of-control event and a risk-adjusted discount rate. In April 2017, the agreement with Yale was amended such that if the change-of-control event is an IPO, the change-of-control payment shall be due to Yale on the first trading day Yale is free to sell its equity interest in the Company and the change-of-control fee shall be reduced by the dollar value of Yale's equity interest in the Company on the first trading day when Yale is free to sell its equity interest in the Company. Yale's equity interest in the Company is subject to a lock-up agreement which generally restricts Yale's shares from being traded until October 31, 2017, and accordingly, the amount due to Yale in connection with the change-of-control provision of the agreement, if any, will be determined upon expiration of the lock-up period in October 2017.

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Valuation of Contingent Equity Liability

BMS. The fair value of the contingent equity liability recognized in connection with the Company's license agreement with BMS (see Note 12) was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the contingent equity liability was determined using the PWERM, which considered as inputs the probability of occurrence of events that would trigger the issuance of shares, the expected timing of such events, the value of the contingently issuable equity and a risk-adjusted discount rate. As of December 31, 2016, the assumed probability of occurrence of the event that was most probable of triggering the issuance of shares was 75%, the expected timing of such an event was estimated to be less than one year, the value of the contingently issuable equity was \$18,750 and the discount rate was assessed to be 0%. As of March 31, 2017, the assumed probability of occurrence of the event that was most probable of triggering the issuance of shares was 85%, the expected timing of such an event was estimated to be less than one year, the value of the contingently issuable equity was \$18,750 and the discount rate was assessed to be 0%. Based on these inputs, the Company determined that the fair value of the contingent equity liability was \$14,063 as of December 31, 2016 and \$15,938 as of March 31, 2017.

AstraZeneca. The fair value of the contingent equity liability recognized in connection with the Company's license agreement with AstraZeneca (see Note 12) was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the contingent equity liability was determined using the PWERM, which considered as inputs the probability of occurrence of events that would trigger the issuance of shares, the expected timing of such events, the value of the contingently issuable equity and a risk-adjusted discount rate. The contingently issuable equity is issuable in two tranches, each for a fixed dollar amount of \$5,000, for a total amount of \$10,000. Using the PWERM, the Company assessed the fair value of each tranche of the contingent equity liability separately.

In October 2016, upon completion of the Series A First Closing (see Note 9), the first tranche of contingently issuable equity became issuable to AstraZeneca. As a result, the Company issued to AstraZeneca 538,150 Series A preferred shares with an aggregate fair value of \$5,000, or \$9.2911 per share, in satisfaction of the obligation to issue the first tranche of equity under the agreement. Upon the issuance of the 538,150 Series A preferred shares to AstraZeneca in October 2016, the Company reclassified the carrying value of the first tranche contingent equity liability, equal to the then-current fair value of \$5,000, to the carrying value of Series A preferred shares.

The shares related to the second tranche become issuable upon the earlier of (i) the initiation of a Phase 2b or equivalent clinical trial of a product candidate based on the licensed patent rights and (ii) any liquidity event, including an IPO, any change of control or any assignment of the Company's rights or obligations under the license agreement. As of December 31, 2016, the Company determined that the fair value of the second tranche contingent equity liability was \$4,875. In determining this fair value, the assumed probability of occurrence of the event that was most probable of triggering the issuance of shares was 65%, the expected timing of such an event was estimated to be less than one year, the value of the contingently issuable equity was \$7,500 and the discount rate was assessed to be 0%. As of March 31, 2017, the Company determined that the fair value of the second tranche contingent equity liability was \$6,375. In determining this fair value, the assumed probability of occurrence of the event that was most probable of triggering the issuance of shares was 85%, the expected timing of such an event was estimated to be less than three months, the value of the contingently issuable equity was \$7,500 and the discount rate was assessed to be 0%.

The following table provides a roll forward of the aggregate fair values of the Company's warrant liability, derivative liability and contingent equity liability, for which fair value is determined by Level 3 inputs:

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****(Amounts in thousands, except share and per share amounts)****(Unaudited)**

| | <u>Warrant Liability</u> | <u>Derivative Liability</u> | <u>Contingent Equity Liability</u> |
|------------------------------|------------------------------|---------------------------------|--|
| Balance at December 31, 2016 | \$ 780 | \$ 512 | \$ 18,938 |
| Change in fair value | 454 | (289) | 3,375 |
| Balance at March 31, 2017 | <u>\$ 1,234</u> | <u>\$ 223</u> | <u>\$ 22,313</u> |

In connection with the closing of the IPO in May 2017, the conditions for issuing shares in connection with the contingent equity liabilities were satisfied, and accordingly, the Company issued 1,345,374 and 538,149 common shares, respectively, to BMS and AstraZeneca. The contingent equity liabilities were adjusted to fair value immediately prior to the completion of the IPO, and upon issuance of the common shares, the contingent equity liabilities were reclassified to equity (see Note 17).

Beneficial Conversion Feature

In connection with the second tranche closing of Series A preferred shares on February 17, 2017, the Company determined that the conversion option associated with the shares sold met the definition of a beneficial conversion feature (“BCF”) as the fair value of the underlying common shares exceeded the adjusted conversion price. The BCF was recognized at its fair value of \$12,006 as a reduction to the carrying value of the Series A preferred shares and a corresponding adjustment to additional paid-in capital. The fair value was determined using Level 3 inputs, equal to the product of the number of shares sold in the second tranche closing multiplied by the difference between the adjusted conversion price and the per share value of common shares at the commitment date (see Note 9).

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

| | <u>March 31, 2017</u> | <u>December 31, 2016</u> |
|------------------------------|---------------------------|------------------------------|
| Prepaid clinical trial costs | \$ 860 | \$ 388 |
| Other | 23 | 15 |
| | <u>\$ 883</u> | <u>\$ 403</u> |

5. Equity Method Investment

On August 29, 2016, the Company executed a stock purchase agreement with Kleo Pharmaceuticals, Inc. (“Kleo”), a privately held Delaware corporation, to purchase 3,000,000 shares of Kleo’s common stock at an initial closing, with a commitment to purchase an aggregate of 5,500,000 additional shares of common stock, in each case at a share price of \$1.00 per share (the “Kleo SPA”). Kleo is a development-stage biopharmaceutical company focused on advancing the field of immunotherapy by developing small molecules that emulate biologics. Under the terms of the Kleo SPA, the Company purchased 3,000,000 shares upon the initial closing on August 31, 2016, and the remaining 5,500,000 shares are to be purchased in four equal tranches of 1,375,000 shares beginning six months from the initial closing and then every three months thereafter. In March 2017, the Company completed the first tranche purchase of 1,375,000 shares for cash consideration of \$1,375.

In connection with the Kleo SPA, the Company agreed to purchase an additional 500,000 shares of Kleo common stock from an officer and stockholder of Kleo. On March 30, 2017, the Company completed the purchase of these shares. The consideration paid for these shares consisted of a cash payment of \$250 and the Company’s issuance of 32,500 common shares with a fair value of \$10.82 per share on the date of issuance, or \$352.

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The Company has a variable interest in Kleo through its equity investment. Kleo is a variable interest entity due to the equity investment at risk being insufficient to finance its activities. An assessment of whether or not the Company has the power to direct activities that most significantly impact Kleo's economic performance and to identify the party that obtains the majority of the benefits of the investment was performed as of March 31, 2017 and December 31, 2016, and will be performed as of each subsequent reporting date. After each of these assessments, the Company concluded that the activities that most significantly impact Kleo's economic performance are the ability to direct the research activities, the ability to select vendors to perform the research, the ability to maintain research staff and the ability to raise additional funds. Based on the outcome of these assessments, the Company concluded that consolidation of Kleo is not appropriate, and has therefore accounted for the investment under the equity method.

The Company's purchase of 3,000,000 shares of Kleo's common stock during the year ended December 31, 2016 and the additional 1,875,000 shares of Kleo's common stock during the three months ended March 31, 2017 represented an 18.6% and a 27.9% interest in the outstanding shares of Kleo as of December 31, 2016 and March 31, 2017, respectively. In connection with the initial investment, the Company also received the right to designate two of the five members of Kleo's board of directors. The Company accounts for its investment in Kleo under the equity method of accounting. The Company has recorded its investments in Kleo to date based on the costs of those investments, as adjusted for the Company's proportional share of Kleo's net income or loss in each period. The difference between the cost of the Company's investments in Kleo and its proportionate share of the net assets of Kleo was allocated to goodwill and indefinite-lived intangible assets. The Company will record future adjustments to the carrying value of its investment at each reporting date equal to its proportionate share of Kleo's net income or loss for the corresponding period. The Company recorded other expense and a corresponding reduction in the carrying value of its investment in Kleo of \$218 for its proportionate share of Kleo's net loss for the three months ended March 31, 2017.

The carrying value of the Company's investment in Kleo was \$4,511 and \$2,753 as of March 31, 2017 and December 31, 2016, respectively, and is reported as equity method investment on the consolidated balance sheet. The carrying value of the investment represents the Company's maximum loss exposure as of March 31, 2017.

The following table provides a roll forward of the carrying value of the Company's equity method investment:

| | <u>Carrying Value</u> |
|---|-----------------------|
| Balance at December 31, 2016 | \$ 2,753 |
| Purchases of Kleo common stock | 1,976 |
| Loss recognized in connection with equity method investment | (218) |
| Balance at March 31, 2017 | <u>\$ 4,511</u> |

Summarized financial information for Kleo was as follows:

| | <u>March 31, 2017</u> | <u>December 31, 2016</u> |
|---------------------|---------------------------|------------------------------|
| Current assets | \$ 4,243 | \$ 4,269 |
| Total assets | \$ 4,657 | \$ 4,317 |
| Current liabilities | \$ 601 | \$ 413 |
| Total liabilities | \$ 1,600 | \$ 656 |

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| | <u>Three Months Ended</u> <u>March 31, 2017</u> |
|----------------------|--|
| Revenue | \$ — |
| Loss from Operations | \$ (1,174) |
| Net loss | \$ (1,169) |

6. Accrued Expenses

Accrued expenses consisted of the following:

| | <u>March 31,</u> <u>2017</u> | <u>December 31,</u> <u>2016</u> |
|--|---------------------------------|------------------------------------|
| Accrued employee compensation and benefits | \$ 311 | \$ 27 |
| Accrued clinical trial costs | 4,639 | 2,204 |
| Accrued professional fees | 1,689 | 516 |
| Accrued income taxes | 292 | 99 |
| Other | — | 134 |
| | <u>\$ 6,931</u> | <u>\$ 2,980</u> |

7. Notes Payable***Credit Agreement***

On August 30, 2016, the Company entered into a one-year credit agreement (the “Credit Agreement”) with Wells Fargo Bank, National Association (“Wells Fargo”) providing for a term loan in the principal amount of \$5,000 (the “Loan”) and borrowed the full \$5,000 available under the Credit Agreement. Borrowings under the Credit Agreement bear interest at a rate equal to monthly LIBOR plus 1.50% per annum, and the Credit Agreement requires monthly, interest-only payments beginning on September 30, 2016 and continuing through August 30, 2017 (the “Maturity Date”), when all amounts of unpaid principal and interest become due. The monthly LIBOR rate is reset each month (“LIBOR Period”). As of March 31, 2017, the interest rate applicable to the Loan was 2.48% per annum. In the event of a default, the interest rate applicable is equal to the monthly LIBOR rate then in effect, increased by 4.0% per annum. The Company’s obligations under the Credit Agreement are guaranteed by an outside director and shareholder of the Company (the “Guarantor”). A second outside director and shareholder of the Company entered into an agreement with the Guarantor under which the second director agreed to reimburse the Guarantor for one-half of any guaranty obligations that the Guarantor pays to Wells Fargo.

The Credit Agreement also provides that the Company may voluntarily prepay the Loan at any time; however, if the Company elects to prepay the Loan or the Loan otherwise is accelerated and becomes payable prior to the Maturity Date, the Company will pay a prepayment premium, which will be the additional interest that would have accrued if the Loan remained outstanding through the end of the current monthly LIBOR Period. The Credit Agreement contains affirmative and negative covenants, but does not contain any financial covenants.

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There were no principal payments due or paid under the Credit Agreement during the three months ended March 31, 2017.

In connection with entering into the Credit Agreement on August 30, 2016, the Company agreed to issue warrants to purchase \$1,000 of common shares to each of the Guarantor and Co-Guarantor. The number of common shares issuable upon exercise of each warrant is determined by dividing \$1,000 by the price per share paid by investors in the Series A First Closing (see Note 9). On January 26, 2017, the Company issued the warrants to the Guarantor and Co-Guarantor (see Note 8).

The Company determined that the obligation to issue the warrants represented a liability that was considered outstanding for accounting purposes on August 30, 2016, the date of the Credit Agreement (see Note 8). The fair value of the warrant liability upon issuance represented a premium paid for the guaranty of the Loan, and, accordingly, the Company recorded the issuance-date fair value of the warrant liability of \$934 as a debt discount and as a warrant liability in the Company's consolidated balance sheet. In addition, the Company paid an arrangement fee of \$150 to the lender and incurred legal costs of \$47, both of which were recorded as a debt discount. The debt discount is reflected as a reduction of the carrying value of the notes payable on the Company's consolidated balance sheet and is being amortized to interest expense over the term of the note using the effective interest method.

The Company recognized interest expense of \$298 during the three months ended March 31, 2017. The Company recognized \$273 related to the accretion of the debt discount during the three months ended March 31, 2017. As of March 31, 2017, the unamortized debt discount was \$511.

Notes Payable to Related Parties

On December 31, 2016, the Company entered into stock purchase agreements with each of the stockholders of BPI, acquiring 100% of the issued and outstanding shares of BPI for aggregate purchase consideration of \$595. The Company funded the acquisition through the issuance of promissory notes to each of the former stockholders of BPI. The former stockholders of BPI are shareholders of the Company and also serve as the Company's Chairman of the board of directors, Chief Executive Officer, and Chief Medical Officer, respectively. As of March 31, 2017, the notes were payable in five annual payments, the first four of which are interest only, with the final payment to include the principal balance outstanding plus any accrued and unpaid interest. The notes bear interest at a rate of 4.5% per annum and mature on December 31, 2021. The notes became immediately due and payable upon specified events, including immediately prior to the consummation of an initial public offering of the Company's common shares or upon the occurrence of a change of control of the Company. There are no affirmative, negative or financial covenants associated with the notes.

In connection with the closing of the Company's IPO in May 2017, the notes were paid in full, including principal of \$595, and accrued and unpaid interest of \$9 (see Note 17).

8. Warrants

ALS Biopharma Warrants

On August 10, 2015, as partial consideration issued in connection with a license agreement with ALS Biopharma LLC ("ALS Biopharma") (see Note 12), the Company issued to ALS Biopharma a warrant to purchase 275,000 common shares at an exercise price of \$5.60 per share. The warrant was immediately exercisable upon issuance and expires 10 years from the issuance date. The warrant was classified as equity and recorded at its fair value on the date of issuance.

On August 10, 2015, in connection with the same license agreement, the Company issued to ALS Biopharma a warrant to purchase 325,000 common shares at an exercise price of \$5.60 per share. The warrant became exercisable upon the Company's filing of an investigational new drug application ("IND") for a patented product under the license agreement, and expires 10 years from the issuance date. On May 31, 2016, the Company filed an IND for a

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patented product under the license agreement. The warrant was classified as equity and recorded at its fair value on May 31, 2016.

Guarantor and Co-Guarantor Warrants

The Company agreed to issue warrants to purchase \$1,000 of common shares to each of the Guarantor and Co-Guarantor of the Credit Agreement (see Note 7), who are members of the Company's board of directors (see Note 15). The number of common shares issuable upon exercise of each warrant is determined by dividing \$1,000 by the price per share paid by investors in the Series A First Closing (see Note 9). On January 26, 2017, the Company issued the warrants to the Guarantor and Co-Guarantor, pursuant to which each director received a warrant to purchase 107,500 common shares at an exercise price of \$9.2911 per share. The warrants were immediately exercisable and expire upon the earlier to occur of (i) the fifth anniversary of the issuance date of the warrants and (ii) the second anniversary of the Company's IPO.

As of December 31, 2016, the Company determined that the obligation to issue the warrants represented a liability that was considered outstanding for accounting purposes on August 30, 2016, the date the Company entered into the Credit Agreement. The Company classified the warrants as a liability on its consolidated balance sheet because each warrant represents a freestanding financial instrument that is not indexed to the Company's own shares. As of March 31, 2017, the Company continued to classify these warrants as a liability on the consolidated balance sheet because the warrants contain anti-dilution price protection provisions through January 26, 2018. As a result, changes in the fair value of the warrant liability will continue to be recognized as a component of other income (expense), net until the earliest of (i) the exercise of the warrants, (ii) the expiration of the warrants or (iii) January 26, 2018. The warrant liability was initially recorded at fair value upon entering into the Credit Agreement and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability are recognized as a component of other income (expense), net in the Company's consolidated statement of operations and comprehensive loss.

