# 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 September 30, 2024

OR

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

Commission File Number: 001-41477



# Biohaven Ltd.

(Exact name of registrant as specified in its charter)

**British Virgin Islands** 

Not applicable

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

c/o Biohaven Pharmaceuticals, Inc.

215 Church Street, New Haven, Connecticut
(Address of principal executive offices)

**06510** (Zip Code)

(203) 404-0410

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

I	Title of each class	Trading Symbol	Name of each exchange on which registered
Ī	Common Shares, no par value	BHVN	New York Stock Exchange

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  $\boxtimes$  No  $\square$ 

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

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Emerging growth company	
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# **PART I - FINANCIAL INFORMATION**

# Item 1. Unaudited Condensed Consolidated Financial Statements

# **BIOHAVEN LTD.**

# **CONDENSED CONSOLIDATED BALANCE SHEETS**

(Amounts in thousands, except share amounts)

	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 84,390	\$ 248,402
Marketable securities	294,426	133,417
Prepaid expenses	55,168	35,242
Income tax receivable	5,318	13,252
Other current assets	1,198	12,133
Total current assets	440,500	442,446
Property and equipment, net	18,276	17,191
Intangible assets	18,400	18,400
Goodwill	1,390	1,390
Other non-current assets	31,957	33,785
Total assets	\$ 510,523	\$ 513,212
Liabilities and Shareholders' Equity		<del></del>
Current liabilities:		
Accounts payable	\$ 19,744	\$ 15,577
Accrued expenses and other current liabilities	63,520	39,846
Forward contract liability	69,030	_
Total current liabilities	152,294	 55,423
Non-current operating lease liabilities	25,312	27,569
Derivative liability, non-current	12,320	_
Other non-current liabilities	4,591	2,245
Total liabilities	194,517	 85,237
Commitments and contingencies (Note 11)		
Shareholders' Equity:		
Preferred shares, no par value; 10,000,000 shares authorized, no shares issued and outstanding as of September 30, 2024 and December 31, 2023	_	_
Common shares, no par value; 200,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 94,899,193 and 81,115,723 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	1,381,699	887,528
Additional paid-in capital	93,038	39,804
Accumulated deficit	(1,158,871)	(499,292)
Accumulated other comprehensive income (loss)	140	(65)
Total shareholders' equity	316,006	427,975
Total liabilities and shareholders' equity	\$ 510,523	\$ 513,212

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

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

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

(Unaudited)

	Three Months End	ded S	September 30,	Nine Months End	ed S	September 30,
	2024		2023	2024		2023
Operating expenses:						
Research and development	\$ 157,607	\$	95,517	\$ 628,398	\$	238,468
General and administrative	20,561		15,030	66,782		43,872
Total operating expenses	178,168		110,547	695,180		282,340
Loss from operations	(178,168)		(110,547)	(695,180)		(282,340)
Other income, net	17,805		4,686	36,288		18,757
Loss before (benefit) provision for income taxes	 (160,363)		(105,861)	(658,892)		(263,583)
(Benefit) provision for income taxes	(59)		(3,287)	687		(171)
Net loss	\$ (160,304)	\$	(102,574)	\$ (659,579)	\$	(263,412)
Net loss per share — basic and diluted	\$ (1.70)	\$	(1.50)	\$ (7.50)	\$	(3.86)
Weighted average common shares outstanding—basic and diluted	94,372,159		68,320,125	87,936,923		68,258,757
Comprehensive loss:						
Net loss	\$ (160,304)	\$	(102,574)	\$ (659,579)	\$	(263,412)
Other comprehensive income (loss), net of tax	218		138	205		(126)
Comprehensive loss	\$ (160,086)	\$	(102,436)	\$ (659,374)	\$	(263,538)

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

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

# (Amounts in thousands)

(Unaudited)

		Nine Months End	ed Sept	
		2024		2023
Cash flows from operating activities:		/\		()
Net loss	\$	(659,579)	\$	(263,412)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization		5,394		5,018
Non-cash share-based compensation		59,269		12,916
Issuance of common shares as payment for acquisition of IPR&D asset		10,811		
Issuance of common shares as payment under license and other agreements		71,627		_
Fair value of forward contract and derivative liabilities under license agreement		102,529		
Change in fair value of forward contract and derivative liabilities		(21,179)		_
Issuance of warrant under license agreement		3,340		_
Other non-cash items, net		(6,749)		(4,696)
Changes in operating assets and liabilities, net of effects of acquisition:				
Prepaid expenses and other current and non-current assets		(290)		28,428
Accounts payable		2,425		(1,188)
Accrued expenses and other current and non-current liabilities		20,691		6,090
Net cash used in operating activities		(411,711)		(216,844)
Cash flows from investing activities:	_			
Proceeds from maturities of marketable securities		312,364		214,224
Proceeds from sales of marketable securities		_		4,920
Purchases of marketable securities		(466,053)		(82,822)
Purchases of property and equipment		(4,000)		(2,578)
Cash acquired from acquisition of IPR&D asset		391		_
Net cash (used in) provided by investing activities		(157,298)		133,744
Cash flows from financing activities:				
Proceeds from issuance of common shares		394,881		_
Payment of issuance costs		(800)		_
Change in restricted cash due to Former Parent				(35,184)
Proceeds from equity incentive plan and employee share purchase plan		8,582		
Other financing activities, net		2,258		1,857
Net cash provided by (used in) financing activities		404,921		(33,327)
Effects of exchange rates on cash, cash equivalents, and restricted cash		(13)		(187)
Net decrease in cash, cash equivalents, and restricted cash		(164,101)		(116,614)
Cash, cash equivalents, and restricted cash at beginning of period		252,120		242,604
Cash, cash equivalents, and restricted cash at end of period	\$	88,019	\$	125,990

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

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 1. Nature of the Business and Basis of Presentation

Biohaven Ltd. ("we," "us," "our," "Biohaven" or the "Company") was incorporated in Tortola, British Virgin Islands in May 2022. Biohaven is a biopharmaceutical company focused on the discovery, development and commercialization of life-changing treatments in key therapeutic areas, including immunology, neuroscience, and oncology. The Company is advancing its innovative portfolio of therapeutics, leveraging its proven drug development experience and multiple, proprietary drug development platforms. Biohaven's extensive clinical and preclinical programs include Kv7 ion channel modulation for epilepsy and mood disorders; extracellular protein degradation for immunological diseases; Transient Receptor Potential Melastatin 3 ("TRPM3") antagonism for migraine and neuropathic pain: Tyrosine Kinase 2/Janus Kinase 1 ("TYK2/JAK1") inhibition for neuroinflammatory disorders; glutamate modulation for obsessive compulsive disorder ("OCD") and spinocerebellar ataxia ("SCA"); myostatin inhibition for neuromuscular and metabolic diseases, including spinal muscular atrophy ("SMA") and obesity; and antibody recruiting bispecific molecules ("ARMs") and antibody drug conjugates ("ADCs") for cancer.

The Company is subject to risks and uncertainties common to companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts may require additional capital, additional personnel and infrastructure, and further regulatory and other capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

# Separation from Biohaven Pharmaceutical Holding Company Ltd.

On October 3, 2022, Biohaven Pharmaceutical Holding Company Ltd. (the "Former Parent") completed the distribution (the "Distribution") to holders of its common shares of all of the outstanding common shares of Biohaven Ltd. and the spin-off of Biohaven Ltd.

from the Former Parent (the "Spin-Off") described in Biohaven's Information Statement attached as Exhibit 99.1 to Biohaven's Registration Statement on Form 10, as amended (Reg. No. 001-41477). Collectively, we refer to the Distribution and Spin-Off throughout this Quarterly Report on Form 10-Q as the "Separation." As a result of the Separation, Biohaven Ltd. became an independent, publicly traded company as of October 3, 2022, and commenced regular way trading under the symbol "BHVN" on the New York Stock Exchange (the "NYSE") on October 4, 2022. Where we describe historical business activities in this report, we do so as if the Former Parent's activities related to such assets and liabilities had been performed by the Company.

#### **Basis of Presentation**

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and pursuant to the rules and regulations of the SEC. The accompanying condensed consolidated financial statements include the accounts of Biohaven Ltd. and our wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

# **Going Concern**

In accordance with Accounting Standards Codification ("ASC") 205-40, Going Concern, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the condensed consolidated financial statements are issued.

Through November 12, 2024, the Company has funded its operations primarily with funding from the Former Parent, proceeds from the sale of its common shares, and the cash contribution received from the Former Parent at the Separation. The Company has incurred recurring losses since its inception and expects to continue to generate operating losses for the foreseeable future.

As of the date of issuance of these condensed consolidated financial statements, the Company expects its existing cash, cash equivalents, and marketable securities will be sufficient to fund operating and financial commitments, and other cash requirements for at least one year after the issuance date of these financial statements.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 1. Nature of the Business and Basis of Presentation (Continued)

To execute its business plans, the Company will require funding to support its continuing operations and pursue its growth strategy. Until such time as the Company can generate significant revenue from product sales or royalties, if ever, it expects to finance its operations through the sale of public or private equity, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company's shareholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

# 2. Summary of Significant Accounting Policies

Our significant accounting policies are described in Note 2, "Summary of Significant Accounting Policies" to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 Form 10-K"). Updates to our accounting policies are discussed below in this Note 2.

# Unaudited Interim Condensed Consolidated Financial Information

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with GAAP for interim financial information. The accompanying unaudited condensed consolidated financial statements do not include all of the information and footnotes required by GAAP for complete consolidated financial statements. The accompanying year-end condensed consolidated balance sheet was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. The unaudited interim condensed 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 September 30, 2024, the results of its operations for the three and nine months ended September 30. 2024 and 2023, and its cash flows for the nine months ended September 30, 2024 and 2023. The results for the three and nine months ended September 30, 2024 are not necessarily

indicative of results to be expected for the year ending December 31, 2024, any other interim periods or any future year or period. The financial information included herein should be read in conjunction with the financial statements and notes in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

#### Reclassifications

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

# **Use of Estimates**

The preparation of condensed 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 condensed consolidated financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual for research and development expenses and valuation of forward contract and derivative liabilities. In addition. management's assessment of the Company's ability to continue as a going concern involves the estimation of the amount and timing of future cash inflows and outflows. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

# Restricted Cash

Restricted cash included in other current assets in the condensed consolidated balance sheets consists primarily of employee contributions to the Company's employee share purchase plan held for future purchases of the Company's outstanding shares.

Restricted cash included in other non-current assets in the condensed consolidated balance sheets represents collateral held by banks for a letter of credit ("LOC") issued in connection with the leased office space in Yardley, Pennsylvania and LOCs issued in connection with the leased office and lab spaces in Cambridge, Massachusetts and Pittsburgh, Pennsylvania. See Note 11, "Commitments and Contingencies" for additional information on the real estate leases.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 2. Summary of Significant Accounting Policies (Continued)

The following represents a reconciliation of cash and cash equivalents in the condensed consolidated balance sheets to total cash, cash equivalents and restricted cash as of September 30, 2024 and September 30, 2023, respectively, in the condensed consolidated statements of cash flows:

	As	of September 30, 2024	As	of September 30, 2023
Cash and cash equivalents	\$	84,390	\$	111,697
Restricted cash held on behalf of Former Parent		_		28
Restricted cash (included in other current assets)		582		11,890
Restricted cash (included in other non-current assets)		3,047		2,375
Total cash, cash equivalents and restricted cash at the end of the period in the condensed consolidated statement of cash	¢	99 010	¢.	125,000
flows	<u> </u>	88,019	<u>\$</u>	125,990

# Forward Contracts and Derivative Liabilities

The Company evaluates certain of its financial and business development transactions to determine the accounting classification of equity linked instruments issued in those transactions. The Company first assesses whether a freestanding equity linked instrument meets liability classification in accordance with ASC 480-10 *Distinguishing Liabilities from Equity* and ASC 815-40 *Derivatives and Hedging - Contracts in Entity's Own Equity*. Under ASC 480-10 an instrument is considered liability classified if the instrument is mandatorily redeemable, obligate the issuer to settle an instrument or the underlying shares by paying cash or other assets, or must or may require settlement by issuing variable number of shares.

If an instrument does not meet liability classification under ASC 480-10, the Company assesses the requirements under ASC 815-40, which states that contracts that require or may require net cash settlement are liabilities recorded at fair value. If the instrument does not require liability classification under ASC 815-40, in order to conclude equity classification, the Company assesses whether the instrument is indexed to its common stock and whether the instrument is classified as equity under ASC 815-40 or other applicable GAAP.

Equity linked instruments that are accounted for in accordance with ASC 815-40 are reported as liabilities on the condensed consolidated balance sheets at fair

value. Any change in fair value, as determined at each measurement period, is recorded as a component of other income, net on the condensed consolidated statements of operations and comprehensive loss. Changes in fair value are reported on the condensed consolidated statements of cash flows as change in fair value of forward contract and derivative liabilities.

The Company accounted for certain consideration agreed to in connection with the amendment, dated as of May 1, 2024 (the "Knopp Amendment"), to the Membership Interest Purchase Agreement, dated as of February 24, 2022 (the "Purchase Agreement") entered into with Knopp Biosciences, LLC ("Knopp") as derivative liabilities under ASC 815 (see Notes 4, "Fair Value of Financial Assets and Liabilities" and 10, "License, Acquisitions and Other Agreements").

# Warrants

The Company evaluates warrants issued as either equity instruments, liabilities or derivative liabilities in accordance with ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and/or ASC Topic 815, *Derivatives and Hedging* ("ASC 815"), depending on the specific terms of the warrant agreement.

The Company assessed the warrants issued to Knopp in May 2024 (the "Knopp Warrants") and concluded that they met the criteria for equity classification under ASC 480 and ASC 815. Accordingly, the Knopp Warrants were recorded within additional paid-in capital on the condensed consolidated balance sheet at the time of issuance and are not subject to remeasurement. See Note 6, Shareholders' Equity for further detail on the Knopp Warrants.