The fair value of the warrant liability was determined to be \$934 on the date of issuance. The Company remeasured the liability as of March 31, 2017 and December 31, 2016 and determined that the fair value of the warrant liability was \$1,234 and \$780, respectively. The Company recorded a gain of \$454 recorded within other income (expense), net in the consolidated statements of operations for the three months ended March 31, 2017.

9. Convertible Preferred Shares

As of March 31, 2017, the Company's memorandum and articles of association, as amended and restated, authorized the Company to issue 11,242,172 Series A preferred shares. The holders of Series A preferred shares have liquidation rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company. Therefore, the Series A preferred shares are classified outside of shareholders' equity (deficit).

In October 2016, the Company issued and sold an aggregate of 4,305,209 Series A preferred shares, at an issuance price of \$9.2911 per share, for proceeds of \$37,295, net of offering costs of \$2,705 (the "Series A First Closing"). The \$2,705 of offering costs consisted of \$1,730 payable in cash and 105,010 shares of the Company's Series A preferred shares valued at \$975, or \$9.2911 per share, which were issued directly to the two placement agents involved in the Series A financing. The preferred share purchase agreement provided for the issuance of additional Series A preferred shares in a second and final tranche (the "Series A Second Closing"). Also, in October 2016, the Company issued to AstraZeneca 538,150 Series A preferred shares with an aggregate fair value of \$5,000, or \$9.2911 per share, in satisfaction of the obligation to issue the first tranche of contingently issuable equity under the Company's license agreement with AstraZeneca (see Note 12).

In February 2017, the Company completed the Series A Second Closing through the issuance and sale of an aggregate of 4,305,182 Series A preferred shares at an issuance price of \$9.2911 per share for cash proceeds of

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\$38,636, net of offering costs of \$2,606. The \$2,606 of offering costs for the second tranche consisted of \$1,364 payable in cash and 105,009 shares of the Company's Series A preferred shares valued at \$1,242, or \$11.83 per share, which were issued directly to the two placement agents involved in the Series A financing. The conversion option associated with the Series A preferred shares sold in the second closing met the definition of a BCF as the fair value of the underlying common shares of \$9.85 per share exceeded the stated conversion price of \$9.2911 (or \$7.0613, as adjusted, as described below under Conversion). Upon the sale and issuance of the Series A preferred shares, \$2,406 of the BCF was immediately accreted, as this represented the difference between the stated conversion price and per share value of the common shares. The remaining portion of the BCF is being amortized using the effective interest method over the period from the date of issuance to the date of the earliest possible conversion, October 1, 2017. For the three months ended March 31, 2017, the Company recorded accretion of the BCF of \$4,000.

In May 2017, upon the completion of the Company's IPO, all of the outstanding Series A preferred shares were automatically converted into an aggregate of 9,358,560 common shares pursuant to the related agreements (see Note 17). Upon conversion of the Series A preferred shares, the remaining unamortized BCF was reclassified to additional paid-in capital as a deemed dividend (see Note 17).

The holders of the Series A preferred shares had the following rights and preferences prior to the conversion to common shares:

Voting

The holders of Series A preferred shares were entitled to vote, together with the holders of common shares, on all matters submitted to shareholders for a vote. The holders of Series A preferred shares were entitled to the number of votes equal to the number of common shares into which their Series A preferred shares could convert.

Conversion

Each Series A preferred share was convertible into common shares at the option of the shareholder at any time after the date of issuance. In addition, pursuant to the Company's memorandum and articles of association, as amended and restated, each Series A preferred share would be automatically converted into common shares, at the applicable conversion ratio then in effect, upon the earlier of (i) a firm commitment public offering with proceeds to the Company of at least \$50,000, before deducting underwriting discounts and commissions or (ii) the date specified by the vote or written consent of the holders of a majority of the then outstanding Series A preferred shares.

The conversion ratio of Series A preferred shares was determined by dividing the Original Issue Price by the Conversion Price. The Original Issue Price of the Series A preferred shares was \$9.2911 per share. The Conversion Price of the Series A preferred shares was \$9.2911 per share, subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization and other adjustments as set forth in the Company's memorandum and articles of association, as amended and restated. On the date of issuance, each Series A preferred share was convertible into one common share. In the event that any Series A preferred share investor did not participate in the second and final tranche of the Series A preferred financing, that investor's shares would have been convertible into common shares at a ratio of one common share for every 1,000 Series A preferred shares. In addition, if the Company decided not to move forward with a Phase 3 clinical trial on its product candidate, rimegepant, or if the Company failed to initiate a Phase 3 clinical trial prior to October 1, 2017, the Conversion Price of the Series A preferred shares would have been reduced to \$7.0613 per share.

Dividends

The holders of Series A preferred shares were entitled to receive dividends in preference to any dividend on common shares at the rate of 8.0% per year of the Original Issue Price. Dividends accrued daily and compounded annually, whether or not declared, would be payable when, as and if declared by the board or directors of the Company and were noncumulative. The Company was not permitted to declare, pay or set aside any dividends on shares of any other class or series of capital stock of the Company unless the holders of Series A preferred shares then outstanding first received, or simultaneously received, dividends on each outstanding Series A preferred share.

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Accruing dividends, whether or not declared, were payable upon any liquidation event. Declared but unpaid dividends would have been payable upon the conversion of the Series A preferred shares into common shares.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company or a Deemed Liquidation Event (as described below), the holders of Series A preferred shares then outstanding were entitled to receive, in preference to holders of common shares, an amount equal to the greater of (i) the Original Issue Price per share, plus all dividends declared but unpaid on such shares or (ii) the amount such holders would have received had all of their Series A preferred shares been converted into common shares immediately prior to such liquidation event. If upon any such liquidation event, the assets of the Company available for distribution were insufficient to permit payment in full to the holders of Series A preferred shares, the proceeds would be ratably distributed among the holders of Series A preferred shares in proportion to the respective amounts that they would have received if they were paid in full.

After payments have been made in full to the holders of Series A preferred shares, the remaining assets of the Company available for distribution would be distributed among the holders of common shares ratably in proportion to the number of shares held by each such holder.

Unless a majority of the holders of the then outstanding Series A preferred shares elected otherwise, a Deemed Liquidation Event would include a merger or consolidation (other than one in which shareholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

Redemption

The Company's memorandum and articles of association, as amended and restated, did not provide redemption rights to the holders of Series A preferred shares.

10. Common Shares

As of December 31, 2016 and March 31, 2017, the Company's memorandum and articles of association, as amended and restated, authorized the Company to issue 38,000,000 no par value common shares.

Each common share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Common shareholders are entitled to receive dividends, as may be declared by the board of directors, if any. Through March 31, 2017, no dividends had been declared.

In February 2016, the Company issued 429,000 common shares at an issuance price of \$7.00 per share for proceeds of \$2,980, net of issuance costs of \$23.

In May 2016 and July 2016, the Company issued an aggregate of 1,090,500 common shares at an issuance price of \$7.70 per share for proceeds of \$8,299, net of issuance costs of \$97.

In July 2016, concurrently with the issuance of the Company's common shares to Connecticut Innovations Incorporated ("CII"), the Company and CII entered into a put agreement (the "Put Agreement"). The Put Agreement grants CII the right to sell (the "Put Option") to the Company all or any part of CII's warrant rights (if any), shares (if any) or notes (if any). The Put Option becomes exercisable upon the Company's breach of the covenant to maintain a presence in Connecticut, as defined in the Put Agreement. Upon CII's exercise of the Put Option, the Company would be obligated to purchase CII's shares for a price that is the greater of (i) the current market price of such share and (ii) the original purchase price of such share. The right to put the shares will terminate at such time that the shares may be sold (i) pursuant to an effective registration statement under the Securities Act of 1933 (the

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“Securities Act”), (ii) pursuant to Rule 144 promulgated under the Securities Act, but in each case, only after the termination of any applicable “lock-up” restrictions and, in the case of (ii), only if the common shares are then listed for trading on a national securities exchange. The fair value of the Put Option was determined to be \$0 upon execution of the Put Agreement and as of March 31, 2017 because the ability to maintain a presence in Connecticut is within the Company’s control.

In April 2017, the Company effected an increase in the number of authorized common shares from 38,000,000 shares to 50,000,000 shares (see Note 17).

On May 3, 2017, the Company’s registration statement on Form S-1 relating to the IPO was declared effective by the SEC. The IPO closed on May 9, 2017 and the Company issued and sold 9,900,000 common shares at a public offering price of \$17.00 per share for net proceeds of \$152,889 after deducting underwriting discounts and commissions of \$11,781 and other offering expenses of approximately \$3,630. Upon the closing of the IPO, all convertible preferred shares then outstanding converted into an aggregate of 9,358,560 common shares. In addition, on May 9, 2017, the underwriters of the IPO fully exercised their option to purchase additional shares, and on May 11, 2017, the Company issued and sold 1,485,000 additional common shares for additional net proceeds of \$23,478 after deducting underwriting discounts and commissions of \$1,767. Thus, the aggregate net proceeds to the Company from the IPO, after deducting underwriting discounts and commissions and offering expenses, were \$176,367.

In connection with the completion of its IPO, the Company issued an additional aggregate of 1,883,523 common shares to BMS and AstraZeneca in satisfaction of obligations to contingently issue equity securities pursuant to the license agreements (see Note 12), for no additional consideration.

Also in connection with the completion of its IPO in May 2017, the Company amended its memorandum and articles of association to authorize the issuance of up to 200,000,000 no par value common shares and 10,000,000 no par value undesignated preferred shares.

11. Share-Based Compensation

2014 Equity Incentive Plan

The Company’s 2014 Equity Incentive Plan, as amended, (the “2014 Plan”) provides for the Company to sell or issue common shares or restricted common shares, or to grant incentive stock options or nonqualified stock options for the purchase of common shares, to employees, members of the board of directors and consultants of the Company. The 2014 Plan is administered by the board of directors, or at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the common share on the date of grant and the term of stock option may not be greater than ten years.

The total number of common shares that may be issued under the 2014 Plan was 4,000,000 shares as of December 31, 2016. In January 2017, the Company effected an increase, effective October 28, 2016, in the number of common shares reserved for issuance under the 2014 Plan from 4,000,000 to 4,899,230 shares. The total number of common shares that may be issued under the 2014 Plan was 4,899,230 shares as of March 31, 2017. As of March 31, 2017 and December 31, 2016, 553,886 and 1,034,805 shares remained available for future grant under the 2014 Plan, respectively.

Vesting periods are determined at the discretion of the board of directors. Stock options granted to employees and directors typically vest over three years. Stock options granted to non-employees typically vest over three years. The Company measures and records the value of these options over the period of time services are provided and, as such, unvested portions are subject to remeasurement at subsequent reporting periods.

During the three months ended March 31, 2017, the Company granted options to purchase 422,382 common shares to employees and directors, and there were no options granted during the three months ended March 31, 2016. The Company recorded share-based compensation expense for options granted to employees and directors of \$1,153 and \$432 during the three months ended March 31, 2017 and 2016, respectively.

During the three months ended March 31, 2017, the Company granted options to purchase 58,537 common shares to non-employees, and there were no options granted during the three months ended March 31, 2016. The Company recorded share-based compensation expense for options granted to non-employees of \$733 and \$255 during the three months ended March 31, 2017 and 2016, respectively.

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In May 2017, the Company's shareholders approved the 2017 Equity Incentive Plan (the "2017 Plan"). The 2017 Plan became effective on May 3, 2017 in connection with the Company's IPO. Upon the effectiveness of the 2017 Plan, no further grants will be made under the 2014 Plan (see Note 17).

Stock Option Valuation

The assumptions that the Company used to determine the grant-date fair value of stock options granted to employees and directors under the 2014 Plan during the three months ended March 31, 2017 were as follows, presented on a weighted average basis, noting there were no stock options granted to employees and directors during the three months ended March 31, 2016:

| | Three Months Ended March 31, 2017 |
|----------------------------|--|
| Risk-free interest rate | 1.96% |
| Expected term (in years) | 5.51 |
| Expected volatility | 70.46% |
| Expected dividend yield | 0% |
| Exercise price | \$ 9.38 |
| Fair value of common share | \$ 8.68 |

The assumptions that the Company used to determine the grant-date fair value of stock options granted to non-employees under the 2014 Plan during the three months ended March 31, 2017 were as follows, presented on a weighted average basis, noting there were no stock options granted to non-employees during the three months ended March 31, 2016:

| | Three Months Ended March 31, 2017 |
|----------------------------|--|
| Risk-free interest rate | 2.45% |
| Expected term (in years) | 10.0 |
| Expected volatility | 69.98% |
| Expected dividend yield | 0% |
| Exercise price | \$ 9.29 |
| Fair value of common share | \$ 8.68 |

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Stock Options

Stock option activity under the 2014 Plan is summarized as follows:

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (in years) | Aggregate Intrinsic Value |
|--|---------------------|--|---|---------------------------------|
| Outstanding as of December 31, 2016 | 3,864,425 | \$ 3.61 | 9.21 | \$ 15,991 |
| Granted | 480,919 | 9.37 | | |
| Exercised | — | — | | |
| Forfeited | — | — | | |
| Outstanding as of March 31, 2017 | <u>4,345,344</u> | \$ 4.24 | \$ 9.18 | \$ 28,578 |
| Options exercisable as of March 31, 2017 | 2,442,114 | \$ 3.02 | \$ 8.17 | \$ 19,051 |
| Options unvested as of March 31, 2017 | 1,903,230 | \$ 5.81 | \$ 8.82 | \$ 9,527 |

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common shares for those stock options that had exercise prices lower than the fair value of the Company's common shares. There have been no exercises as of March 31, 2017.

The weighted average grant-date fair value per share of stock options granted for the three months ended March 31, 2017 was \$5.57. There were no stock options granted during the three months ended March 31, 2016.

The total fair value of options vested for the three months ended March 31, 2017 and 2016 was \$1,034 and \$0, respectively.

Share-Based Compensation

Share-based compensation expense was classified in the consolidated statements of operations and comprehensive loss as follows:

| | <u>Three Months Ended March 31,</u> | |
|-------------------------------------|-------------------------------------|---------------|
| | <u>2017</u> | <u>2016</u> |
| Research and development expenses | \$ 999 | \$ 335 |
| General and administrative expenses | 887 | 352 |
| | <u>\$ 1,886</u> | <u>\$ 687</u> |

As of March 31, 2017, total unrecognized compensation cost related to the unvested share-based awards was \$7,685, which is expected to be recognized over a weighted average period of 2.01 years.

2017 Employee Share Purchase Plan

In May 2017, the Company's shareholders approved the 2017 Employee Share Purchase Plan (the "2017 ESPP"). The 2017 ESPP became effective on May 3, 2017 in connection with the Company's IPO (see Note 17).

12. License Agreements

Yale Agreement

In September 2013, the Company entered into an exclusive license agreement with Yale (the "Yale Agreement") to obtain a license to certain patent rights for the commercial development, manufacture, distribution, use and sale of products and processes resulting from the development of those patent rights, related to the use of riluzole in treating various neurological conditions, such as general anxiety disorder, post-traumatic stress disorder and depression. As part of the consideration for this license, the Company issued Yale 250,000 common shares and granted Yale the right to purchase up to 10% of the securities issued in specified future equity offerings by the Company. In the event that Yale's fully diluted ownership position following the closing of the Company's first two

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financings with institutional investors resulting in an investment of at least \$3,500 fell below 1% of the Company's fully diluted common shares outstanding, the Company would be required to issue to Yale an additional number of shares of common shares such that Yale's ownership position is restored to no less than 1%. The obligation to contingently issue equity to Yale was determined to be a liability, which was accounted for at fair value and remeasured at each reporting date. The fair value of the obligation at inception of the Yale Agreement was \$0 based on the Company's assessment that the probability of issuing additional shares that would reduce Yale's ownership percentage below 1% was remote. The fair value of the liability remained at \$0 through the completion of the Company's common share issuances in January 2014 and July 2015, at which time the contingent obligation terminated, as Yale's ownership position remained above 1%.