# Fair Value Measurements

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

 Level 1—Quoted prices in active markets for identical assets or liabilities.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 2. Summary of Significant Accounting Policies (Continued)

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

The carrying values of other current assets, accounts payable, and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

The Company has accounted for certain consideration agreed to in connection with the Knopp Amendment as forward contract liabilities, which are recorded on the condensed consolidated balance sheets at fair value. Any changes in fair value, as determined each measurement period, are recorded as a component of other income, net on the condensed consolidated statements of operations and comprehensive loss. The fair value of the forward contract liabilities is determined based on significant inputs not observable in the market, and therefore represents a Level 3 measurement within the fair value hierarchy. The valuations are based on a Monte Carlo simulation of the Company's share price, which requires judgement and assumption on the volatility of Biohaven's share price, discounted to present value using a risk-free rate plus Biohaven specific credit risk since payable in a variable number of shares. (see Notes 4, "Fair Value of Financial Assets and Liabilities" and 10, "License, Acquisitions and Other Agreements").

# Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting—Improvements to

Reportable Segment Disclosures, which improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The amendments in ASU No. 2023-07 apply to public entities, including those with a single reportable segment, and are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact ASU No. 2023-07 will have on its consolidated financial statements

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, to improve the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. The ASU also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is currently evaluating the impact ASU No. 2023-09 will have on its consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40), which requires disclosure, in the notes to the financial statements, of specified information about certain costs and expenses. This ASU is effective for public entities for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. The Company is currently evaluating the impact ASU 2024-03 will have on its consolidated financial statements.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

# 3. Marketable Securities

The amortized cost, gross unrealized holding gains, gross unrealized holding losses and fair value of debt securities available-for-sale by type of security at September 30, 2024 and December 31, 2023 were as follows:

	Amor	tized Cost	Allowance for Credit Losses	N	et Amortized Cost	Gr	oss Unrealized Gains	Gr	oss Unrealized Losses	Fair Value
September 30, 2024										
Debt securities										
U.S. treasury bills	\$	294,211	\$ _	\$	294,211	\$	215	\$	_	\$ 294,426
December 31, 2023										
Debt securities										
U.S. corporate bonds	\$	46,228	\$ _	\$	46,228	\$	7	\$	(24)	\$ 46,211
Foreign corporate bonds		7,180	_		7,180		_		(7)	7,173
U.S. treasury bills		113,908	_		113,908		27		_	113,935
Total	\$	167,316	\$ 	\$	167,316	\$	34	\$	(31)	\$ 167,319

The fair value of debt securities available-for-sale by classification in the condensed consolidated balance sheets was as follows:

	September 30, 2024	December 31, 2023
Cash and cash equivalents	\$ _	\$ 33,902
Marketable securities	294,426	133,417
Total	\$ 294,426	\$ 167,319

The net amortized cost and fair value of debt securities available-for-sale at September 30, 2024 and December 31, 2023 are shown below by contractual maturity. Actual maturities may differ from contractual maturities because securities may be restructured, called or prepaid, or the Company intends to sell a security prior to maturity.

	September 30, 2024					December	31,	2023
	Net Amortized Cost			Fair Value	N	let Amortized Cost		Fair Value
Due to mature:								
Less than one year	\$	294,211	\$	294,426	\$	167,316	\$	167,319

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 3. Marketable Securities (Continued)

The Company did not hold any debt securities available-for-sale that were in an unrealized loss position at September 30, 2024. Summarized below are the debt securities available-for-sale the Company held at December 31, 2023 that were in an unrealized loss position, aggregated by the length of time the investments have been in that position:

	Less than 12 months					
	Number of Securities		Fair Value		Unrealized Losses	
December 31, 2023						
Debt securities						
U.S. corporate bonds	6	\$	29,537	\$	(24)	
Foreign corporate bonds	1		7,173		(7)	
Total	7	\$	36,710	\$	(31)	

The Company did not have any investments in a continuous unrealized loss position for more than twelve months as of September 30, 2024 or December 31, 2023.

The Company reviewed its securities and concluded that they are performing assets, considering factors such as the credit quality of the investment security based on research performed by external rating agencies and the prospects of realizing the carrying value of the security based on the investment's current prospects for recovery. As of September 30, 2024, the Company did not intend to sell its securities and did not believe it was more likely than not that it would be required to sell its securities prior to the anticipated recovery of their amortized cost basis.

#### Net Investment Income

Gross investment income includes income from debt securities available-for-sale, money-market funds, cash and restricted cash. Net investment income included in other income, net in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023 were as follows:

		Three Months End	ded Se	ptember 30,	Nine Months End	ed S	eptember 30,
		2024		2023	2024		2023
Debt securities (including realized losses)	\$	3,843	\$	2,280	\$ 8,912	\$	7,914
Other investments		1,850		1,551	6,252		4,278
Gross investment income (including realized losses)	'	5,693		3,831	15,164		12,192
Investment expenses		(45)		(65)	(115)		(203)
Net investment income	\$	5,648	\$	3,766	\$ 15,049	\$	11,989

We utilize the specific identification method in computing realized gains and losses. There were no proceeds from the sale of available-for-sale debt securities or related gross realized capital gains or losses for the three months ended September 30, 2024 and 2023. The proceeds from the sale of available-for-sale debt securities and the related gross realized capital losses for the nine months ended September 30, 2024 and 2023 were as follows:

	Nine Months Ended September 30,					
	2024	2023				
Proceeds from sales	\$ <b>–</b> \$	4,920				
Gross realized capital losses	\$ — \$	39				

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

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

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

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

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.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

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

Financial assets measured at fair value on a recurring basis on the condensed consolidated balance sheets at September 30, 2024 and December 31, 2023 and financial liabilities measured at fair value on a recurring basis on the condensed consolidated balance sheets at September 30, 2024 were as follows:

			Fair Value Meas	surer	nent Using:	
Balance Sheet Classification	Type of Instrument	Level 1	Level 2		Level 3	Total
September 30, 2024						
Assets:						
Cash and cash equivalents	Money market funds	\$ 65,497	\$ _	\$	_	\$ 65,497
Marketable securities	U.S. treasury bills	15,828	278,598		_	294,426
Other non-current assets	Money market funds	2,548	_		_	2,548
Total assets		\$ 83,873	\$ 278,598	\$	_	\$ 362,471
		 	_			
Liabilities:						
Forward contract liability	Forward contract, current	\$ _	\$ _	\$	69,030	\$ 69,030
Derivative liability, non-current	Written put option, non-current	_	_		12,320	12,320
Total liabilities		\$ _	\$ _	\$	81,350	\$ 81,350
December 31, 2023						
Assets:						
Cash and cash equivalents	Money market funds	\$ 59,199	\$ _	\$	_	\$ 59,199
Cash and cash equivalents	U.S. treasury bills	_	27,901		_	27,901
Cash and cash equivalents	U.S. corporate bonds	_	6,001		_	6,001
Marketable securities	U.S. treasury bills	9,874	76,160		_	86,034
Marketable securities	U.S. corporate bonds	_	40,210		_	40,210
Marketable securities	Foreign corporate bonds		7,173			7,173
Other non-current assets	Money market funds	1,900			<u> </u>	1,900
Total assets		\$ 70,973	\$ 157,445	\$	_	\$ 228,418

The Company had no financial liabilities measured at fair value on a recurring basis on the condensed consolidated balance sheets at December 31, 2023.

There were no securities transferred into or out of Level 3 during the three and nine months ended September 30, 2024 or 2023.

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

# Cash Equivalents

Cash equivalents consisted of cash invested in short-term money market funds and debt securities with an original maturity of 90 days or less at the date of purchase. The carrying value of cash equivalents approximates fair value as maturities are less than three months. When quoted prices are available in an active market, cash equivalents are classified in Level 1 of the fair value hierarchy. Fair values of cash equivalent instruments that do not trade on a regular basis in active markets are classified as Level 2.

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

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

#### Marketable Securities and Other Non-Current Assets

Quoted prices for identical assets in active markets are considered Level 1 and consist of on-the-run U.S. Treasuries and money market funds. The fair values of the Company's Level 2 debt securities are obtained from quoted market prices of debt securities with similar characteristics, quoted prices from identical assets in inactive markets, or discounted cash flows to estimate fair value.

#### Forward Contract and Derivative Liabilities

In connection with the Knopp Amendment, Knopp had the option to request a one-time cash true-up payment from the Company in December 2024, as defined in the agreement (the "2024 Knopp True-up"). As of September 30, 2024, the Company determined the fair value of its liability for the 2024 Knopp True-Up to be \$0. Also in connection with the Knopp Amendment, the Company agreed to issue to Knopp additional common shares of the Company with an approximate value of \$75,000 within 60 days of the first anniversary of execution of the Knopp Amendment (the "2025 Additional Consideration"). In addition, Knopp has the option to request a one-time cash true-up payment from the Company in December 2025, as defined in the agreement (the "2025 Knopp True-up"). See Note 10, "License, Acquisitions and Other Agreements," for further details.

The following table provides a roll forward of the fair value of the Company's forward contract and derivative liabilities related to the Knopp Amendment for which fair value is determined by Level 3 inputs from inception on May 1, 2024 to September 30, 2024:

	Carrying Value
Fair value at May 1, 2024	\$ 93,290
Change in fair value of forward contract and derivative liabilities in other income, net	(11,940)
Fair value at September 30, 2024	\$ 81,350

The fair value of the forward contract and remaining derivative liability recognized in connection with the Knopp Amendment were determined based on significant inputs not observable in the market, and therefore represents a Level 3 measurement within the fair value hierarchy. The valuation is based on a Monte Carlo simulation of Biohaven's share price, which requires judgement and assumption on the volatility of Biohaven's share price, discounted to present value using a risk-free rate plus Biohaven specific credit risk since payable in a variable number of shares for the 2025 Additional Consideration or potentially cash for the 2025 Knopp True-up. A summary of the unobservable inputs (Level 3 inputs) used in measuring the Company's forward contract and derivative liability related to the Knopp Amendment as of September 30, 2024 and May 1, 2024 are as follows, presented on a weighted-average basis based on relative fair value:

	As of September 30, 2024	As of May 1, 2024
Time to payment and potential payment (years)	0.74	1.08
Volatility (annual)	65.0 %	80.0 %
Discount rate	12.7 %	14.8 %

Our expectations of the volatility of Biohaven's share price at the reporting date could be materially different than our actual future volatility, and if so, would mean the estimated fair value could be significantly higher or lower than the fair value determined. The Company expects the fair value of the forward contract to be approximately \$75,000 on the first anniversary of the Knopp Amendment. An increase in the derivative liability related to the 2025 Knopp True-up between the reporting date and settlement date of the derivative would have a material adverse effect on the Company's financial performance.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

# 5. Balance Sheet Components

# Property and Equipment, Net

Property and equipment, net consisted of the following:

	As	of September 30, 2024	As	of December 31, 2023
Building and land	\$	14,078	\$	11,728
Leasehold improvements		824		802
Computer hardware and software		875		875
Office and lab equipment		11,362		9,961
Furniture and fixtures		1,793		1,550
	\$	28,932	\$	24,916
Accumulated depreciation		(11,201)		(8,283)
		17,731		16,633
Equipment not yet in service		544		558
Property and equipment, net	\$	18,276	\$	17,191

Depreciation expense was \$1,000 and \$2,918 for the three and nine months ended September 30, 2024, respectively, and \$857 and \$2,421 for the three and nine months ended September 30, 2023, respectively.

Equipment not yet in service primarily consisted of lab equipment that had not been placed into service as of September 30, 2024 and December 31, 2023.

# **Other Non-current Assets**

Other non-current assets consisted of the following:

	As	of September 30, 2024	As of Decembe 31, 2023		
Operating lease right-of-use assets	\$	28,909	\$	31,385	
Other		3,048		2,400	
Other non-current assets	\$	31,957	\$	33,785	

# **Accrued Expenses and Other Current Liabilities**

Accrued expenses and other current liabilities consisted of the following:

	As o	of September 30, 2024	of December 31, 2023
Accrued employee compensation and benefits	\$	15,881	\$ 837
Accrued clinical trial costs		35,454	29,501
Operating lease liabilities - current portion		3,676	3,308
Other accrued expenses and other current liabilities		8,509	6,200
Accrued expenses and other current liabilities	\$	63,520	\$ 39,846

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

# 6. Shareholders' Equity

Changes in shareholders' equity for the three and nine months ended September 30, 2024 and September 30, 2023 were as follows:

Common Shares											
	Shares		Amount	А	dditional Paid- in Capital		Accumulated Deficit		mulated Other mprehensive Loss	s	Total hareholders' Equity
Balances as of December 31, 2023	81,115,723	\$	887,528	\$	39,804	\$	(499,292)	\$	(65)	\$	427,975
Net loss	_						(179,504)				(179,504)
Issuance of common shares as payment for acquisition of IPR&D asset	242,958		10,347		_		_		_		10,347
Issuance of common shares as payment under license and other agreements	97,233		5,637		_		_		_		5,637
Issuance of common shares under 2022 Equity Incentive Plan	351,307		7,452		(5,296)		_		_		2,156
Non-cash share-based compensation expense	_		_		34,877		_		_		34,877
Other comprehensive loss	_		<u> </u>				<u> </u>		(41)		(41)
Balances as of March 31, 2024	81,807,221		910,964		69,385		(678,796)		(106)		301,447
Net loss	_		_		_		(319,771)		_		(319,771)
Issuance of common shares, net of offering costs	8,544,951		317,720		_		_		_		317,720
Issuance of common shares as payment for acquisition of IPR&D asset	10,452		446		_		_		_		446
Issuance of common shares as payment under license and other agreements	1,872,874		65,981		_		_		_		65,981
Issuance of common shares under 2022 Equity Incentive Plan and 2022 Employee Share Purchase Plan	110,834		3,442		(1,125)		_		_		2,317
Issuance of warrant as payment under license agreement	_		_		3,340		_		_		3,340
Non-cash share-based compensation expense	_		_		12,232		_		_		12,232
Other comprehensive income	_		_		_		_		28		28
Balances as of June 30, 2024	92,346,332		1,298,553		83,832		(998,567)		(78)		383,740
Net loss	_		_		_		(160,304)		_		(160,304)
Issuance of common shares, net of offering costs	2,154,857		76,361		_		_		_		76,361
Issuance of common shares as payment for acquisition of IPR&D asset	428		18		_		_		_		18
Issuance of common shares under 2022 Equity Incentive Plan	397,422		6,758		(2,954)		_		_		3,804
Issuance of common shares as payment under license and other agreements	154		9		_		_		_		9
Non-cash share-based compensation expense	_		_		12,160		_		_		12,160
Other comprehensive income	_		_		_		_		218		218
Balance as of September 30, 2024	94,899,193	\$	1,381,699	\$	93,038	\$	(1,158,871)	\$	140	\$	316,006