The Yale Agreement provides for a change-of-control payment to Yale upon the occurrence of a change-of-control event, as defined in the agreement, including an IPO. Upon the occurrence of a change-of-control event, the Company is obligated to pay to Yale the lesser of (i) 5% of the dollar value of all initial and future potential consideration paid or payable by the acquirer and (ii) \$1,500. If the change-of-control event is an IPO, the amount the Company will be obligated to pay to Yale will be reduced by the value of Yale's equity investment in the Company on the first day that Yale is free to sell its equity interest. The Company classifies the change-of-control payment obligation as a liability on its consolidated balance sheet because it represents a contingent obligation to pay a variable amount of cash that may be based, in part, on the value of the Company's own shares. The issuance-date fair value of the derivative liability was recognized as research and development expense in the consolidated statement of operations and comprehensive loss upon entering into the agreement with Yale. The derivative liability is remeasured to fair value at each reporting date. Changes in the fair value of the derivative liability are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. In April 2017, the agreement with Yale was amended such that if the change-of-control event is an IPO, the change-of-control payment shall be due to Yale on the first trading day when Yale is free to sell its equity interest in the Company and the change-of-control fee shall be reduced by the dollar value of Yale's equity interest in the Company on the first trading day when Yale is free to sell its equity interest in the Company. Yale's equity interest in the Company is subject to a lock-up agreement which generally restricts Yale's shares from being traded until October 31, 2017, and accordingly, the amount due to Yale in connection with the change-of-control provision of the agreement, if any, will be determined upon expiration of the lock-up period. The Company will continue to remeasure the derivative liability to fair value at each reporting date and will recognize changes in the fair value of the derivative liability until the expiration of the lock-up in October 2017 (see Note 17).

During the three months ended March 31, 2017 and 2016, the Company recorded other expense of \$289 and \$3, respectively, for the change in the fair value of the derivative liability. The fair value of the derivative liability was \$223 and \$512 as of March 31, 2017 and December 31, 2016, respectively.

In addition, 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 products from the licensed patents, subject to a minimum amount of up to \$1,000 per year. 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.

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

The Company recorded research and development expenses of \$3 during the three months ended March 31, 2017, for reimbursement of patent fees in connection with the Yale Agreement.

MGH Agreement

In September 2014, the Company entered into a license agreement (the "MGH Agreement") with The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH"), pursuant to which MGH granted the

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Company a license to certain patent rights for the commercial development, manufacture, distribution and use of any products or processes resulting from development of those patent rights, related to treating depression with a combination of ketamine and scopolamine. The Company is also obligated to pay MGH annual license maintenance fees of between \$30 and \$50, beginning in 2017, future milestone payments of up to \$750 upon the achievement of specified clinical and regulatory milestones and up to \$2,500 upon the achievement of specified commercial milestones. The Company has also agreed to pay MGH royalties of a low single-digit percentage based on net sales of products licensed under the agreement. If the Company receives revenue from sublicensing any of its rights under the agreement, the Company is also obligated to pay a portion of that revenue to MGH.

The MGH Agreement also requires the Company to meet certain due diligence requirements based upon specified milestones. The Company can elect to extend the deadline for its compliance with the due diligence requirements by a maximum of one year by making payments to MGH of up to \$300 in the aggregate. The Company is required to reimburse MGH for any fees that MGH incurs related to the filing, prosecution, defending, and maintenance of patent rights licensed under the agreement. The MGH Agreement expires upon expiration of the patent rights under the MGH Agreement, unless earlier terminated by either party.

The Company did not recognize any research and development expense associated with the MGH Agreement during the three months ended March 31, 2017 and 2016.

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 trigriluzole, 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.

In connection with the ALS Biopharma Agreement, the Company also issued to ALS Biopharma (i) 50,000 common shares; (ii) an immediately exercisable warrant to purchase 275,000 common shares at an exercise price of \$5.60 per share; and (iii) a warrant to purchase 325,000 common shares at an exercise price of \$5.60 per share, which warrant would become exercisable upon the Company’s achievement of a specified regulatory milestone (see Note 8). The ALS Biopharma Agreement terminates on a country-by-country basis as the last patent rights expire in each such country. If the Company abandons its development, research, licensing or sale of all products covered by one or more claims of any patent or patent application assigned under the ALS Biopharma Agreement, or if the Company ceases operations, it has agreed to reassign the applicable patent rights back to ALS Biopharma.

The Company recorded research and development expenses of \$0 and \$375 during the three months ended March 31, 2017 and 2016, respectively, as a result of the ALS Biopharma Agreement, which amounts consist of the fair value of the shares and warrants upon their issuance to ALS Biopharma.

Rutgers Agreement

In June 2016, the Company entered into an exclusive license agreement (the “Rutgers Agreement”) with Rutgers, The State University of New Jersey (“Rutgers”), licensing several patents and patent applications related to the use of riluzole to treat various cancers. Under the Rutgers Agreement, the Company is required to pay Rutgers annual license maintenance fees in the aggregate of \$75 for the first five years following execution of the agreement, then \$25 per year thereafter until the first commercial sale of a licensed product, at which point the Company will pay Rutgers minimum annual royalties totaling in the low six-digits. The Company is also obligated to pay Rutgers up to \$825 in the aggregate upon the achievement of specified clinical and regulatory milestones. The Company also

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agreed to pay Rutgers royalties of a low single-digit percentage of net sales of licensed products sold by the Company, its affiliates or its sublicensees, subject to a minimum amount of up to \$100 per year. If the Company grants any sublicense rights under the Rutgers Agreement, the Company must pay Rutgers a low double-digit percentage of sublicense income it receives.

Under the Rutgers Agreement, in the event that the Company experiences a change of control or sale of substantially all of its assets prior to the initiation of a Phase 3 clinical trial related to products licensed under the agreement, and such change of control or sale results in a full liquidation of the Company, the Company will be obligated to pay Rutgers a change-of-control fee equal to 0.3% of the total value of the transaction, but not less than \$100. The Company determined that the change-of-control payment should be accounted for as a liability because it represents a contingent obligation to pay a variable amount of cash that may be based, in part, on the value of the Company's own shares. The fair value of the obligation upon execution of the Rutgers Agreement was \$0 based on the Company's assessment that the probability of a change-in-control event occurring prior to the initiation of a Phase 3 clinical trial related to products licensed under the agreement was remote. The fair value of the liability remained at \$0 through March 31, 2017.

The Rutgers Agreement also requires the Company to meet certain due diligence requirements based upon specified milestones. The Company can elect to extend the deadline for its compliance with the due diligence requirements by a maximum of one year upon payments to Rutgers of up to \$500 in the aggregate. Under the Rutgers Agreement, the Company is required to reimburse Rutgers for any fees that Rutgers incurs related to the filing, prosecution, defending, and maintenance of patent rights licensed under the agreement. The Rutgers Agreement expires upon expiration of the patent rights under the agreement or ten years from the date of first commercial sale of a licensed product, whichever is later, unless terminated by either party.

The Company recorded no research and development expense during the three months ended March 31, 2017 related to the Rutgers Agreement.

BMS Agreement

In July 2016, the Company entered into an exclusive, worldwide license agreement (the "BMS Agreement") with BMS for the development and commercialization rights to rimegepant and BHV-3500, as well as other CGRP-related intellectual property. In exchange for these rights, the Company agreed to pay BMS initial payments, milestone payments and royalties on net sales of licensed products under the agreement.

The Company is obligated to make milestone payments to BMS upon the achievement of specified development and commercialization milestones. The development milestone payments due under the agreement depend on the licensed product being developed. With respect to rimegepant, the Company is obligated to pay up to \$127,500 in the aggregate upon the achievement of the development milestones. For any product other than rimegepant, the Company is obligated to pay up to \$74,500 in the aggregate upon the achievement of the development milestones. In addition, the Company is obligated to pay up to \$150,000 for each licensed product upon the achievement of commercial milestones. If the Company receives revenue from sublicensing any of its rights under the agreement, it is also obligated to pay a portion of that revenue to BMS. The Company is also obligated to make tiered royalty payments to BMS based on annual worldwide net sales, with percentages in the low to mid teens.

Under the BMS Agreement, the Company is obligated to use commercially reasonable efforts to develop licensed products and to commercialize at least one licensed product using the patent rights licensed from BMS and is solely responsible for all development, regulatory and commercial activities and costs. The Company is also required to reimburse BMS for any fees that BMS incurs related to the filing, prosecution, defending, and maintenance of patent rights licensed under the BMS Agreement. Under the BMS Agreement, BMS transferred to the Company manufactured licensed products, including certain materials that will be used by the Company to conduct clinical trials.

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The BMS Agreement will terminate on a licensed product-by-licensed product and country-by-country basis upon the expiration of the royalty term with respect to each licensed product in each country. BMS has the right to terminate the agreement upon the Company's insolvency or bankruptcy, the Company's uncured material breach of the agreement, including the failure to meet its development and commercialization obligations, or if the Company challenges any of BMS's patent rights. The Company has the right to terminate the BMS Agreement if BMS materially breaches the agreement or if, after the Company provides notice, it chooses not to move forward with development and commercialization in a specific country.

The BMS Agreement required the Company to complete a financing transaction with gross proceeds of at least \$30,000, of which a minimum of \$22,000 was to be from investment in equity prior to October 17, 2016, unless extended by mutual agreement of the Company and BMS. The BMS Agreement was amended, effective October 14, 2016, to extend the deadline for completing the financing transaction to October 31, 2016, on which date the Series A First Closing was completed (see Note 9).

Under the BMS Agreement, the Company also agreed to issue BMS common shares in the amount of \$12,500, which shares are contingently issuable upon the earliest to occur of (i) the initiation of a Phase 3 trial for the first licensed compound to reach such milestone, (ii) the Company's IPO or (iii) an event resulting in the change of control of the Company. Under the terms of the BMS Agreement, if the qualifying financing transaction involves the issuance of preferred shares, BMS is entitled to receive preferred shares instead of common shares, at its option. BMS also had the right to purchase up to 8%, on a fully diluted basis, of shares issued in a qualifying financing transaction (as defined in the BMS Agreement) on the same terms and rights as all other investors involved in the financing. The number of shares issuable to BMS under the agreement will be determined by dividing \$12,500 by a price per share equal to the lower of (i) the price per share paid by investors in the Series A First Closing, or \$9.2911 (see Note 9), or (ii) the price per share paid by investors in any subsequent financing event that occurs prior to the events specified above.

The obligation to contingently issue equity to BMS is classified as a liability on the consolidated balance sheet because it represents an obligation to issue a variable number of shares for a fixed dollar amount. Upon entering into the BMS Agreement, the issuance-date fair value of the contingent equity liability was recognized as research and development expense in the consolidated statement of operations and comprehensive loss. The Company remeasured the fair value of the contingent equity liability as of March 31, 2017 and recognized expense of \$1,875 for the increase in the fair value of the liability to \$15,938. Changes in the fair value of the contingent equity liability are recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. Changes in the fair value of the contingent equity liability continued to be recognized until the occurrence of a triggering event, which occurred in May 2017 with the completion of the IPO.

In May 2017, in connection with the completion of its IPO, the Company issued 1,345,374 common shares to BMS in satisfaction of its obligation to contingently issue equity securities pursuant to the license agreement (see Note 17) and remeasured the contingent equity liability to fair value.

The Company recorded no research and development expense related to the BMS Agreement during the three months ended March 31, 2017.

AstraZeneca Agreement

In October 2016, the Company entered into an exclusive license agreement (the "AstraZeneca Agreement") with AstraZeneca, pursuant to which AstraZeneca granted the Company a license to certain patent rights for the commercial development, manufacture, distribution and use of any products or processes resulting from development of those patent rights, including BHV-5000 and BHV-5500. In exchange for these rights, the Company agreed to pay AstraZeneca an upfront payment, milestone payments and royalties on net sales of licensed products under the agreement. The regulatory milestones due under the agreement depend on the indication of the licensed product being developed as well as the territory where regulatory approval is obtained. Development milestones due under the agreement with respect to Rett syndrome total up to \$30,000, and, for any indication other than Rett syndrome, total up to \$60,000. Commercial milestones are based on net sales of all products licensed under the

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agreement and total up to \$120,000. The Company has also agreed to pay tiered royalties based on net sales of all products licensed under the agreement of mid single-digit to low double-digit percentages. If the Company receives revenue from sublicensing any of its rights under the 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 AstraZeneca Agreement.

The AstraZeneca Agreement expires upon the expiration of the patent rights under the agreement, unless earlier terminated by either party, or on a country-by-country basis ten years after the first commercial sale.

As part of the consideration under the AstraZeneca Agreement, the Company agreed to issue to AstraZeneca common shares in the amount of \$10,000 if the Company completed a qualifying equity financing resulting in proceeds of at least \$30,000 prior to December 29, 2016. Under the terms of the AstraZeneca Agreement, if the qualifying financing transaction involved the issuance of preferred shares, AstraZeneca would be entitled to receive preferred shares instead of common shares, at its option. The number of shares issued would be determined based on the price per share paid by investors in the qualifying financing transaction. Upon the occurrence of the qualifying financing transaction, 50% of the shares would be issuable upon the closing of the transaction (the "First Tranche") and the other 50% would become issuable upon the earlier of (i) the initiation of a Phase 2b or equivalent clinical trial of a product candidate based on the licensed patent rights or (ii) any liquidity event, including an IPO of the Company, any change of control of the Company or any assignment of the Company's rights and obligations under the AstraZeneca Agreement (the "Second Tranche"). The number of shares issuable to AstraZeneca in each of the First Tranche and the Second Tranche is determined by dividing \$5,000 by the price per share paid by investors in the Company's Series A First Closing, or \$9.2911 (see Note 9). In addition, AstraZeneca had the right to purchase up to 8%, on a fully diluted basis, of shares issued in such qualifying financing transaction, on the same terms and rights as all other investors involved in the financing.

In October 2016, upon completion of the Series A First Closing (see Note 9), the contingency associated with the First Tranche of contingently issuable equity related to the occurrence of a qualified financing was satisfied. As a result, the Company issued to AstraZeneca 538,150 Series A preferred shares with an aggregate fair value of \$5,000, or \$9.2911 per share. Upon issuance of the 538,150 Series A preferred shares to AstraZeneca, the Company reclassified the contingent equity liability associated with the First Tranche of \$5,000 to the carrying value of Series A preferred shares.

As of March 31, 2017, the Company determined that the fair value of the contingent equity liability associated with the Second Tranche was \$6,375, which resulted in the recognition of other expense of \$1,500 during the three months ended March 31, 2017. Changes in the fair value of the contingent equity liability is recognized as a component of other income (expense), net in the consolidated statement of operations and comprehensive loss. Changes in the fair value of the contingent equity liability continued to be recognized until the occurrence of a triggering event, which occurred in May 2017 with the completion of the IPO.

In May 2017, in connection with the completion of its IPO, the Company issued 538,149 common shares to AstraZeneca in satisfaction of its obligation to contingently issue the Second Tranche of equity securities pursuant to the license agreement (see Note 17) and remeasured the contingent equity liability to fair value.

The Company recorded no research and development expense related to the AstraZeneca Agreement for the three months ended March 31, 2017.

Agreement with Catalent

In March 2015, the Company entered into a development and license agreement with Catalent U.K. Swindon Zydis Limited ("Catalent") pursuant to which the Company obtained license rights to the Zydis technology in BHV-0223. BHV-0223 was developed under this agreement, and Catalent has manufactured BHV-0223 for clinical testing. Upon entering the agreement, the Company is obligated to pay Catalent up to \$1,575 upon the achievement

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of specified regulatory and commercial milestones. The Company is also obligated to make royalty payments of a low single-digit percentage based on net sales of products licensed under the agreement.

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

The development and license agreement terminates on a country-by-country basis upon the later of (i) 10 years after the launch of the most recently launched product in such country and (ii) the expiration of the last valid claim covering each product in such country, unless earlier voluntarily terminated by the Company. 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 the Company fails to meet specified development timelines, which it may extend in certain circumstances.

The Company recorded no research and development expense related to the Catalent agreement during the three months ended March 31, 2017 and 2016.

13. Net Loss per Share*Net Loss per Share Attributable to Common Shareholders of Biohaven Pharmaceutical Holding Company Ltd.*

Basic and diluted net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd. was calculated as follows:

| | <u>Three Months Ended March 31,</u> | |
|--|-------------------------------------|-------------------|
| | <u>2017</u> | <u>2016</u> |
| Numerator: | | |
| Net loss | \$ (18,753) | \$ (2,986) |
| Net loss attributable to non-controlling interests | — | 35 |
| Accretion of beneficial conversion feature on Series A preferred shares | (4,000) | — |
| Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd. | <u>\$ (22,753)</u> | <u>\$ (2,951)</u> |
| Denominator: | | |
| Weighted average common shares outstanding—basic and diluted | <u>13,088,861</u> | <u>11,776,429</u> |
| Net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd.— basic and diluted | <u>\$ (1.74)</u> | <u>\$ (0.25)</u> |

The Company's potential dilutive securities, which include stock options and warrants to purchase common shares, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd. is the same. The Company excluded the following potential common shares, presented based on

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amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

| | Three Months Ended March 31, | |
|------------------------------------|-------------------------------------|------------------|
| | 2017 | 2016 |
| Options to purchase common shares | 4,345,344 | 3,247,500 |
| Warrants to purchase common shares | 815,000 | 275,000 |
| | <u>5,160,344</u> | <u>3,522,500</u> |

The Company has agreed under its agreements with AstraZeneca and BMS to issue common shares upon the achievement of specified milestones or upon the occurrence of specified events (see Note 12). Because the necessary conditions for issuance of the shares had not been met as of March 31, 2017, the Company excluded these shares from the table above and from the calculation of diluted net loss per share for the three months ended March 31, 2017.