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 6. Shareholders' Equity (Continued)

	Shares	Amount	Additional Paid- in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Shareholders' Equity
Balances as of December 31, 2022	68,190,479	\$ 615,742	\$ 13,869	\$ (91,124)	\$ 284	\$ 538,771
Net loss		_	_	(70,492)		(70,492)
Issuance of common shares under 2022 Equity Incentive Plan	22,000	504	(172)	_	_	332
Non-cash share-based compensation expense	_	_	3,765	_	_	3,765
Other comprehensive loss	_	_	_	_	(118)	(118)
Balances as of March 31, 2023	68,212,479	616,246	17,462	(161,616)	166	472,258
Net loss	_	_	_	(90,346)	_	(90,346)
Issuance of common shares under 2022 Equity Incentive Plan and 2022 Employee Share Purchase Plan	104,474	1,264	(470)	_	_	794
Non-cash share-based compensation expense	_	_	4,695	_	_	4,695
Other comprehensive loss	_	_	_	_	(146)	(146)
Balance as of June 30, 2023	68,316,953	617,510	21,687	(251,962)	20	387,255
Net loss	_	_	_	(102,574)	_	(102,574)
Issuance of common shares under 2022 Equity Incentive Plan	47,190	1,251	(520)	_	_	731
Non-cash share-based compensation expense	_	_	4,456	_	_	4,456
Other comprehensive income	_	_	_	_	138	138
Balance as of September 30, 2023	68,364,143	\$ 618,761	\$ 25,623	\$ (354,536)	\$ 158	\$ 290,006

# **Knopp Amendment**

In May 2024, the Company entered into the Knopp Amendment under which the parties thereto agreed to revise the success-based payment and royalty payment obligations under the Membership Purchase Agreement. As consideration, the Company issued 1,872,874 Biohaven Shares to Knopp, valued at approximately \$65,981 in May 2024.

As further consideration for the revisions to the success-based payment and royalty payment obligations in the Knopp Amendment, the Company issued to Knopp a warrant to purchase 294,195 of the Company's common shares with a purchase price of \$67.98, subject to certain specified development milestones and the Company achieving a specified market capitalization.

The warrant was recorded at its initial fair value of \$3,340 within additional paid-in capital on the condensed consolidated balance sheet during the second quarter of

2024 and is not subject to remeasurement. See Note 10 for further detail on the Knopp Amendment.

# 2024 Public Offerings

On April 22, 2024, the Company closed an underwritten public offering of 6,451,220 of its common shares, which included the exercise in full of the underwriters' option to purchase additional shares, at a price of \$41.00 per share. The net proceeds raised in the offering, after deducting underwriting discounts and expenses of the offering payable by Biohaven, were approximately \$247,830. The Company intends to use the net proceeds received from the offering for general corporate purposes.

On October 2, 2024, the Company closed an underwritten public offering of 6,052,631 of its common shares, which included the exercise in full of the underwriters' option to purchase additional shares, at a price of \$47.50 per share. The net proceeds raised in the offering, after deducting underwriting discounts and expenses of the offering payable by Biohaven, were approximately \$269,935. The Company intends to use the net proceeds received from the offering for general corporate purposes.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 6. Shareholders' Equity (Continued)

# **Pyramid Acquisition**

In January 2024, the Company acquired Pyramid pursuant to the Pyramid Agreement. In consideration for the Pyramid acquisition, Biohaven made an upfront payment of 255,794 Company common shares, valued at approximately \$10,894. As of September 30, 2024, 253,838 of these common shares have been issued by the Company.

During the first quarter of 2024, the Company recorded \$5,689 of R&D expense in the condensed consolidated statement of operations and comprehensive loss for a developmental milestone which became due under the Pyramid Agreement, to be paid in 98,129 Company common shares. As of September 30, 2024, 97,387 of these common shares have been issued by the Company. Refer to Note 10, "License, Acquisitions and Other Agreements" for further discussion of the Pyramid acquisition.

# **Equity Distribution Agreement**

In October 2023, the Company entered into an equity distribution agreement pursuant to which the Company may offer and sell common shares having an aggregate offering price of up to \$150,000 from time to time through or to the sales agent, acting as its agent or principal (the "Equity Distribution Agreement"). Sales of the Company's common shares, if any, will be made in sales deemed to be "at-the-market offerings". The sales agent is not required to sell any specific amount of securities but will act as the Company's sales agent using commercially reasonable efforts consistent with its normal trading and sales practices, on mutually agreed terms between the sales agent and the Company. The Company currently plans to use the net proceeds from any at-the-market offerings of its common shares for general corporate purposes.

In August 2024, the Company entered into an amendment to the Equity Distribution Agreement pursuant to which the Company may offer and sell common shares having an aggregate offering price of up to \$450,000 from time to time through or to the sales agent, acting as its agent or principal.

As of September 30, 2024, the Company sold and issued 4,248,588 common shares under the Equity Distribution Agreement, as amended, for total net proceeds of approximately \$146,250. As of September 30, 2024, additional common shares having an aggregate offering price of up to \$300,000 remain available to be issued

# 7. Accumulated Other Comprehensive (Loss) Income

Shareholders' equity included the following activity in accumulated other comprehensive (loss) income for the three and nine months ended September 30, 2024:

	Three Months September 30		Nine N Ended Se 30, 2	lonths eptember 2024
Net unrealized investment gains (losses):				
Beginning of period balance	\$	(3)	\$	3
Other comprehensive income <sup>(1)</sup>		218		212
End of period balance		215		215
		-		
Foreign currency translation adjustments:				
Beginning of period balance		(75)		(68)
Other comprehensive loss <sup>(1)</sup>		_		(7)
End of period balance		(75)	'	(75)
Total beginning of period accumulated other		(30)		(0.5)
comprehensive loss		(78)		(65)
Total other comprehensive income		218		205
Total end of period accumulated other comprehensive income	\$	140	\$	140

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

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 7. Accumulated Other Comprehensive (Loss) Income (Continued)

Shareholders' equity included the following activity in accumulated other comprehensive income for the three and nine months ended September 30, 2023:

	Three Mont		Nine Months September 3	
Net unrealized investment gains (losses):			-	
Beginning of period balance	\$	(262)	\$	(145)
Other comprehensive income before reclassifications <sup>(1)</sup>		178		22
Amounts reclassified from accumulated other comprehensive income <sup>(1)(2)</sup>		_		39
Other comprehensive income <sup>(1)</sup>		178		61
End of period balance		(84)		(84)
Foreign currency translation adjustments:				
Beginning of period balance		282		429
Other comprehensive loss <sup>(1)</sup>		(40)		(187)
End of period balance		242		242
Total beginning of period accumulated other comprehensive income		20		284
Total other comprehensive income (loss)		138		(126)
Total end of period accumulated other comprehensive income	\$	158	\$	158
•				

<sup>(1)</sup> There was no tax on other comprehensive income (loss) and immaterial tax on amounts reclassified from accumulated other comprehensive income (loss) during the period.