14. Commitments and Contingencies***Lease Agreement***

In December 2016, the Company entered into an assignment agreement to assume an operating lease for its office space in New Haven, Connecticut. The lease agreement expires in October 2018, and the Company has the option to extend the term through October 2021. During the three months ended March 31, 2017, the Company recorded rent expense of \$16. The agreement requires future minimum lease payments for the years ending December 31, 2017 (remaining nine months) and 2018 of \$30 and \$35, respectively.

License Agreements

The Company has entered into license agreements with various parties under which it is obligated to make contingent and non-contingent payments (see Note 12).

Research Commitments

The Company has entered into agreements with several CROs to provide services in connection with its preclinical studies and clinical trials. As of March 31, 2017, the Company had committed to minimum payments under these arrangements totaling \$12,473.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company's amended and restated memorandum and articles of association also provide for indemnification of directors and officers in specific circumstances. To date, the Company has not incurred any material costs as a result of such indemnification provisions. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of March 31, 2017 or December 31, 2016.

Legal Proceedings

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities.

15. Related Party Transactions***License Agreement with Yale***

On September 30, 2013, the Company entered into the Yale Agreement with Yale (see Note 12). Yale is a related party because the Company's Chief Executive Officer is one of the inventors of the patents that the Company has licensed from Yale and, as such, is entitled to a specified share of the glutamate product-related royalty revenues that may be received by Yale under the Yale Agreement. As partial consideration for the license under the Yale

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Agreement, on September 30, 2013, the Company issued to Yale 250,000 common shares, representing 5.1% of the Company's then outstanding equity on a fully diluted basis. The fair value of the shares, totaling \$152, was recognized as research and development expense at the time of issuance of the shares. During the three months ended March 31, 2017 and 2016, the Company recognized research and development expense under the Yale Agreement of \$0 and \$8, respectively. As of March 31, 2017 and December 31, 2016, the Company owed no amounts to Yale.

Guarantor and Co-Guarantor Warrants

The Guarantor and Co-Guarantor of the Credit Agreement with Wells Fargo are each shareholders and members of the board of directors of the Company. The Company agreed to issue warrants to Guarantor and Co-Guarantor in exchange for their respective guaranties (see Notes 7 and 8). The warrants were issued on January 26, 2017, pursuant to which each director received a warrant to purchase 107,500 common shares at an exercise price of \$9.2911 per share.

Kleo Pharmaceuticals, Inc.

On August 29, 2016, the Company executed a stock purchase agreement with Kleo to purchase 3,000,000 shares of Kleo common stock at a purchase price of \$1.00 per share in an initial closing, which was completed on August 31, 2016, and committed to purchase an aggregate 5,500,000 additional shares of Kleo common stock at a purchase price of \$1.00 per share (see Note 5). Kleo is a related party because the Company has determined that it exercises significant influence over the operating and financial policies of Kleo. In connection with its investment in Kleo, the Company received the right to designate two members of Kleo's board of directors, who are the Chairman of the Company's board of directors and another outside director of the Company. Also, the Chief Executive Officer and controlling stockholder of Kleo is a shareholder of the Company. In addition to the purchases under the stock purchase agreement described above, on August 29, 2016, the Company entered into an agreement with the Chief Executive Officer of Kleo to purchase 500,000 shares of Kleo common stock from him, which purchase was completed in March 2017 (see Note 5). As of March 31, 2017, the Company owned 27.9% of Kleo's outstanding capital stock. The Company has also entered into a clinical development master services agreement with Kleo to assist Kleo with clinical development. As of March 31, 2017, the Company had not performed any services or received any payments under this agreement.

Biohaven Pharmaceuticals, Inc.

BPI is a related party because its three founders, each of whom beneficially owned one-third of the equity of BPI prior to the Company's acquisition of BPI on December 31, 2016 (see Note 16), are shareholders of the Company and also serve as the Company's Chairman of the board of directors, Chief Executive Officer and Chief Medical Officer, respectively. Since the Company's incorporation in September 2013, the Company is deemed to have had a variable interest in BPI, and BPI is deemed to have been a VIE, of which the Company is the primary beneficiary. Accordingly, the Company has consolidated the results of BPI since September 2013. All transactions between the Company and BPI have been eliminated in consolidation. On December 31, 2016, the Company acquired 100% of the capital stock of BPI for aggregate purchase consideration of \$595 in the form of promissory notes to each of the former stockholders of BPI. In May 2017, the promissory notes were paid in full (see Note 17).

16. Acquisition of Biohaven Pharmaceuticals, Inc.

On December 31, 2016, the Company entered into stock purchase agreements with each of the stockholders of BPI, acquiring 100% of the issued and outstanding shares of BPI for aggregate purchase consideration of \$595. Prior to the acquisition, the Company was deemed to have had a variable interest in BPI, and BPI was deemed to be a VIE of which the Company was the primary beneficiary. As a result, the Company has consolidated the results of BPI since the Company's incorporation in September 2013, and, prior to the acquisition of BPI, recognized a non-controlling interest in its consolidated balance sheet representing 100% of the capital stock of BPI not owned by the Company. The three founders of BPI, each of whom beneficially owned one-third of the equity of BPI, also serve as

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the Company's Chairman of the board of directors, Chief Executive Officer, and Chief Medical Officer, respectively (see Note 15).

The Company funded the acquisition through the issuance of promissory notes to each of the former stockholders of BPI. The notes are payable in five annual payments, the first four of which are interest only, with the final payment to include the principal balance outstanding plus any accrued and unpaid interest. The notes bear interest at a rate of 4.5% per annum and mature on December 31, 2021. The notes would become immediately due and payable upon specified events, including immediately prior to the consummation of the IPO of the Company's common shares or upon the occurrence of a change of control of the Company. There are no affirmative, negative or financial covenants associated with the notes. In May 2017, in connection with the completion of the IPO, the notes became immediately due and payable, and the Company paid the notes, including principal and unpaid interest, in full (see Note 17).

Because the Company consolidated BPI as a VIE prior to the acquisition, the acquisition of all of the capital stock of BPI did not result in a change of control for accounting purposes and was accounted for as an equity transaction. Accordingly, as of the acquisition date, the \$86 carrying value of the non-controlling interest on December 31, 2016 was derecognized and the difference between the carrying value of the non-controlling interest of \$86 and the purchase price of \$595 was recorded as a \$509 reduction to additional paid-in capital. There were no changes during the three months ended March 31, 2017.

For the three months ended March 31, 2016, the Company recorded a net loss attributable to non-controlling interests of \$35 when the Company consolidated BPI as a VIE.

17. Subsequent Events

For its unaudited consolidated financial statements as of March 31, 2017, and for the three months then ended, the Company evaluated subsequent events through June 16, 2017, the date on which those financial statements were issued.

Increase in Authorized Common Shares

On April 21, 2017, the Company effected an increase in the number of authorized common shares from 38,000,000 shares to 50,000,000 shares. Additionally, in connection with the completion of its IPO in May 2017, the Company amended its memorandum and articles of association to authorize the issuance of up to 200,000,000 no par value common shares and 10,000,000 no par value undesignated preferred shares.

2017 Equity Incentive Plan

In April 2017, the Company's shareholders approved the 2017 Plan, which became effective on May 3, 2017 in connection with the Company's IPO. The 2017 Plan provides for the grant of incentive share options, nonstatutory share options, share appreciation rights, restricted share awards, restricted share unit awards, performance-based share awards and other share-based awards. Additionally, the 2017 Plan provides for the grant of performance cash awards. The number of common shares potentially issuable under the 2017 Plan is 7,611,971 shares, which is the sum of (i) 2,712,741 newly reserved shares, (ii) 372 shares which remained available for issuance under the 2014 Plan upon the effectiveness of the 2017 Plan and (iii) the maximum number of common shares subject to outstanding awards under the 2014 Plan that could potentially expire or terminate for any reason prior to exercise or settlement; be forfeited because of the failure to meet a contingency or condition required to vest such shares or otherwise return to the Company; or be reacquired or withheld (or not issued) to satisfy a tax withholding obligation in connection with an award or to satisfy the exercise price of an award. The number of common shares that may be issued under the 2017 Plan may be increased by the Company's board of directors on January 1 of each year, beginning on January 1, 2018 and continuing through and including January 1, 2027, by a number of common shares determined by the Company's board of directors in an amount not to exceed 4% of the total number of common shares outstanding on December 31 of the preceding calendar year. The common shares underlying any awards that expire or are otherwise terminated, are settled in cash, are repurchased by the Company, or are reacquired in satisfaction of tax withholding obligations or as consideration for the exercise price of an award under the 2017 Plan will be added back to the common shares available for issuance under the 2017 Plan.

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2017 Employee Share Purchase Plan

In April 2017, the Company's shareholders approved the 2017 ESPP, which became effective on May 3, 2017 in connection with the Company's IPO. A total of 339,139 common shares were initially reserved for issuance under this plan. The number of common shares that may be issued under the 2017 ESPP will automatically increase on January 1 of each year, beginning on January 1, 2018 and continuing through and including January 1, 2027, by the least of (i) 600,000 common shares, (ii) 1% of the total number of common shares outstanding on December 31 of the preceding calendar year and (iii) a number of shares determined by the Company's board of directors.

Initial Public Offering

On May 3, 2017, the Company's registration statement on Form S-1 relating to its IPO was declared effective by the SEC. The IPO closed on May 9, 2017 and the Company issued and sold 9,900,000 common shares at a public offering price of \$17.00 per share for net proceeds of \$152,889 after deducting underwriting discounts and commissions of \$11,781 and other offering expenses of approximately \$3,630. Upon the closing of the IPO, all convertible preferred shares then outstanding converted into an aggregate of 9,358,560 common shares. Upon the conversion of the preferred shares, the remaining unamortized portion of the BCF of \$8,006 was reclassified to additional paid-in-capital as a deemed dividend. In addition on May 9, 2017, the underwriters of the IPO fully exercised their option to purchase additional shares, and on May 11, 2017, the Company issued and sold 1,485,000 additional common shares for additional net proceeds of \$23,478 after deducting underwriting discounts, commissions, and other offering costs. Thus, the aggregate net proceeds to the Company from the IPO, after deducting underwriting discounts and commissions and other offering costs, were \$176,367.

In connection with the completion of its IPO, the Company issued an additional aggregate of 1,883,523 common shares to BMS and AstraZeneca in satisfaction of the obligation to contingently issue equity securities pursuant to the license agreements (see Note 12) for no additional consideration. The contingent equity liabilities were adjusted to fair value of \$32,020 immediately prior to the completion of the IPO, and upon issuance of the common shares, the contingent equity liabilities were reclassified to equity.

Payment of Notes Payable to Related Parties

In connection with the closing of the Company's IPO in May 2017, the notes payable to related parties were paid in full, including principal of \$595. Accrued and unpaid interest of \$9 was paid in June 2017.

Yale Agreement

The Yale Agreement provides for a change-of-control payment to Yale upon the occurrence of a change-of-control event, as defined in the agreement, including an IPO. In April 2017, the agreement with Yale was amended such that if the change-of-control event is an IPO, the change-of-control payment shall be due to Yale on the first trading day when Yale is free to sell its equity interest in the Company and the change-of-control fee shall be reduced by the dollar value of Yale's equity interest in the Company on the first trading day when Yale is free to sell its equity interest in the Company. Yale's equity interest in the Company is subject to a lock-up agreement which generally restricts Yale's shares from being traded until October 31, 2017, and accordingly, the amount due to Yale in connection with the change-of-control provision of the agreement, if any, will be determined upon expiration of the lock-up period. The Company will continue to remeasure the derivative liability to fair value at each reporting date and will recognize changes in the fair value of the derivative liability until the expiration of the lock-up period in October 2017 (see Note 17).

Purchases of Kleo Common Stock

In June 2017, the Company purchased 1,375,000 shares of Kleo common stock for cash consideration of \$1,375 pursuant to its commitment under the Kleo SPA (see Note 5).

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

**MANAGEMENT’S DISCUSSION AND ANALYSIS OF
FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes for the year ended December 31, 2016 included in our final prospectus for our initial public offering of our common shares (“IPO”) filed with the Securities and Exchange Commission (“SEC”) pursuant to Rule 424(b)(4) on May 5, 2017. Some of the statements contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, constitute forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations and projections about future events. The following information and any forward-looking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, particularly including those risks identified in Part II-Item 1A “Risk Factors” and our other filings with the SEC.

Our actual results and timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q. Statements made herein are as of the date of the filing of this Form 10-Q with the SEC and should not be relied upon as of any subsequent date. Even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking

statements contained in this Quarterly Report on Form 10-Q, they may not be predictive of results or developments in future periods. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made.

Overview

We are a clinical-stage biopharmaceutical company with a portfolio of innovative, late-stage product candidates targeting neurologic diseases, including rare disorders. Our product candidates are small molecules based on two distinct mechanistic platforms—calcitonin gene-related peptide, or CGRP, receptor antagonists and glutamate modulators—which we believe have the potential to significantly alter existing treatment approaches across a diverse set of neurologic indications with high unmet need in both large markets and orphan indications. The most advanced product candidate from our CGRP receptor antagonist platform is rimegepant, an orally available, potent and selective small molecule human CGRP receptor antagonist that we are developing for the acute treatment of migraine. In July 2016, we acquired exclusive, worldwide rights to our CGRP receptor antagonist platform, including rimegepant and another product candidate, BHV-3500, which we are developing for the prevention of chronic and episodic migraine, through a license agreement with Bristol-Myers Squibb Company, or BMS. In the second half of 2017, we intend to initiate two Phase 3 clinical trials of rimegepant and to commence IND-enabling studies to allow us to ultimately pursue clinical trials of BHV-3500.

We are developing three product candidates that modulate the body's glutamate system. Two of these product candidates, trigriluzole and BHV-0223, act as glutamate transporter modulators, while our product candidate BHV-5000 is an antagonist of the glutamate *N*-methyl-D-aspartate, or NMDA, receptor. We are developing trigriluzole for the treatment of ataxias, with an initial focus on spinocerebellar ataxia, or SCA. We have received both orphan drug designation and fast track designation from the U.S. Food and Drug Administration, or FDA, for trigriluzole for the treatment of SCA and in May 2017 we completed enrollment of patients in a Phase 2/3 clinical trial, for which we expect to report topline results in the first quarter of 2018.

We are developing BHV-0223 for the treatment of amyotrophic lateral sclerosis, or ALS. In December 2016, we received orphan drug designation from the FDA for BHV-0223 to treat ALS. In the second half of 2017, we plan to commence a trial comparing the bioequivalence of BHV-0223 and riluzole in healthy volunteers. Depending on the outcome of this bioequivalence study, we plan to submit a new drug application, or NDA, to the FDA and pursue the regulatory approval of BHV-0223 for ALS under Section 505(b)(2) of the U.S. Federal Food, Drug, and Cosmetic Act.

We are also developing BHV-5000, an orally available, first-in-class, low-trapping NMDA receptor antagonist, for the treatment of symptoms associated with Rett syndrome, including breathing irregularities. Rett syndrome is a rare and severe genetic neurodevelopmental disorder for which no approved treatments are currently available. We acquired worldwide rights to BHV-5000 under an exclusive license agreement with AstraZeneca AB, or AstraZeneca, in October 2016. We anticipate completing our commercial-grade formulation efforts for BHV-5000 in the third quarter of 2017. We plan to conduct a Phase 1 clinical trial of BHV-5000 to evaluate its pharmacokinetic properties and then in 2018 to commence a single Phase 2/3 clinical trial of BHV-5000 for the treatment of breathing irregularities associated with Rett syndrome that, if successful, we believe could support our application for regulatory approval.

Since our inception in September 2013, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring and developing product candidates and related intellectual property rights, planning for commercialization, and conducting discovery, research and development

activities for our product candidates. We do not have any products approved for sale and have not generated any revenue from product sales. Prior to our IPO in May 2017, we funded our operations primarily with proceeds from the sale of preferred shares and common shares through private placements and borrowings under a credit agreement with a bank. Through March 31, 2017, we had received net cash proceeds of \$96.4 million from sales of our preferred shares and common shares through private placements and gross proceeds of \$5.0 million from borrowings under the credit agreement.

On May 3, 2017, our registration statement on Form S-1 relating to our IPO was declared effective by the SEC. The IPO closed on May 9, 2017 and we issued and sold 9,900,000 common shares at a public offering price of \$17.00 per share, for net proceeds of \$152.9 million after deducting underwriting discounts and commissions of \$11.8 million and other offering expenses of \$3.6 million. Upon the closing of the IPO, convertible preferred shares then outstanding converted into an aggregate of 9,358,560 common shares.

In addition, on May 9, 2017, the underwriters of the IPO fully exercised their option to purchase additional shares, and on May 11, 2017, we issued and sold 1,485,000 additional common shares resulting in additional net proceeds of \$23.5 million after deducting offering expenses of \$1.8 million. Thus, the aggregate net proceeds we received from the IPO, after deducting underwriting discounts and commissions and offering expenses, were \$176.4 million. In connection with the completion of the IPO, we issued an additional aggregate of 1,883,523 common shares to BMS and AstraZeneca in satisfaction of obligations to contingently issue equity securities pursuant to our license agreements for no additional consideration.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current product candidates and programs. Our net loss was \$18.8 million and \$3.0 million for the three months ended March 31, 2017 and 2016, respectively. As of March 31, 2017, we had an accumulated deficit of \$94.2 million. 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. We also expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the public or private sale of equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of March 31, 2017, we had cash of \$52.3 million. We completed our IPO in May 2017, resulting in net proceeds of \$176.4 million. We believe that our existing cash resources, including the net proceeds from our IPO, together with our cash as of March 31, 2017, will enable us to repay our indebtedness and to fund our operating expenses and capital expenditure requirements for at least 15 months from the issuance of the financial Statements. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and Capital Resources.” Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales and 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, we may generate revenue in the future from product sales.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or 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, related benefits, travel and share-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements;
- facilities costs, depreciation and other expenses, which include rent and utilities; and
- payments made in cash, equity securities or other forms of consideration under third-party licensing agreements.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Our 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 incurred under license agreements. We do not allocate employee costs or facility expenses, including depreciation 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 discovery as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

The table below summarizes our research and development expenses incurred by program:

| | Three Months Ended | |
|--|--------------------|-----------------|
| | March 31, | |
| | 2017 | 2016 |
| | (in thousands) | |
| BHV-0223 | \$ 244 | \$ 192 |
| Trigriluzole | 2,582 | 1,460 |
| Rimegepant | 2,961 | — |
| BHV-3500 | 1,636 | — |
| Research and discovery and unallocated costs | 3,317 | 718 |
| Total research and development expenses | <u>\$ 10,740</u> | <u>\$ 2,370</u> |

Research and development activities are central to our business model. 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 increase substantially over the next several years as we increase personnel costs, including share-based compensation, commence Phase 3 clinical trials of rimegepant, continue our ongoing Phase 2/3 clinical trial of trigriluzole, conduct other 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;
- establishing 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;
- establishing 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;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and

- maintaining a continued acceptable safety profile of the product candidates following approval.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. Any changes in the outcome of any of these variables with respect to the development of our product candidates in preclinical and clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. For example, if the FDA or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate. Drug commercialization will take several years and millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel expense and share-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs as well as investor and public relations expenses associated with being a public company. We anticipate the additional costs for these services will increase our general and administrative expenses by approximately \$1.5 million to \$2.0 million on an annual basis. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

Other Income (Expense)

Interest Expense

Interest expense consists of interest on outstanding borrowings under our credit agreement with Wells Fargo Bank, National Association, or Wells Fargo, entered into in August 2016 at the applicable interest rate as well as amortization of the debt discount relating to that loan. Interest expense also includes interest on our notes payable to related parties, which we issued in December 2016 in connection with our acquisition of Biohaven Pharmaceuticals, Inc., or BPI, at the applicable interest rate. Upon the closing of the IPO, we paid principal and interest aggregating \$0.6 million under the notes payable to related parties.

Change in Fair Value of Warrant Liability

In connection with entering into our credit agreement with Wells Fargo, we agreed to issue warrants to purchase our common shares to two of our directors in connection with a guarantee of our obligations under the agreement. We classify the warrants as a liability on our consolidated balance sheet that we remeasure to fair value at each reporting date, and we recognize changes in the fair value of the warrant liability as a component of other income (expense), net in our consolidated statement of operations and comprehensive loss. We will continue to recognize changes in the fair value of the warrant liability until the warrants are exercised, expire or qualify for equity classification.

Change in Fair Value of Derivative Liability

Our license agreement with Yale University, or Yale, provides for a change-of-control payment to Yale upon the occurrence of a change-of-control event, as defined in the agreement, including an initial public offering. We

classify the change-of-control payment obligation as a liability on our consolidated balance sheet that we remeasure to fair value at each reporting date, and we recognize changes in the fair value of the derivative liability as a component of other income (expense), net in our consolidated statement of operations and comprehensive loss. In April 2017, the agreement with Yale was amended such that if the change-of-control event is an IPO, the change-of-control payment shall be due to Yale on the first trading day when Yale is free to sell its equity interest in the Company and the change-of-control fee shall be reduced by the dollar value of Yale's equity interest in the Company on the first trading day when Yale is free to sell its equity interest in the Company. Yale's equity interest in the Company is subject to a lock-up, which generally restricts Yale's shares from being traded until October 31, 2017 and accordingly, the amount due to Yale in connection with the change-of-control provision of the agreement, if any, will be determined upon expiration of the lock-up period. The Company will continue to remeasure the derivative liability to fair value at each reporting date and will recognize changes in the fair value of the derivative liability until the expiration of the lock-up agreement in October 2017.

Change in Fair Value of Contingent Equity Liability

Our license agreements with BMS and AstraZeneca require us to issue shares of capital stock upon the occurrence of specified financing or change-of-control events or development milestones, as defined in the agreements. We classify these contingent obligations to issue shares as liabilities on our consolidated balance sheet that we remeasure to fair value at each reporting date, and we recognize changes in the fair values of the contingent equity liabilities as a component of other income (expense), net in our consolidated statement of operations and comprehensive loss. We continued to recognize changes in the fair values of the contingent equity liabilities until the occurrence of a respective triggering event. Upon the closing of the IPO in May 2017, the conditions for issuing shares to BMS and AstraZeneca under the terms of the respective license agreements were satisfied, and accordingly, we issued 1,345,374 and 538,149 common shares, respectively, to BMS and AstraZeneca valued at \$22.9 million and \$9.1 million, respectively. The contingent equity liabilities were adjusted to fair value immediately prior to the completion of the IPO, and upon issuance of the common shares, the contingent equity liabilities were reclassified to equity.

Loss from Equity Method Investment

In August 2016, we executed a stock purchase agreement with Kleo Pharmaceuticals, Inc., a privately-held Delaware Corporation, or Kleo, to purchase shares of Kleo's common stock at an initial closing, with a commitment to purchase an aggregate of 5,500,000 additional shares of common stock in four tranches over a 15-month period through December 2017. As of March 31, 2017, and December 31, 2016, we owned approximately 27.9% and 18.6%, respectively, of the outstanding shares of Kleo. We account for our investment in Kleo under the equity method of accounting. As a result, our proportionate share of Kleo's net income or loss each reporting period is included in other income (expense), net in our consolidated statement of operations and comprehensive loss and results in a corresponding adjustment to the carrying value of the equity method investment on our consolidated balance sheet.

Provision for Income Taxes

As a company incorporated in the British Virgin Islands, or BVI, we are principally subject to taxation in the BVI. Under the current laws of the BVI, tax on a company's income is assessed at a zero percent tax rate. As a result, we have not recorded any income tax benefits from our losses incurred in the BVI during each reporting period, and no net operating loss carryforwards will be available to us for those losses.

In addition, in each reporting period, our tax provision includes the effects of consolidating the results of operations of BPI, either through December 30, 2016 as a variable interest entity or as of and subsequent to December 31, 2016 as our wholly owned subsidiary. BPI is subject to taxation in the United States. For the three months ended March 31, 2016, we recorded no tax benefits for the losses incurred by BPI due to BPI's history of cumulative losses through that date and recorded a full valuation allowance against BPI's deferred tax assets, which consisted primarily of its U.S. net operating loss carryforwards for the three months ended March 31, 2016.

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As of December 31, 2016, we fully utilized BPI's remaining U.S. net operating loss carryforwards due to BPI's profitability in that period and we recorded a full release of the valuation allowance, which was a nominal amount. As a result, we recorded an income tax provision of \$0.2 million for the three months ended March 31, 2017 due to taxable income associated with the BPI entity.

Net Income (Loss) Attributable to Non-Controlling Interests

From our inception through December 30, 2016, we consolidated the results of BPI as a variable interest entity. Although we did not have an ownership interest in BPI through that date, we determined that BPI was a variable interest entity, of which we were the primary beneficiary.

Net income (loss) attributable to non-controlling interests in our consolidated statement of operations and comprehensive loss through December 30, 2016 consisted of the portion of the net income or loss of BPI that was not allocated to us. Changes in the amount of net income (loss) attributable to non-controlling interests were directly impacted by changes in the net income or loss of BPI. On December 31, 2016, we acquired 100% of the issued and outstanding shares of BPI. As a result, for the three months ended March 31, 2017 and for periods thereafter, we no longer report any non-controlling interests related to BPI.

Results of Operations

Comparison of the Three Months Ended March 31, 2017 and 2016

The following table summarizes our results of operations for the three months ended March 31, 2017 and 2016:

| | Three Months Ended March 31, | | Change |
|--|---------------------------------|-------------------|--------------------|
| | 2017 | 2016 | |
| | (in thousands) | | |
| Operating expenses: | | | |
| Research and development | \$ 10,740 | \$ 2,370 | \$ 8,370 |
| General and administrative | 3,757 | 613 | 3,144 |
| Total operating expenses | <u>14,497</u> | <u>2,983</u> | <u>11,514</u> |
| Loss from operations | <u>(14,497)</u> | <u>(2,983)</u> | <u>(11,514)</u> |
| Other income (expense): | | | |
| Interest expense | (305) | — | (305) |
| Change in fair value of warrant liability | (454) | — | (454) |
| Change in fair value of derivative liability | 289 | (3) | 292 |
| Change in fair value of contingent equity liability | (3,375) | — | (3,375) |
| Loss from equity method investment | (218) | — | (218) |
| Total other income (expense), net | <u>(4,063)</u> | <u>(3)</u> | <u>(4,060)</u> |
| Loss before provision for income taxes | <u>(18,560)</u> | <u>(2,986)</u> | <u>(15,574)</u> |
| Provision for income taxes | 193 | — | 193 |
| Net loss and comprehensive loss | <u>(18,753)</u> | <u>(2,986)</u> | <u>(15,767)</u> |
| Net loss attributable to non-controlling interests | — | 35 | (35) |
| Accretion of beneficial conversion feature on Series A preferred shares | <u>(4,000)</u> | | <u>(4,000)</u> |
| Net loss attributable to common shareholders of Biohaven Pharmaceutical Holding Company Ltd. | <u>\$ (22,753)</u> | <u>\$ (2,951)</u> | <u>\$ (19,802)</u> |

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Research and Development Expenses

| | Three Months Ended March 31, | | Change |
|--|---------------------------------|-----------------|-----------------|
| | 2017 | 2016 | |
| | (in thousands) | | |
| Direct research and development expenses by program: | | | |
| BHV-0223 | \$ 244 | \$ 192 | \$ 52 |
| Trigriluzole | 2,582 | 1,460 | 1,122 |
| Rimegepant | 2,961 | — | 2,961 |
| BHV-3500 | 1,636 | — | 1,636 |
| Research and discovery and unallocated costs: | | | |
| Personnel related (including share-based compensation) | 1,877 | 639 | 1,238 |
| Other | 1,440 | 79 | 1,361 |
| Total research and development expenses | <u>\$ 10,740</u> | <u>\$ 2,370</u> | <u>\$ 8,370</u> |

Research and development expenses were \$10.7 million for the three months ended March 31, 2017, compared to \$2.4 million for the three months ended March 31, 2016. The increase of \$8.4 million was primarily due to increases of \$3.0 million in direct costs for our rimegepant program, \$1.6 million in direct costs for our BHV-3500 program, \$1.1 million in spending related to our trigriluzole program in which we commenced patient enrollment in the fourth quarter of 2016 and \$2.6 million in research and discovery and unallocated costs.

The increase in direct costs for our rimegepant and BHV-3500 programs was primarily a result of our acquiring certain intellectual property rights pursuant to a license agreement executed with BMS in July 2016. The increase in direct costs for our trigriluzole program primarily related to the purchase of clinical trial supplies and clinical trial support in preparation for the Phase 2/3 clinical trial.

The increase in research and discovery and unallocated costs was primarily due to an increase of \$1.2 million in personnel-related costs, including share-based compensation, as a result of hiring additional personnel in our research and development department. Personnel-related costs for the three months ended March 31, 2017 and 2016 included share-based compensation expense of \$1.0 million and \$0.3 million, respectively. The increase in other unallocated costs was primarily due to research and development consultants that support activities across multiple drug candidate programs as well as the purchase of supplies used across all drug candidate programs.

General and Administrative Expenses

General and administrative expenses were \$3.8 million for the three months ended March 31, 2017, compared to \$0.6 million for the three months ended March 31, 2016. The increase of \$3.2 million was primarily due to increases of \$0.9 million in personnel-related costs, including share-based compensation due to hiring of additional personnel in our general and administrative functions, \$2.1 million in professional fees related to the preparation, audit and review of our financial statements as well as ongoing business operations and \$0.1 million in facility-related costs. Personnel-related costs for the three months ended March 31, 2017 and 2016 included share-based compensation expense of \$0.9 million and \$0.4 million, respectively.

Other Income (Expense), Net

Other income (expense), net was a net expense of \$4.1 million for the three months ended March 31, 2017, compared to \$3,000 for the three months ended March 31, 2016. The increase of \$4.1 million in net expense was primarily due to an increase of \$3.4 million in the fair value of the contingent equity liability associated with our license agreements with BMS and AstraZeneca, an increase of \$0.5 million in the change of the fair value of the

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warrant liability of the warrants associated with our Wells Fargo credit agreement, an increase of \$0.2 million of loss from equity method investment and an increase in interest expense of \$0.3 million due to interest on borrowings under our Credit Agreement with Wells Fargo that we entered into in August 2016. These increases in other expense were partially offset by a decrease of \$0.3 million in the change in the fair value of the derivative liability associated with our license agreement with Yale.

Provision for Income Taxes

We recorded a provision for income taxes of \$0.2 million for the three months ended March 31, 2017, compared to no provision for income taxes for the three months ended March 31, 2016. We recorded a tax provision for the three months ended March 31, 2017 for the U.S. federal and state income taxes of BPI's profitable operations in the United States during that period and due to the fact that, as of December 31, 2016, we fully utilized BPI's remaining U.S. net operating loss carryforwards.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. Prior to the completion of our IPO in May 2017, we funded our operations primarily with proceeds from the sale of preferred shares and common shares through private placements and borrowings under our credit agreement with Wells Fargo. Through March 31, 2017, we had received net cash proceeds of \$96.4 million from sales of our preferred shares and common shares and gross proceeds of \$5.0 million from borrowings under the credit agreement. As of March 31, 2017, we had cash of \$52.3 million.

On May 3, 2017, our registration statement on Form S-1 relating to our IPO was declared effective by the SEC. The IPO closed on May 9, 2017 and we issued and sold 9,900,000 common shares at a public offering price of \$17.00 per share, resulting in net proceeds of \$152.9 million after deducting underwriting discounts and commissions and other offering expenses. In addition, on May 9, 2017, the underwriters of our IPO fully exercised their option to purchase additional shares, and on May 11, 2017, we issued and sold an additional 1,485,000 common shares, resulting in additional net proceeds to us of \$23.5 million, after deducting underwriting discounts and commissions and other offering expenses. Thus, the aggregate net proceeds we received from the IPO, after deducting underwriting discounts and commissions and offering expenses, were \$176.4 million.

Upon the closing of the IPO, we paid principal and interest aggregating \$0.6 million due under the notes payable to related parties.

Cash in excess of immediate requirements is invested primarily in non-interest-bearing accounts with a view to liquidity and capital preservation.

Cash Flows

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

| | Three Months Ended | |
|---|---------------------------|-------------|
| | March 31, | |
| | 2017 | 2016 |
| | (in thousands) | |
| Net cash used in operating activities | \$ (7,652) | \$ (1,545) |
| Net cash used in investing activities | (1,578) | — |
| Net cash provided by financing activities | 37,951 | 2,980 |
| Net increase in cash | \$ 28,721 | \$ 1,435 |

Operating Activities

During the three months ended March 31, 2017, operating activities used \$7.7 million of cash, resulting from our net loss of \$18.8 million, partially offset by non-cash charges of \$5.9 million and net cash provided by changes in our operating assets and liabilities of \$5.2 million. Net cash provided by changes in our operating assets and liabilities for the three months ended March 31, 2017 consisted primarily of a \$3.0 million increase in accrued expenses and a \$2.7 million increase in accounts payable. The increases in accrued expenses and accounts payable were primarily due to increases in clinical trial costs and professional fees associated with the preparation, audit and review of our financial statements.