# 8. Non-Cash Share-Based Compensation

# Non-Cash Share-based Compensation Expense

The Company measures non-cash share-based compensation at the grant date based on the fair value of the award and recognizes non-cash shared-based compensation as expense over the requisite service period of the award (generally three years) using the straight-line method. Non-cash share-based compensation expense, consisting of expense for share options, restricted share units ("RSUs"), performance share options, and the Employee Share Purchase Plan ("ESPP"), was classified in the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended September 30,					ths Ended iber 30,		
	2024		2023		2024	2023		
Research and development expenses	\$ 7,164	\$	2,184	\$	35,526	\$ 6,882		
General and administrative expenses	4,996		2,272		23,743	6,034		
Total non-cash share-based compensation expense	\$ 12,160	\$	4,456	\$	59,269	\$ 12,916		

# Share Options

All share option grants are awarded at fair value on the date of grant. The fair value of share options is estimated using the Black-Scholes option pricing model. Stock options generally expire 10 years after the grant date.

The aggregate intrinsic value of share options is calculated as the difference between the exercise price of the share options and the fair value of the Company's common shares for those share options that had exercise prices lower than the fair value of the Company's common shares at September 30, 2024.

As of September 30, 2024, total unrecognized compensation cost related to the unvested share options was \$78,570, which is expected to be recognized over a weighted average period of 2.13 years, which does not consider the impact of a change in control. The weighted average grant date fair value per share of share options granted under the Company's share option plan during the nine months ended September 30, 2024 and 2023 was \$30.60 and \$18.01, respectively. The Company

<sup>(2)</sup> Amounts reclassified from accumulated other comprehensive income (loss) for specifically identified debt securities are included in other income, net on the condensed consolidated statement of operations and comprehensive loss.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 8. Non-Cash Share-Based Compensation (Continued)

expects approximately 7,901,963 of the unvested stock options to vest over the requisite service period.

The following table is a summary of the Company's share option activity for the nine months ended September 30, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2023	11,379,429	\$ 11.48		
Granted	2,503,161	\$ 42.04		
Exercised	(684,124)	\$ 9.49		
Forfeited	(104,448)	\$ 20.53		
Outstanding as of September 30, 2024	13,094,018	\$ 17.36	8.44	\$ 427,203
Options exercisable as of September 30, 2024	5,192,055	\$ 13.72	8.30	\$ 188,273
Vested and expected to vest as of September 30, 2024	13,094,018	\$ 17.36	8.44	\$ 427,203

# **Restricted Share Units**

The Company's RSUs are considered nonvested share awards and require no payment from the employee. For each RSU, employees receive one common share at the end of the vesting period. The employee can elect to receive the one common share net of taxes or pay for taxes separately and receive the entire share. Compensation cost is recorded based on the market price of the Company's common shares on the grant date and is recognized on a straight-line basis over the requisite service period.

As of September 30, 2024, there was \$8,989 of total unrecognized compensation cost related to Company RSUs that are expected to vest. These costs are expected to be recognized over a weighted-average period of 2.31 years, which does not consider the impact of a change in control. The total fair value of RSUs vested during the three and nine months ended September 30, 2024 was \$221 and \$3,991.

The following table is a summary of the RSU activity for the nine months ended September 30, 2024:

	Number of shares	A۱	Weighted verage Grant Date Fair Value
Unvested as of December 31, 2023	_	\$	_
Granted	381,011	\$	41.88
Forfeited	(6,045)	\$	41.93
Vested	(95,309)	\$	41.88
Unvested as of September 30, 2024	279,657	\$	41.87

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 9. Net Loss Per Share

Basic and diluted net loss per share attributable to common shareholders of Biohaven was calculated as follows:

		Three Months Ended September 30,			Nine Months Ended September 30,			
		2024		2023		2024		2023
Numerator:								
Net loss	\$	(160,304)	\$	(102,574)	\$	(659,579)	\$	(263,412)
Denominator:								
Weighted average common shares outstanding— basic and diluted	,	94,372,159		68,320,125		87,936,923		68,258,757
Net loss per share — basic and diluted	\$	(1.70)	\$	(1.50)	\$	(7.50)	\$	(3.86)

The Company's potential dilutive securities include share options which have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common shareholders of the Company is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common shareholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of September 30,			
	2024	2023		
Options to purchase common shares	13,094,018	9,740,921		
Warrants to purchase common shares	294,195	_		
Restricted share units	279,657	_		
Total	13,667,870	9,740,921		

# 10. License, Acquisitions and Other Agreements

The Company has entered into various licensing, developmental and acquisition agreements which provide the Company with rights to certain know-how, technology and patent rights. The agreements generally include upfront fees, milestone payments upon achievement of certain developmental, regulatory and commercial and sales milestones, as well as sales-

based royalties, with percentages that vary by agreement.

# License and Other Agreements

As of September 30, 2024, the Company has potential future developmental, regulatory and commercial milestone payments under its license and other agreements of up to approximately \$140,650, \$641,975, and \$2,150,450, respectively. See below for a detailed discussion of these agreements. The Company has not recorded these potential contingent consideration payments as liabilities in the accompanying condensed consolidated balance sheet as none of the future events which would trigger a milestone payment were considered probable of occurring at September 30, 2024.

# Yale Agreements

In September 2013, the Company entered into an exclusive license agreement (the "Yale Agreement") with Yale University to obtain a license to certain patent rights for the commercial development, manufacture, distribution, use and sale of products and processes resulting from the development of those patent rights, related to the use of riluzole in treating various neurological conditions, such as general anxiety disorder, post-traumatic stress disorder and depression.

The Yale Agreement was amended and restated in May 2019. As of September 30, 2024, under the amended Yale Agreement, the Company has remaining contingent regulatory approval milestone payments of up to \$2,000 and annual royalty payments of a low single-digit percentage based on net sales of riluzole-based products from the licensed patents or from products based on troriluzole. Under the amended and restated agreement, the royalty rates are reduced as compared to the original agreement. In addition, under the amended and restated agreement, the Company may develop products based on riluzole or troriluzole. The amended and restated agreement retains a minimum annual royalty of up to \$1,000 per year, beginning after the first sale of product under the agreement. If the Company grants any sublicense rights under the Yale Agreement, it must pay Yale University a low single-digit percentage of sublicense income that it receives.

For the three and nine months ended September 30, 2024 and 2023, the Company did not record any material milestone or royalty payments under the Yale Agreement.