During the three months ended March 31, 2016, operating activities used \$1.5 million of cash, resulting from our net loss of \$3.0 million, partially offset by non-cash charges of \$0.7 million and net cash provided by changes in our operating assets and liabilities of \$0.8 million. Net cash provided by changes in our operating assets and liabilities for the three months ended March 31, 2016 consisted primarily of a \$0.6 million increase in accrued expenses, a \$0.1 million increase in accounts payable and a \$0.1 million decrease in prepaid expenses and other current assets. The increase in accrued expenses and accounts payable was due to our increased level of operating activities and the timing of vendor invoicing and payments.

Investing Activities

During the three months ended March 31, 2017, we used \$1.6 million of cash in investing activities, primarily consisting of our investment in Kleo.

During the three months ended March 31, 2016, we did not use any cash in investing activities.

Financing Activities

During the three months ended March 31, 2017, net cash provided by financing activities was \$38.0 million, primarily consisting of net proceeds of \$38.6 million from our issuance of Series A preferred shares, partially offset by \$0.7 million of payments of offering costs associated with our IPO.

During the three months ended March 31, 2016, net cash provided by financing activities was \$3.0 million, primarily consisting of net proceeds from our issuance of common shares.

Credit Agreement

On August 30, 2016, we entered into a one-year credit agreement with Wells Fargo providing for a term loan in the principal amount of \$5.0 million, or the Credit Agreement, and we borrowed the full \$5.0 million available. Our obligations under the Credit Agreement are guaranteed by a member of our board of directors, who is also a shareholder. A second member of our board of directors and shareholder entered into a separate agreement with the loan guarantor to serve as a secondary guarantor for 50% of the loan balance. In connection with their guaranties of the loan, we issued to each of these two directors an immediately exercisable warrant to purchase 107,500 common shares at an exercise price of \$9.2911 per share. Borrowings under the Credit Agreement bear interest at a variable rate equal to monthly LIBOR, which was 0.98% as of March 31, 2017, plus 1.50% per annum. In the event of a default, the interest rate applicable is equal to the monthly LIBOR rate then in effect, increased by 4.0% per annum. The Credit Agreement requires monthly, interest-only payments through the maturity date of August 30, 2017, at which date all remaining amounts will be due and payable. The Credit Agreement contains affirmative and negative covenants, but does not contain any financial covenants.

Notes Payable to Related Parties

On December 31, 2016, we entered into stock purchase agreements with each of the stockholders of BPI, acquiring 100% of the issued and outstanding shares of BPI for aggregate purchase consideration of \$0.6 million. We funded the acquisition through the issuance of promissory notes to each of the former stockholders of BPI. The three former beneficial stockholders of BPI are shareholders of our company and currently serve as our chief executive officer, our chief medical officer and the chairman of our board of directors, respectively. The notes were originally payable in

five annual payments, the first four of which were interest only, with the final payment to include the principal balance outstanding plus any accrued and unpaid interest. The notes bore interest at a rate of 4.5% per annum and were scheduled to mature on December 31, 2021. The notes would become immediately due and payable upon specified events, including immediately prior to the consummation of our IPO or upon the occurrence of a change of control of our company. There were no affirmative, negative or financial covenants associated with the notes.

Upon the closing of the IPO, we paid principal and interest aggregating \$0.6 million due under the notes payable to related parties.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials of our product candidates. In addition, as a result of our IPO, we expect to incur additional costs associated with operating as a public company. Our expenses will also increase as we:

- initiate our two planned Phase 3 clinical trials of rimegepant, conduct our ongoing Phase 2/3 potentially pivotal trial of trigriluzole and complete our planned bioequivalence study for BHV-0223;
- initiate 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;
- support formulation efforts of BHV-5000 and initiate our planned Phase 1 clinical trial for that product candidate;
- initiate formulation and clinical development for BHV-3500;
- complete commercial-grade formulation work and stability testing for all our programs;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure in anticipation of commercializing any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, medical, and development personnel;
- expand our infrastructure and facilities to accommodate our growing employee base;
- begin to operate as a public company;
- maintain, expand and protect our intellectual property portfolio; and
- acquire or in-license other product candidates and technologies.

We believe that the net proceeds from our IPO in May 2017, together with our existing cash as of March 31, 2017, will enable us to repay our indebtedness and to fund our operating expenses and capital expenditure requirements for at least the next 15 months, including the completion of our ongoing Phase 2/3 clinical trial of trigriluzole. 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 commercialize rimegepant, if we receive regulatory approval, and to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for rimegepant, trigriluzole or our other product candidates, we expect to incur significant

commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize.

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

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of manufacturing commercial-grade product and necessary inventory to support commercial launch;
- the costs associated with in-licensing additional products candidates to augment our current pipeline; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, other third-party funding, strategic alliances, licensing arrangements or marketing and distribution arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may 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.

We will also incur costs as a public company that we have not previously incurred or have previously incurred at lower rates, including but not limited to, increased costs and expenses for fees to members of our board of directors, increased personnel costs, increased directors and officers insurance premiums, audit and legal fees, investor relations fees and expenses for compliance with reporting requirements under the Exchange Act and rules implemented by the SEC and the New York Stock Exchange.

Contractual Obligations and Commitments

The disclosure of our contractual obligations and commitments is set forth under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” in our final prospectus filed with the SEC on May 5, 2017. See Note 14 to our consolidated financial statements included in Item 1, “Consolidated Unaudited Financial Statements,” of this Quarterly Report on Form 10-Q for a discussion of obligations and commitments.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis.

Our actual results may differ from these estimates under different assumptions or conditions. During the three months ended March 31, 2017, there were no material changes to our critical accounting policies. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations— Critical Accounting Policies and Significant Judgments and Estimates” in our final prospectus dated May 3, 2017 for the IPO, which was filed with the SEC on May 5, 2017 and the notes to the consolidated financial statements included in Item 1, “Consolidated Unaudited Financial Statements,” of this Quarterly Report on Form 10-Q. We believe that of our critical accounting policies, the following accounting policies involve the most judgment and complexity:

- accrued research and development expenses;
- share-based compensation;
- determination of the fair value of common shares;
- valuation of warrant liability;
- valuation of derivative liability; and
- valuation of contingent equity liability.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing at the beginning of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

Interest Rate Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of March 31, 2017 and December 31, 2016, we had cash of \$52.3 million and \$23.6 million, respectively. As of March 31, 2017, we generally held our cash in non interest-bearing money market accounts. Our primary exposure to market risk at that point in time was interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents and the low risk profile of our investments at March 31, 2017, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents.

Prior to the completion of our IPO in May 2017, we adopted an investment policy related to the use of the net proceeds from the sale of our common shares in our IPO, pursuant to which we plan to hold such net proceeds in non-interest bearing accounts, with the goal of capital preservation and liquidity so that such funds are readily available to fund our operations.

As of March 31, 2017, we had \$5.0 million of borrowings outstanding under the Credit Agreement. Amounts outstanding under the Credit Agreement bear interest at a variable rate equal to monthly LIBOR, which was 0.98% as of March 31, 2017, plus a margin of 1.50%. An immediate 10% change in monthly LIBOR rates would not have had a material impact on our debt-related obligations, financial position or results of operations. In addition, given

the short-term nature of the Credit Agreement, which matures in August 2017, we do not believe our exposure to interest rate risk is significant.

Our notes payable to related parties outstanding as of March 31, 2017 bore interest at fixed interest rates and, therefore, did not expose us to interest rate risk. Upon the closing of the IPO, we paid principal and interest aggregating \$0.6 million due under the notes payable to related parties.

We do not engage in any hedging activities against changes in interest rates. We do not have any foreign currency or other derivative financial instruments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Based on the evaluation of our disclosure controls and procedures as of March 31, 2017, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2017, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weaknesses discussed below. Notwithstanding these material weaknesses, our management has concluded that the financial statements included elsewhere in this Quarterly Report present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with generally accepted accounting principles (“GAAP”).

In connection with the preparation of our financial results for the years ended December 31, 2014 and 2015, our management concluded that, as of December 31, 2015, our internal control over financial reporting was not effective as a result of material weaknesses in our control over financial reporting. The material weaknesses remained unremediated as of December 31, 2016 and March 31, 2017. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses identified in our internal control over financial reporting included the following:

We did not design or maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of trained professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. This material weakness contributed to the following material weakness:

- We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries. Additionally, we did not design and maintain controls over the appropriate classification and presentation of accounts and disclosures in the financial statements.
- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions. Specifically, we did not design and maintain controls to analyze, account for and disclose complex licensing agreements, income taxes, variable interest

entities, debt arrangements, equity method investments, share-based compensation arrangements, derivative liabilities, warrants to purchase common shares and contingently issuable equity.

- We did not design and maintain controls over our supervision and review of the completeness and accuracy of third-party vendors' computations supporting our common share valuations.
- We did not design and maintain controls over the operating effectiveness of information technology, or IT, general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain effective controls over program change management; user access, including segregation of duties; or computer operations.

Changes in Internal Controls over Financial Reporting

During the three months ended March 31, 2017, we hired a corporate controller to begin to address the above-referenced material weaknesses.

Except as described above, there has been no change in our internal control over financial reporting during the three months ended March 31, 2017 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

You should carefully consider the risks described below, as well as general economic and business risks and the other information in this Quarterly Report on Form 10-Q. 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 stock to decline. Additional risks or uncertainties not presently known to us or that we currently deem immaterial may also harm our business.

Risks Related to Our Financial Position and Need for Additional Capital

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

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

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

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

Since our inception, we have incurred significant operating losses. Our net loss was \$18.8 million and \$63.5 million for the three months ended March 31, 2017 and the year ended December 31, 2016, respectively. As of March 31, 2017, we had an accumulated deficit of \$94.2 million. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. None of our product candidates have been approved for marketing in the United States, or in any other jurisdiction, and 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:

- continue the development of our product candidates, including the initiation of two Phase 3 clinical trials and a long-term safety study of rimegepant for the acute treatment of migraine, the completion of our ongoing Phase 2/3 clinical trial of trigriluzole for the treatment of spinocerebellar ataxia, or SCA, and the initiation and conduct of additional clinical trials and preclinical studies for our other product candidates for various neurological indications;
- 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, regulatory, scientific and accounting 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 U.S. Food and Drug Administration, or FDA, or other regulatory authorities such as the European Medicines Agency, or 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, in our trigriluzole clinical program, we recently enrolled the first patient in our Phase 2/3 clinical trial of trigriluzole for the treatment of SCA, and, given the small number of SCA patients, we believe that, if successful, this Phase 2/3 clinical trial will be the only pivotal trial necessary to support regulatory approval. Likewise, due to the small number of patients with Rett syndrome, we believe that BHV-5000 will require only a single pivotal trial. However, the FDA ordinarily requires two well-controlled clinical trials prior to marketing approval of a product candidate. If the FDA requires us to conduct additional clinical trials of trigriluzole or BHV-5000, 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. Furthermore, we expect to incur additional costs associated with operating as a public company.

As of March 31, 2017, we had cash of \$52.3 million, and in May 2017, we received an additional \$176.4 million in net proceeds from the sale of our common shares in our IPO. We expect that our existing cash, including the net proceeds from our IPO, will enable us to repay our indebtedness and to fund our operating expenses and capital expenditure requirements through October 2018. 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;

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- 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. See “—Our status as a British Virgin Islands, or BVI, business company means that our shareholders enjoy certain rights that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs” for additional information related to our ability to timely raise capital. 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.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our most recent audited financial statements.

Our report from our independent registered public accounting firm for the year ended December 31, 2016 includes an explanatory paragraph stating that our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected and we may be unable to continue as a going concern. If we are unable to continue

as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

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

In July 2016, we acquired the rights to rimegepant and another product candidate, BHV-3500, pursuant to a license agreement with Bristol-Myers Squibb Company, or BMS, and in October 2016, we acquired the rights to BHV-5000 pursuant to a license agreement with AstraZeneca AB, or AstraZeneca. We are subject to significant obligations under these agreements, including payment obligations upon achievement of specified milestones and royalties on product sales, as well as other material obligations. We may be obligated to pay BMS up to \$127.5 million in development milestones for rimegepant or a derivative thereof, up to \$74.5 million in development milestones for any licensed product other than rimegepant, and up to \$150.0 million in commercial milestones for each licensed product. We may also be obligated to pay AstraZeneca up to \$30.0 million in development milestones for licensed products for the treatment of Rett syndrome, up to \$60.0 million in development milestones for licensed products for indications other than Rett syndrome, and up to \$120.0 million in commercial milestones. We are also obligated to pay fixed royalties based on net sales of rimegepant, BHV-3500 and BHV-5000, or any other product that is a licensed product under those agreements. If these payments become due under the terms of our license agreements with BMS and AstraZeneca, we may not have sufficient funds available to meet our obligations and our development efforts may be materially harmed.

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

Moreover, under our agreement with BMS, until 2023, neither we nor our affiliates may, ourselves or through or in collaboration with a third party, engage directly or indirectly in the clinical development or commercialization of competitive compounds related to the CGRP-based mechanism of action of the licensed products. In the event that we are or become non-compliant with this provision due to licensing, collaboration or acquisition activity, we must either divest ourselves of the competitive compound within a certain period of time or negotiate with BMS to have the competitive compound included as a licensed product under our agreement with BMS. The failure to so divest or reach terms with BMS may result in the termination of our license with BMS. These prohibitions could adversely impact or delay our ability to effect certain transactions, such as our ability to acquire or be acquired by a third party.

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 or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

Risks Related to the Development of Our Product Candidates

We depend entirely on the success of a limited number of product candidates, which are in clinical development and none of which have completed a pivotal trial. If we do not obtain regulatory approval for and successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We expect that a substantial portion of our efforts and expenses over the next few years will be devoted to the development of our product candidates; specifically, the commencement of two Phase 3 trials of rimegepant, the conducting of our ongoing Phase 2/3 trial of trigriluzole, and other preclinical and clinical activities related to BHV-0223, BHV-5000 and BHV-3500. 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 our product candidates will receive regulatory approval or will be successfully commercialized even if they receive regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to comprehensive regulation by the FDA and similar foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical studies and clinical trials that the product candidate is safe and effective for use in each target indication. Drug development is a long, expensive and uncertain process, and delay or failure can occur at any stage of any of our clinical trials. Failure to obtain regulatory approval for our product candidates in the United States will prevent us from commercializing and marketing our product candidates. The success of our product candidates will depend on several additional factors, including:

- completing clinical trials that demonstrate their efficacy and safety;
- receiving marketing approvals from applicable regulatory authorities;
- completing any post-marketing studies required by applicable regulatory authorities;
- establishing commercial manufacturing capabilities;
- launching commercial sales, marketing and distribution operations;
- the prevalence and severity of adverse events experienced with our product candidates;
- acceptance of our product candidates by patients, the medical community and third-party payors;

- a continued acceptable safety profile following approval;
- obtaining and maintaining healthcare coverage and adequate reimbursement for our product candidates;
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved; and
- qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape. It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would materially harm our business, financial condition and results of operations.

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

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

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage preclinical studies or clinical trials. The results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Further, we have limited clinical data for each of our product candidates and have not completed Phase 3 clinical trials for any 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. For example, the favorable results of the Phase 2b trial of rimegepant may not be predictive of similar results in subsequent trials. In particular, we are developing a new dosage form of rimegepant for use in our planned Phase 3 clinical trials of rimegepant. We cannot be certain that we will observe the same results in our Phase 3 trials with the new dosage form as we did in the Phase 2b clinical trial of rimegepant. In later-stage clinical trials, we will likely be subject to more rigorous statistical analyses than in completed earlier stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to produce positive results in our planned pre-clinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be materially adversely affected.

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

Because we in-licensed rimegepant and BHV-3500 from BMS and BHV-5000 from AstraZeneca, we were not involved in and had no control over the preclinical and clinical development of these product candidates prior to entering into these in-license agreements. In addition, we are relying on BMS and AstraZeneca to have conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of the applicable product candidate, and having correctly collected and interpreted the data from these studies and trials. To the extent any of these has not occurred, our expected development time and costs may be increased, which could adversely affect our prospects for marketing approval of, and receiving any future revenue from, these product candidates.

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

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

- the FDA disagreeing as to the design, protocol or implementation of our clinical trials;
- the delay or refusal of regulators or institutional review boards, or IRBs, to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol or dropping out of a trial;
- negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns that could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- reports from pre-clinical or clinical testing of other similar therapies that raise safety or efficacy concerns;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;

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- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality or stability of the product candidate falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of the product candidate to commence or complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

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

We will need to take a variety of steps before commencing our two planned Phase 3 clinical trials and 12-month safety study of rimegepant and our planned clinical trials of BHV-0223 and BHV-5000. With respect to rimegepant, we had an end of Phase 2 meeting with the FDA in March 2017 at which we reviewed the Phase 2b clinical trial data with the FDA and presented our overall plan for our planned Phase 3 clinical trials and safety study and our proposed path to registration. At the meeting, we agreed to submit our trial protocols to the FDA prior to the commencement of our Phase 3 trials. The FDA could disagree with the proposed design of our planned Phase 3 clinical trials and safety study and could require, in any trial or all trials, a larger number of patients or a longer course of treatment than our current expectations. If the FDA takes such positions, the costs of our planned Phase 3 clinical trials and safety study of rimegepant could increase significantly and the potential commercialization of rimegepant could be delayed. The FDA also may require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit such data before it will consider a NDA.

In addition, prior to commencing our two planned Phase 3 clinical trials, we will have to obtain sufficient clinical supply of rimegepant and complete a study to compare the pharmacokinetics for a new formulation of rimegepant with the prior formulation. We cannot be certain that the results observed in our Phase 2b clinical trial will be replicated with the new formulation.

In order to commence our planned clinical trials of BHV-0223 and BHV-5000, we will have to complete development of a commercial-grade formulation and obtain sufficient clinical supply of both product candidates.

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

We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Any delays in completing our clinical trials will increase our

costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue from product sales. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

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

Our future success is dependent upon our ability to successfully develop, obtain regulatory approval for and then successfully commercialize one or more of our product candidates. The time required to obtain approval by the FDA is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval is generally uncertain, may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. 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 a New Drug Application, or NDA, from the FDA or approval from the EMA or other applicable foreign regulatory agency.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we must demonstrate to the satisfaction of the FDA, EMA or any comparable foreign regulatory agency, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. The FDA, EMA 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 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 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 or the applicable foreign regulatory agency that our product candidates are safe and effective for their proposed indications;
- the FDA's, EMA'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 or other applicable foreign regulatory agencies' disagreement with the interpretation of data from preclinical studies or clinical trials;

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- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's, EMA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the FDA's, EMA'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 or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA, EMA 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 ongoing Phase 2/3 clinical trial for trigriluzole for the treatment of SCA, the FDA has stated that elements of the SARA (i.e., gait, stance, sitting and speech disturbance) appear capable of reflecting a clinically meaningful benefit for patients depending on how the scoring of these items is defined. If the scoring categories are based on clinically important distinctions, use of these items as a primary endpoint in studies intended to support approval could be appropriate. However, the FDA has stated its concern that our use of the SARA scale, as currently constructed, as a primary endpoint is not appropriate in this trial. No drug has been approved for the treatment of SCA and, therefore, a clear regulatory pathway for approval has not previously been established. Although we selected the SARA scale, which is a validated scale that has been used in a third-party clinical trial for the treatment of hereditary ataxias (including SCA), as the primary outcome measure for the trial based on advice of an advisory panel of ataxia experts, we plan to continue to interact with the FDA to discuss its concerns and consider incorporating any feedback in our analysis of the clinical trial data that we collect and measure with the SARA. Because we have already begun our Phase 2/3 clinical trial and the FDA has not suggested an alternative scale that it believes would be acceptable to assess clinical benefit in SCA, we have limited options to incorporate an alternate scale that has been validated and is accepted by the field's experts as measuring clinically meaningful changes. As such, we cannot guarantee that the FDA or any future advisory committee will be satisfied with our approach using the SARA. We cannot guarantee that any regulatory agency or future advisory committee would interpret a successful outcome using the SARA as our primary measure in the same fashion that we would.

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

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

FDA guidance regarding the approval of drugs for the treatment of acute migraine has recently changed. No drug has been approved under the new guidance, and it is not certain how such guidance will be interpreted and applied by the FDA. We intend to seek advice and guidance from the FDA including, at a minimum, requesting a pre-NDA meeting with the FDA prior to the submission of an NDA for any of our product candidates. If the feedback we receive is different from what we currently anticipate, this could delay the development and regulatory approval process for these product candidates.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and other key global markets. To obtain regulatory approval in other countries, we must comply

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

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

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

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

For example, in its Phase 2b clinical trial, rimegepant dosed at 75 mg showed statistically significant improvement as compared to placebo on all four key migraine symptoms—pain, nausea, photophobia, phonophobia—which are inherently subjective endpoints that are difficult to measure. Patients in the trial were provided with an electronic data capturing device, or an electronic subject diary, which they used to record and rank their assessments of pain, nausea, photophobia and phonophobia at specified time points after they had taken the study medication following the occurrence of a moderate to severe migraine headache. The measurements from the trial were based on subjective patient feedback as recorded on their electronic subject diary, which can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical study. The placebo effect also tends to have a more significant impact on clinical trials involving subjective measures such as pain.

Moreover, undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, the limitation of commercial potential or the delay or denial of regulatory approval by the FDA. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Accordingly, we may need to abandon their development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. Prior to any regulatory approval of rimegepant, we would need to complete a 12-month safety study as well as longer-term nonclinical toxicology and carcinogenicity studies. If any of these studies identify safety issues, we may need to complete additional studies, or abandon development of rimegepant. Many compounds that initially showed promise in preclinical or early-stage testing have later been found to cause side effects that restricted their use and prevented further development of the compound in the tested indication.

In animal studies, at very high doses, rimegepant was observed to have a negative effect on the liver. We observed elevated liver enzymes in one patient that received very high doses of rimegepant in a drug-drug interaction study.

In the completed Phase 2b trial of rimegepant conducted by BMS, one patient dosed with rimegepant experienced an asymptomatic and mild increase in certain hepatic enzymes, which are a type of liver enzyme measured in a liver function test to detect damage and inflammation to the liver. Even though no patient treated with rimegepant in the Phase 2b trial had liver enzyme elevation that exceeded the level that is considered by the FDA to be a potentially meaningful indicator of severe drug-induced liver injury, we cannot guarantee that these safety and tolerability results will be replicated in our Phase 3 trials, and it is possible that rimegepant may be observed to cause unacceptable levels of adverse effects or serious adverse effects.

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

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

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

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to approval or post-marketing studies required by regulatory authorities of such product;

- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

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

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

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

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

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

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the study until its conclusion. If we are unable to enroll a sufficient number of patients in our clinical trials, our timelines for recruiting patients, conducting clinical trials and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of our clinical trials altogether.

We cannot predict how successful we will be at enrolling patients in future clinical trials. Patient enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;

- the size of the patient population required for analysis of the trial’s primary endpoints;
- competition for patients for competitive product candidates undergoing clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the design of the trial;
- the patient referral practices of physicians;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion;
- the ability to obtain and maintain patient consents;
- the number of patients with the indication being studied; and
- the proximity and availability of clinical trial sites for prospective patients.

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

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

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

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

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

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

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

If 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 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 them.

We operate in a highly competitive and rapidly changing industry.

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

With respect to our CGRP receptor antagonists, rimegepant and BHV-3500, we face competition from other companies that market or are developing migraine treatments. These include products in the class of products known as triptans, including the 5-HT_{1F} receptor antagonist lasmiditan being developed by CoLucid Pharmaceuticals, as well as other small molecule CGRP receptor antagonists such as ubrogepant, being developed by Allergan. These products are more advanced in their clinical development than rimegepant and BHV-3500, and therefore may receive marketing approval before our migraine product candidates receive marketing approval, if at all, which could make it more difficult for our products to achieve commercially reasonable market acceptance. In addition, we expect that our migraine product candidates will also compete with opioids and other analgesics, monoclonal antibodies in development and Botox and other treatments that have been approved by the FDA for migraine.

With respect to BHV-0223, which we are developing for the treatment of ALS, we believe our primary competition is Covis Pharmaceuticals, which sells Rilutek, the brand name for riluzole, and the six approved generic versions of Rilutek, which is currently the only approved drug for the treatment of ALS in the United States. We are aware of at least two other companies marketing or planning to market new formulations of riluzole. MonoSol Rx has filed an IND with the FDA to conduct clinical trials for a riluzole oral soluble film, and Italfarmaco SpA, or Italfarmaco, a private Italian company, markets an oral liquid suspension formulation of riluzole in the United Kingdom and elsewhere in Europe under the brand name Teglutik. To our knowledge, no other companies are marketing sublingual formulations of riluzole. Other companies of which we are not aware may also be developing formulations using the API riluzole; if such companies pursued regulatory approval of such product candidates using the Section 505(b)(2) regulatory pathway, those product candidates would potentially compete with BHV-0223. For example, Italfarmaco has obtained orphan designation for Teglutik, and is eligible to obtain orphan exclusivity subject to a showing of clinical superiority to riluzole. If Teglutik is shown to be clinically superior to Rilutek and receives marketing approval before BHV-0223, then BHV-0223 may need to demonstrate clinical superiority to Teglutik to receive marketing approval.

With respect to trigriluzole, which we are currently developing for the treatment of ataxias, with SCA as our initial indication, there are currently no approved drug treatments for spinocerebellar ataxias in the United States. With respect to BHV-5000, which we are developing for the treatment of Rett syndrome, there are currently no approved treatments for Rett syndrome in the United States.

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

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical

testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors.

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

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

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

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

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors 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 governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize, and attract additional collaboration partners to invest in the development of our product candidates. Coverage under certain government programs, such as Medicare, Medicaid and Tricare, may not be available for certain of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and adequate reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

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

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

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

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of 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 health care services to contain or reduce costs of health care may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and 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, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMP, regulations and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a

condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

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

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

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

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. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue or any profits from operations. The degree of market acceptance of our product candidates that are approved for commercial sale will depend on a variety of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;

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

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

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. If the actual market for our product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our revenue from product sales may be limited and we may be unable to achieve or maintain profitability.

We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, or if we fail to achieve adequate pricing or reimbursement we will not be successful in commercializing our product candidates, if approved.

We currently have no marketing, sales and distribution capabilities and our product candidates are still in clinical development. If any of our product candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, or to outsource these functions to a third party. Either of these options would be expensive and time-consuming. These costs may be incurred in advance of any approval of our product candidates. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

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

receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

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

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

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

While we believe that rimegepant contains active ingredients that would be treated as NCEs by the FDA and, therefore, if approved, should be afforded five years of data exclusivity, the FDA may disagree with that conclusion and may approve generic products after a period that is less than five years. Moreover, while we believe that trigriluzole, a prodrug of riluzole, and BHV-5000 will also be treated as NCEs under current FDA interpretations, if approved, the FDA may ultimately disagree with our conclusion. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product.

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

Risks Related to Our Dependence on Third Parties

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

We are party to several license agreements under which we in-license patent rights and other intellectual property related to our business, including a license agreement with BMS, under which we were granted an exclusive license relating to rimegepant and BHV-3500, a license agreement with ALS Biopharma and FCCDC, pursuant to which we were assigned intellectual property rights relating to trigriluzole, a license agreement with Catalent, pursuant to which we were granted an exclusive license to use their Zydis technology in the development of BHV-0223, and a license agreement with AstraZeneca, pursuant to which we were granted an exclusive license relating to BHV-5000.

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

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

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

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

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

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

We intend to conduct our future clinical trials, including our two planned Phase 3 clinical trials of rimegepant and our Phase 2/3 clinical trial of trigriluzole, using our own clinical resources while also leveraging expertise and assistance from CROs as appropriate. We do not currently have the ability to independently conduct large-scale clinical trials, such as a Phase 3 clinical trial, without outside assistance.

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

We and our CROs and other vendors are required to comply with cGMP, GCP and GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Union and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and other contractors. Although we rely on CROs to conduct any current or planned GLP-compliant preclinical studies and GCP-compliant clinical trials and have limited influence over their actual

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

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

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

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

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

Although we have auditing rights with all our manufacturing counterparties, we do not have control over a supplier's or manufacturer's compliance with these laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted or of satisfactory quality or continue to be available at acceptable prices. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. In the event that any of our manufacturers fails to comply with regulatory requirements or to perform its obligations

to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, or if the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities. Any replacement of our manufacturers could require significant effort, time and expense, which could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

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

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

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

We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers; we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates 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 APIs and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with

regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates.

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

We also rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. For example, Catalent is the sole-source supplier for the Zydis formulation of BHV-0223. We may also have sole-source suppliers for one or more of our other product candidates. Some of the APIs and other substances and materials used in our product candidates are currently available only from one or a limited number of domestic or foreign suppliers and foreign manufacturers and certain of our finished product candidates are manufactured by one or a limited number of contract manufacturers. In the event an existing supplier fails to supply product on a timely basis or in the requested amount, supplies product that fails to meet regulatory requirements, becomes unavailable through business interruption or financial insolvency or loses its regulatory status as an approved source or if we or our manufacturers are unable to renew current supply agreements when such agreements expire and we do not have a second supplier, we likely would incur added costs and delays in identifying or qualifying replacement manufacturers and materials and there can be no assurance that replacements would be available to us on a timely basis, on acceptable terms or at all. In certain cases we may be required to get regulatory approval to use alternative suppliers, and this process of approval could delay production of our products or development of product candidates indefinitely. We and our manufacturers do not currently maintain inventory of these APIs and other substances and materials. Any interruption in the supply of an API or other substance or material or in the manufacture of a finished product could have a material adverse effect on our business, financial condition, operating results and prospects.

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

As we prepare for later-stage clinical trials and potential commercialization, we will need to take steps to increase the scale of production of our product candidates, which may include transferring production to new third-party suppliers or manufacturers. In order to conduct larger or late-stage scale clinical trials for our product candidates and supply sufficient commercial quantities of the resulting drug product and its components, if that product candidate is approved for sale, our contract manufacturers and suppliers will need to produce our product candidates in larger quantities, more cost effectively and, in certain cases, at higher yields than they currently achieve. These third-party contractors may not be able to successfully increase the manufacturing capacity for any of such product candidates

in a timely or cost-effective manner or at all. Significant scale up of manufacturing may require additional processes, technologies and validation studies, which are costly, may not be successful and which the FDA and foreign regulatory authorities must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the APIs or the finished product. If our third-party contractors are unable to successfully scale up the manufacture of any of our product candidates in sufficient quality and quantity and at commercially reasonable prices, and we are unable to find one or more replacement suppliers or manufacturers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and we are unable to successfully transfer the processes on a timely basis, the development of that product candidate and regulatory approval or commercial launch for any resulting products may be delayed, or there may be a shortage in supply, either of which could significantly harm our business, financial condition, operating results and prospects.

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

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

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

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

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

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

product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

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

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

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

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

research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive;

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

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

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

Our product development programs and the 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 candidate. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

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

addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

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

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

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

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

Risks Related to Regulatory Compliance

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

In the United States, the European Union, and other foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changes the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include:

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- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% 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 a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or 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 addition, the current administration and Congress will likely continue to seek legislative and regulatory changes, including repeal and replacement of certain provisions of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In March 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act, which, if enacted, would have amended or repealed significant portions of the ACA. We believe the U.S. Senate is unlikely to adopt the American Health Care Act as passed by the U.S. House of Representatives. However, the U.S. Senate could adopt the American Health Care Act as passed by the U.S. House of Representatives or other legislation to amend or replace elements of the ACA. It is uncertain whether the American Health Care Act will become law. We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have an adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. The U.S. Department of Health and Human Services, or HHS, set a goal of moving 30% of Medicare payments to alternative payment models tied to the quality or value of services by 2016 and 50% of Medicare payments into these alternative payment models by the end of 2018. In March, HHS announced that it has achieved its goal for 2016. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. 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.

Individual states in the United States have also become 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. 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.

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to

changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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

Although we do not currently have any products on the market, if we obtain FDA approval for our product candidates, 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, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Modifications to the HIPAA

Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, commonly referred to as the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to HIPAA, i.e. health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as 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 the 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; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

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

Our orphan drug exclusivity for BHV-0223 for ALS is contingent upon a showing that BHV-0223 is clinically superior to Rilutek in the treatment of ALS. Clinical superiority may be demonstrated by showing that a drug has greater effectiveness than the approved drug, greater safety in a substantial portion of the target population, or otherwise makes a major contribution to patient care. If we are unable to demonstrate that BHV-0223 is clinically superior to riluzole, we will not be entitled to the benefits of orphan drug exclusivity for BHV-0223 for ALS, which could adversely affect our business and our ability to market and sell BHV-0223 if it is approved for sale.