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 10. License, Acquisitions and Other Agreements (Continued)

In January 2021, the Company entered into a worldwide, exclusive license agreement with Yale University for the development and commercialization of a novel Molecular Degrader of Extracellular Protein ("MoDE") platform (the "Yale MoDE Agreement"). The platform pertains to the clearance of diseasecausing protein and other biomolecules by targeting them for lysosomal degradation using multi-functional molecules. The Yale MoDE Agreement includes an obligation to pay a minimum annual royalty of up to \$1,000 per year, and low single digit royalties on the net sales of licensed products. If the Company grants any sublicense rights under the Yale MoDE Agreement, it must pay Yale University a low single-digit percentage of sublicense income that it receives. As of September 30, 2024, under the Yale MoDE Agreement, the Company has remaining contingent development and commercial milestone payments of up to \$650 and \$2,950, respectively. The Yale MoDE Agreement terminates on the later of twenty years from the effective date, twenty years from the filing date of the first investigational new drug application for a licensed product or the last to expire of a licensed patent.

The Company did not record any material milestone or royalty payments under the Yale MoDE Agreement for the three months ended September 30, 2024. For the nine months ended September 30, 2024, the Company recorded research and development expense of \$150 related to the achievement of a developmental milestone under the Yale MoDE Agreement. For the three and nine months ended September 30, 2023, the Company did not record any material milestone or royalty payments under the Yale MoDE Agreement.

# ALS Biopharma Agreement

In August 2015, the Company entered into an agreement (the "ALS Biopharma Agreement") with ALS Biopharma and Fox Chase Chemical Diversity Center Inc. ("FCCDC"), pursuant to which ALS Biopharma and FCCDC assigned the Company their worldwide patent rights to a family of over 300 prodrugs of glutamate modulating agents, including troriluzole, as well as other innovative technologies. Under the ALS Biopharma Agreement, the Company is obligated to use commercially reasonable efforts to commercialize and develop markets for the patent products. As of September 30, 2024, under the ALS Biopharma Agreement, the Company has remaining contingent regulatory approval milestone payments of up to \$4,000, as well as royalty payments of a low single-digit percentage based on net sales of products licensed

under the ALS Biopharma Agreement, payable on a quarterly basis.

The ALS Biopharma Agreement terminates on a country-by-country basis as the last patent rights expire in each such country. If the Company abandons its development, research, licensing or sale of all products covered by one or more claims of any patent or patent application assigned under the ALS Biopharma Agreement, or if the Company ceases operations, it has agreed to reassign the applicable patent rights back to ALS Biopharma.

For the three and nine months ended September 30, 2024 and 2023, the Company did not record any material milestone or royalty payments under the ALS Biopharma Agreement.

# Taldefgrobep Alfa License Agreement

In February 2022, following the transfer of intellectual property, the Company announced that it entered into a worldwide license agreement with BMS for the development and commercialization rights to taldefgrobep alfa (also known as BMS-986089), a novel, Phase 3-ready anti-myostatin adnectin (the "Taldefgrobep Alfa License Agreement").

As of September 30, 2024, under the Taldefgrobep Alfa License Agreement, the Company has remaining contingent regulatory approval milestone payments of up to \$200,000, as well as tiered, sales-based royalty percentages from the high teens to the low twenties. There were no upfront or contingent payments to BMS related to the Taldefgrobep Alfa License Agreement.

For the three and nine months ended September 30, 2024 and 2023, the Company did not record any material milestone or royalty payments under the Taldefgrobep Alfa License Agreement.

# Agreement with Hangzhou Highlightll Pharmaceutical Co. Ltd.

In March 2023, the Company and Hangzhou Highlightll Pharmaceutical Co. Ltd. ("Highlightll") entered into an exclusive, worldwide (excluding People's Republic of China and its territories and possessions) license agreement (the "Highlightll Agreement") pursuant to which Biohaven obtained the right to research, develop, manufacture and commercialize Highlightll's brain penetrant dual TYK2/JAK1 inhibitor program. In connection with the Highlightll Agreement, the Company was obligated to pay Highlightll a cash payment of \$10,000 and 721,136 common shares (collectively, "the Highlightll Upfront Payments"), upon the completion of certain post-closing activities. In

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 10. License, Acquisitions and Other Agreements (Continued)

December 2023, the Company entered into a second amendment to the Highlightll Agreement, which granted the Company an exclusive option and right of first refusal to any Selective TYK2 Inhibitor being developed by or on behalf of Highlightll or its affiliates and provided for the payment of the Highlightll Upfront Payments. As a result, the Company made a \$10,000 cash payment and issued 721,136 shares, valued at \$21,814 to Highlightll during the fourth quarter of 2023, which was recorded as R&D expense during the fourth quarter of 2023.

As of September 30, 2024, under the Highlightll Agreement, the Company has remaining contingent development, regulatory approval, and commercial milestone payments of up to \$75,000, \$37,500, and \$837,500, respectively. Additionally, the Company has agreed to make tiered royalty payments as a percentage of net sales starting at mid single digits and peaking at low teens digits. During the royalty term, if the Company offers to include China clinical sites in its Phase 3 study sufficient for submission to Chinese National Medical Products Administration and Highlightll, at its sole discretion, agrees, then Highlightll will pay royalties in the low tens digits to the Company on China sales upon approval.

The Highlightll Agreement terminates on a country-by-country basis upon expiration of the royalty term and can also be terminated if certain events occur, e.g., material breach or insolvency.

For the three and nine months ended September 30, 2024 and 2023, the Company did not record any material milestone or royalty payments related to the Highlightll Agreement.

# Other Agreements

In addition to the agreements detailed above, the Company has entered into various other license agreements and development programs. The Company records milestones and other payments, including funding for research arrangements, which become due under these agreements to research and development expense in the condensed consolidated statements of operations and comprehensive loss. Amounts recorded for the period were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,			
	2024		2023	2024		2023
Milestone payments	\$ _	\$	1,250	\$ 1,875	\$	1,250

For the three and nine months ended September 30, 2024 and 2023, the Company did not make any upfront payments under these agreements.

# **Acquisitions**

# Kv7 Platform Acquisition

In April 2022, the Company closed the acquisition from Knopp of Channel Biosciences, LLC ("Channel"), a wholly owned subsidiary of Knopp owning the assets of Knopp's Kv7 channel targeting platform (the "Kv7 Platform Acquisition"), pursuant to the Purchase Agreement, dated February 24, 2022.

Under the Purchase Agreement, the Company agreed to make success-based payments based on developmental and regulatory milestones through approvals in the United States, Europe, the Middle East and Asia ("EMEA") and Japan for the lead asset, BHV-7000 (formerly known as KB-3061), developmental and regulatory milestones for the Kv7 pipeline development in other indications and additional country approvals, and commercial sales-based milestones of BHV-7000. Additionally, the Company agreed to make scaled royalty payments in cash for BHV-7000 and the pipeline programs, with percentages starting at high single digits and peaking at low teens for BHV-7000 and starting at mid-single digits and peaking at low tens digits for the pipeline programs.