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

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

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

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

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

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

The patent prosecution process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions. Key patents covering rimegepant (BHV-3000) and BHV-3500 have been granted in the United States and various other countries throughout the world. Certain other patent applications relating to rimegepant and BHV-3500 are pending in the United States and other countries. None of our owned or in-licensed patents relating to BHV-5000, trigriluzole or BHV-0223 are issued at this time. Patent applications relating to BHV-5000, trigriluzole and BHV-0223 are pending in the United States and various other countries throughout the world, or are pending under the Patent Cooperation Treaty (PCT). As applicable deadlines under the PCT become due, we will have to decide whether and where to pursue patent protection for the various inventions claimed in our patent portfolio, and we will only have the opportunity to obtain patents in those jurisdictions where we pursue protection.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, products. Any such outcome could have a negative effect on our business.

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

Even if patents do successfully issue and even if such patents cover our current or future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable, which could allow third parties to commercialize our technology or products and

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

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

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

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

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

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

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

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

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

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

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

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

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

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

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

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

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

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, and the extension cannot extend the total patent term beyond fourteen years from approval. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. Because riluzole has already been approved, we will not be eligible to obtain patent term extension for any of our patents, should they issue, that cover BHV-0223.

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

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

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

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

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

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

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology, such as compounds or formulations that are similar to our product candidates, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;

- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

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

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the U.S. Patent and Trademark Office, or USPTO, after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing additional opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The USPTO has developed in the last few years regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA, and, in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaboration partners' patent applications and the enforcement or defense of our or our licensors' or collaboration partners' issued patents, all of which could have an adverse effect on our business and financial condition.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, such as *Impression Products, Inc. v. Lexmark International, Inc.*, *Association for Molecular Pathology v. Myriad Genetics, Inc.* (Myriad I), *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, and *Alice Corporation Pty. Ltd. v. CLS Bank International*, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. For example, the April 2010 amendment of the European Patent Convention, which limited the time permitted for filing divisional applications, was subsequently abrogated. This amendment and subsequent abrogation illustrates the uncertainty involved in the prosecution of European patent laws. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. These changes could limit our ability to obtain new patents in the future that may be important for our business.

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

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

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

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

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

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than we or our licensors or collaborators can. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

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

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

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

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

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

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

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

Filing, prosecuting and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby

precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

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

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

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

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

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

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

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

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

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

In addition to seeking patents for some of our technology and product candidates, via intellectual property we own or license, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third

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

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

We may not be able to prevent misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our products, our competitors might be able to enter the market, which would harm our

business. In addition, to the extent that we have responsibility for taking any action related to the prosecution or maintenance of patents or patent application in-licensed from a third party, any failure on our part to maintain the in-licensed rights could jeopardize our rights under the relevant license and may expose us to liability.

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

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

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

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

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

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

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

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- tariffs and trade barriers;
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing foreign reimbursement landscapes;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

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

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

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

We 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 of March 31, 2017, we had 19 employees, all of which were employed directly by our U.S. subsidiary, Biohaven Pharmaceuticals, Inc. 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 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 stock have been subject to securities class action litigation. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

Risks Related to Ownership of Our Common Shares

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

Prior to May 4, 2017, there was no public market for our common shares, and we cannot assure you that an active trading market will continue to develop or be sustained. If an active market for our common shares does not develop or 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.

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, 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:

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

These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our

offerings or business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common shares.

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

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

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

As a public company listed in the United States, we will incur significant legal, accounting and other expenses. We estimate the additional costs we will incur as a result of being a public company to be approximately \$1.5 million to \$2.0 million annually. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and the New York Stock Exchange, may increase legal and financial compliance costs and make some activities more time consuming. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities.

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

In addition, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Concentration of ownership of our common shares among our executive officers, directors and existing principal shareholders may prevent new investors from influencing significant corporate decisions.

Our directors and executive officers, and entities affiliated with them, as well as current holders of more than 5% of our outstanding common shares, in the aggregate, beneficially own 54.4% of our common shares. These shareholders, acting together, would be able to control or significantly influence all matters requiring shareholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

Some of these persons or entities may have interests different than yours. For example, because many of these shareholders purchased their shares at prices substantially below the current market price of our common shares and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other shareholders.

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

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

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

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

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common shares to drop significantly, even if our business is doing well.

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

As of June 14, 2017, we had 35,478,083 common shares outstanding. Of these, approximately 11.4 million shares are freely tradable without restrictions or further registration under the Securities Act except for any shares held by our affiliates as defined in Rule 144 under the Securities Act, and an additional 24.4 million common shares will be available for sale in the public market beginning at the end of October 2017, following the scheduled expiration of lock-up agreements between some of our shareholders and the underwriters in connection with our recent IPO. The representatives of the underwriters may release these stockholders from their lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of shares in the public market.

In addition, we filed a registration statement on Form S-8 registering the issuance of approximately 12.8 million common shares subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans and our employee stock purchase plan. These registered shares will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144.

Additionally, the holders of approximately 26.2 million common shares are entitled to rights with respect to registration of such shares under the Securities Act pursuant to an investors' rights agreement between such holders and us. If we file a registration statement for the purpose of selling additional shares to raise capital and are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired.

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

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

We have broad discretion in the use of proceeds from our recent IPO and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management has broad discretion in the application of the net proceeds from our recent IPO and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common shares. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment.

We expect to, and in some cases have begun to, use the net proceeds from our recent IPO to conduct our two planned Phase 3 clinical trials of rimegepant for the acute treatment of migraine; to fund continued research and development of BHV-3500 for the prevention of chronic and episodic migraine; to complete our ongoing Phase 2/3 clinical trial of trigriluzole for the treatment of spinocerebellar ataxia; to fund continued research and development of BHV-5000 for the treatment of symptoms associated with Rett syndrome, including completion of our planned Phase 1 clinical trial for this indication; to fund other research and development activities, including development of BHV-0223 for the treatment of ALS; to repay indebtedness outstanding under our credit agreement and notes payable to related parties; and for working capital and other general corporate purposes, including the satisfaction of any milestone payment obligations under our license agreements. The failure by our management to apply these funds effectively could result in financial losses that could have an adverse effect on our business, cause the price of our common shares to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from our IPO in a manner that does not produce income or that loses value.

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 Jumpstart Our Business Startups Act of 2012, or 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, 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 and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an “emerging growth company.” We could be an “emerging growth company” until December 31, 2022, which is the end of the fiscal year following the fifth anniversary of the completion of our recent IPO, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common shares held by non-affiliates exceeds \$700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an “emerging growth company” as of the following December 31 (our fiscal year end). 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.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common shares.

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

If we are unable to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common shares.

Prior to the completion of our IPO, we have been a private company with limited accounting personnel and other resources to address our internal control over financial reporting. In preparation of our financial statements to meet the requirements of our IPO, we determined that material weaknesses in our internal control over financial reporting existed during each of fiscal 2014 and 2015 and remained unremediated as of December 31, 2016. These material weaknesses in our internal control over financial reporting are described below.

We did not design or maintain an effective control environment commensurate with our financial reporting requirements. We lacked a sufficient number of trained professionals with an appropriate level of accounting knowledge, training and experience to appropriately analyze, record and disclose accounting matters timely and accurately. This material weakness contributed to the following material weaknesses:

- We did not design and maintain formal accounting policies, procedures and controls to achieve complete, accurate and timely financial accounting, reporting and disclosures, including controls over the preparation and review of account reconciliations and journal entries. Additionally, we did not design and maintain

controls over the appropriate classification and presentation of accounts and disclosures in the financial statements.

- We did not design and maintain formal accounting policies, processes and controls to analyze, account for and disclose complex transactions. Specifically, we did not design and maintain controls to analyze, account for and disclose complex licensing agreements, income taxes, variable interest entities, debt arrangements, equity method investments, share-based compensation arrangements, derivative liabilities, warrants to purchase common shares and contingently issuable equity.
- We did not design and maintain controls over our supervision and review of the completeness and accuracy of third-party vendors' computations supporting our common share valuations.

These material weaknesses contributed to several accounting adjustments being made to our financial statements for the years ended December 31, 2014, 2015 and 2016 and the nine months ended September 30, 2015 and 2016 related to our accounting for our license agreement obligations, income taxes, variable interest entities, share-based compensation, derivative liabilities, warrants and contingent equity, research and development expense, general and administrative expense, and other income (expense). In addition, these material weaknesses contributed to the restatement of our financial statements for the nine months ended September 30, 2016 related to our accounting for license agreement obligations.

We identified an additional material weakness as a result of the material weakness in our control environment in that we did not design and maintain controls over the operating effectiveness of information technology, or IT, general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain effective controls over program change management; user access, including segregation of duties; or computer operations.

These IT deficiencies did not result in a material misstatement to our financial statements; however, the deficiencies, when aggregated, could impact the effectiveness of IT-dependent controls, such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports.

Each of the control deficiencies could result in a misstatement of these accounts or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected, and accordingly, we determined that these control deficiencies constitute material weaknesses.

We have initiated remediation efforts focused on improving our internal control over financial reporting and to specifically address the control deficiencies that led to our material weaknesses. These efforts include the following:

- Initial investment in finance and accounting organization, including:
 - Hiring of our chief financial officer in May 2016; and
 - Hiring of a corporate controller in January 2017.
- Retaining a technical accounting consulting firm in October 2016 to provide additional depth and breadth in our technical accounting and financial reporting capabilities. We intend to continue this arrangement until permanent technical accounting resources are identified and hired.
- Initiating design and implementation of our financial control environment, including policies and procedures, controls, reporting and analysis, and segregation of duties.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has ever performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our share price may decline as a result.

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

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

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

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

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

may be treated by the courts of the BVI as a cause of action in itself so that no retrial of the issues would be necessary provided that in respect of the judgment of the U.S. court:

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

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

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

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

In addition to the statutory rights outlined above, there are common law rights for the protection of shareholders that may be invoked, largely dependent on English common law. Under the general rule pursuant to English common

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

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

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

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

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

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

As a company organized under the laws of the BVI, we are principally subject to taxation in the BVI. Under the current laws of the BVI, tax on a company's income is assessed at a zero percent tax rate. For U.S. federal tax purposes, a corporation is generally considered a "domestic corporation" if it is incorporated or organized in the United States, and a "foreign corporation" if it is incorporated or organized in a non-U.S. jurisdiction. Because we are a British Virgin Islands incorporated entity, we would be classified as a foreign corporation under these general rules. Section 7874 of the Code, or Section 7874, however, contains rules that can result in a foreign corporation being treated as a domestic corporation for U.S. federal tax purposes. Under Section 7874, a foreign corporation will nevertheless be treated as a domestic corporation for U.S. federal tax purposes if (1) the foreign corporation directly or indirectly acquires substantially all of the assets held directly or indirectly by a domestic corporation (including

the indirect acquisition of assets by acquisition of all the outstanding shares of a domestic corporation), (2) the shareholders of the acquired domestic corporation hold at least 80% (by either vote or value) of the shares of the acquiring foreign corporation after the acquisition by reason of holding shares in the acquired domestic corporation (including the receipt of the foreign corporation's shares in exchange for the domestic corporation's shares) (the "ownership test"), and (3) the foreign corporation's "expanded affiliated group" does not have substantial business activities in the foreign corporation's country of organization or incorporation relative to the expanded affiliated group's worldwide activities. For purposes of Section 7874, "expanded affiliated group" means the foreign corporation and all subsidiaries in which the foreign corporation, directly or indirectly, owns more than 50% of the shares by vote and value.

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

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

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

Under the Code, we will be a passive foreign investment company, or PFIC, for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. If we are a PFIC for any taxable year during which a U.S. holder holds our shares, the U.S. holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

Although we do not believe we were a PFIC for our taxable year ended December 31, 2016, and do not currently expect to be a PFIC for our current taxable year or future taxable years, we cannot provide any assurances regarding our PFIC status for any past, current or future taxable years. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies which in some circumstances are unclear and subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans which are subject to change. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our shares from time to time, which may fluctuate

considerably. Under the income test, our status as a PFIC depends on the composition of our income which, in our current and future taxable years, we may not be able to fully control, for example, with respect to income attributed to us from entities owned 25% or more by us. The composition of our income and assets is also affected by how, and how quickly, we spend the cash we raise in any offering, including in our recent IPO.

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(a) Sales of Unregistered Securities

Issuances of Common and Preferred Shares

In January 2017, we issued warrants to two of our directors, each to purchase 107,500 of our common shares with an exercise price of \$9.2911 per share, in connection with the directors’ guaranties related to our credit agreement with Wells Fargo.

In February 2017, we issued an aggregate of 4,305,182 shares of our Series A preferred shares to 45 investors at a purchase price of \$9.2911 per share, for aggregate consideration of \$40.0 million and 105,009 shares of our Series A preferred shares with a value of \$1.2 million to two third parties in connection with their placement services with respect to the Series A preferred financing.

In March 2017, we issued 32,500 common shares plus \$249,750 in cash to one shareholder in exchange for 500,000 shares of common stock of Kleo Pharmaceuticals, Inc.

The offers, sales and issuances of the securities described in the paragraphs above were exempt from registration under Section 4(a)(2) of the Securities Act or Regulation D promulgated under the Securities Act. Each of the purchasers represented to us that they acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. The purchasers also represented to us that they were accredited investors as defined in Rule 501 promulgated under the Securities Act.

Common Shares Issued upon Conversion of Preferred Shares

On May 9, 2017, upon the closing of our IPO, all of our then-outstanding convertible preferred shares were automatically converted into 9,358,560 common shares. The issuance of such common shares was exempt from registration under Section 3(a)(9) of the Securities Act.

Stock Option Grants

From January 1, 2017 through March 31, 2017, we granted options under our 2014 Equity Incentive Plan to purchase an aggregate of 480,919 of our common shares to employees, consultants and directors, having exercise prices ranging from \$9.29 to \$9.85 per share. We have not issued any common shares upon the exercise of stock options.

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(b) Use of IPO Proceeds

On May 3, 2017, our registration statement on Form S-1, as amended (File No 333-217214) was declared effective by the SEC in connection with our IPO, pursuant to which we sold 11,385,000 of our common shares at a public offering price of \$17.00 per share, including the full exercise by the underwriters of their option to purchase additional shares.

We received net proceeds of \$176.4 million, after deducting underwriting discounts and commissions and offering expenses borne by us. None of the expenses incurred by us were direct or indirect payments to any of (i) our directors or officers or their associates, (ii) persons owning 10 percent or more of our common stock, or (iii) our affiliates. Morgan Stanley, Piper Jaffray & Co. and Barclays Capital acted as joint book-running managers for the offering. William Blair acted as lead manager. Needham & Company acted as co-manager.

There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus related to the offering, dated May 3, 2017, as filed with the SEC.

Item 6. Exhibits

| Exhibit No. | Description |
|--------------------|---|
| 3.1 | Amended and Restated Memorandum and Articles of Association (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38080) filed with the SEC on May 12, 2017). |
| 31.1* | Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act. |
| 31.2* | Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act. |
| 32.1** | Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act. |
| 101.INS | XBRL Instance Document |
| 101.SCH | XBRL Taxonomy Extension Schema Document |
| 101.CAL | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document |
| 101.LAB | XBRL Taxonomy Extension Label Linkbase Document |
| 101.PRE | XBRL Taxonomy Extension Presentation Linkbase Document |

* Filed herewith

** These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: June 16, 2017

BIOHAVEN PHARMACEUTICAL HOLDING COMPANY LTD.

By: /s/ Vlad Coric, M.D.

Vlad Coric, M.D.
Chief Executive Officer
(On behalf of the Registrant and as the Principal Executive Officer)

By: /s/ Jim Engelhart

Jim Engelhart
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

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**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Vlad Coric, M.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2017 of Biohaven Pharmaceutical Holding Company Ltd. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: June 16, 2017

/s/ Vlad Coric, M.D.

Vlad Coric, M.D.

President and Chief Executive Officer
(principal executive officer)

**CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jim Engelhart, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2017 of Biohaven Pharmaceutical Holding Company Ltd. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: June 16, 2017

/s/ Jim Engelhart

Jim Engelhart
Chief Financial Officer
(principal financial officer)

**CERTIFICATIONS OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Vlad Coric, M.D., President and Chief Executive Officer of Biohaven Pharmaceutical Holding Company Ltd. (the “Company”), and Jim Engelhart, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2017, to which this Certification is attached as Exhibit 32.1 (the “Periodic Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF , the undersigned have set their hands hereto as of the 16 day of June, 2017.

/s/ Vlad Coric, M.D.

Vlad Coric, M.D.

President and Chief Executive Officer
(principal executive officer)

/s/ Jim Engelhart

Jim Engelhart

Chief Financial Officer
(principal financial officer)

* This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.