In May 2024, the Company entered into the Knopp Amendment under which the parties thereto agreed to replace the scaled high single digit to low teens royalty payment obligations with a flat royalty payment in the mid-single digits for BHV-7000 and the pipeline programs. The parties also agreed to reduce the success-based payments payable under the Purchase Agreement. The Company retains the ability to pay these contingent milestone payments in cash or in the Company's common shares at Biohaven's election, subject to the same increases if the Company elects to pay in the Company's common shares. As of September 30, 2024, under the Purchase Agreement, as amended, the Company had remaining success-based payments comprised of (i) to up to \$185,000 based on regulatory approvals in the United States and EMEA for BHV-7000 and (ii) up to an additional \$60,000 based on regulatory approval in the United States for the other Kv7 pipeline programs.

In consideration of the revisions to the success-based payment and royalty payment obligations, the Company agreed to issue to Knopp 1,872,874 Company common shares, valued at approximately \$75,000, through a private placement within 60 days of the date of

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 10. License, Acquisitions and Other Agreements (Continued)

execution of the Knopp Amendment (the "2024 Additional Consideration") and additional Company common shares with an approximate value of \$75,000 within 60 days of the first anniversary of execution of the Knopp Amendment (the "2025 Additional Consideration"). The Company has also given Knopp the option to request a one-time cash true-up payment from the Company in December 2024 in the event that Knopp continues to hold the Company's common shares representing the 2024 Additional Consideration and the value of such shares has declined (the "2024 Knopp True-Up"), and a one-time cash true-up payment from the Company in December 2025 in the event that Knopp continues to hold the Company's common shares representing the 2025 Additional Consideration and the value of such shares has declined (the "2025 Knopp True-Up"), in each case, subject to certain conditions.

The Company concluded that the agreement to issue the 2024 Additional Consideration at a future date represented a fixed forward contract under ASC 815 and classified the commitment as a forward contract liability on its condensed consolidated balance sheet on the execution date of the Knopp Amendment. The Company initially measured the forward contract associated with the 2024 Additional Consideration at a fair value of \$75,220, which was recorded as R&D expense during the three months ended June 30, 2024 in its condensed consolidated statements of operations and comprehensive loss. In May 2024, the Company issued the 2024 Additional Consideration at an approximate value of \$65,981. The Company recognized no gains or losses related to the 2024 Additional Consideration for the three months ended September 30. 2024 and gains of \$9,239 for the nine months ended September 30, 2024 in other income, net in its condensed consolidated statement of operations and comprehensive loss. The gain on settlement of the 2024 Additional Consideration was due to the decline in fair value of the 2024 Additional Consideration from the execution date to the issuance date due to a decline in Biohaven's share price. Refer to Note 4, "Fair Value of Financial Assets and Liabilities" and Note 6, "Shareholders' Equity" for further discussion.

The 2024 Additional Consideration True-up represents a net cash settled written put option measured at fair value on a recurring basis. The Company has concluded that the 2024 Additional Consideration True-up represents a net cash settled written put option on the Company's shares and is a freestanding derivative liability under ASC 815. Accordingly, the Company classified the 2024 Additional Consideration True-up as a current derivative liability on its condensed consolidated balance sheet. The Company

initially recorded the 2024 Additional Consideration True-up at a fair value of \$15,540, which was recorded as R&D expense during the three months ended June 30, 2024 in its condensed consolidated statements of operations and comprehensive loss. The Company subsequently remeasures the fair value of the derivative liability and recognizes any gains or losses through other income, net in its condensed consolidated statement of operations and comprehensive loss. The Company recognized gains related to the 2024 Additional Consideration True-Up of \$16,130 and \$15,540 for the three and nine months ended September 30, 2024, respectively, in other income, net in its condensed consolidated statement of operations and comprehensive loss. Refer to Note 4, "Fair Value of Financial Assets and Liabilities" for further discussion.

The Company has concluded that the agreement to issue the 2025 Additional Consideration at a future date represents a forward contract settleable in a variable number of shares under ASC 480. and classified the commitment as a current forward contract liability on its condensed consolidated balance sheet. The Company initially measured the 2025 Additional Consideration at a fair value of \$63,940, which was recorded as R&D expense during the three months ended June 30, 2024 in its condensed consolidated statements of operations and comprehensive loss. The Company subsequently remeasures the fair value of the forward contract liability and recognizes any gains or losses through other income, net in its condensed consolidated statement of operations and comprehensive loss. The Company recognized expense of \$3,940 and \$5,090 for the three and nine months ended September 30, 2024, respectively, related to the 2025 Additional Consideration. Refer to Note 4, "Fair Value of Financial Assets and Liabilities" for further discussion.

The Company has concluded that the 2025 Additional Consideration True-up represents a net cash settled written put option on the Company's shares and is a freestanding derivative liability under ASC 815. Accordingly, the Company classified the 2025 Additional Consideration True-up as a non-current derivative liability on its condensed consolidated balance sheet. The Company initially recorded the 2025 Additional Consideration True-up at a fair value of \$13,810, which was recorded as R&D expense during the three months ended June 30, 2024. The Company subsequently remeasures the fair value of the derivative liability and recognizes any gains or losses through other income, net in its condensed consolidated statement of operations and comprehensive loss. The Company recognized expense of \$140 and a gain of \$1,490 for the three and nine months ended September 30, 2024,

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 10. License, Acquisitions and Other Agreements (Continued)

related to the 2025 Additional Consideration True-up. Refer to Note 4, "Fair Value of Financial Assets and Liabilities" for further discussion.

As further consideration for the revisions to the success-based payment and royalty payment obligations in the Knopp Amendment, the Company issued to Knopp a warrant (the "Warrant") to purchase 294,195 Company common shares at a purchase price per share of \$67.98, subject to certain specified development milestones and the Company achieving a specified market capitalization. Refer to Note 6, "Shareholders' Equity" for further discussion.

The Company has not recorded any of the remaining contingent consideration payments to Knopp as a liability in the accompanying condensed consolidated balance sheet as none of the future events which would trigger a milestone payment were considered probable of occurring at September 30, 2024.

# Pyramid Acquisition

In January 2024, the Company acquired Pyramid Biosciences, Inc. ("Pyramid"), pursuant to an Agreement and Plan of Merger, dated January 7, 2024 ("the Pyramid Agreement"). In consideration for the Pyramid acquisition, Biohaven made an upfront payment of 255,794 Company common shares, valued at approximately \$10.894.

The Company accounted for this purchase as an asset acquisition as substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset, IPR&D. The IPR&D asset has no alternative future use and relates primarily to BHV-1510. There was no material value assigned to any other assets or liabilities acquired in the acquisition. As such, the upfront payment discussed above was recorded as a charge to R&D expense in the accompanying condensed consolidated statements of operations and comprehensive loss during the three months ended March 31, 2024.

As of September 30, 2024, under the Pyramid Agreement, the Company has remaining success-based payments comprised of (i) up to \$5,000 based on developmental and regulatory milestones for the lead asset, BHV-1510 (formerly known as PBI-410), (ii) up to an additional \$30,000 based on developmental and regulatory milestones for a second asset (formerly known as PBI-200) and (iii) up to \$40,000 for commercial sales-based milestones of BHV-1510. Contingent developmental and regulatory milestone payments may be paid in cash or Biohaven common shares at the

election of Biohaven and commercial sales-based milestones are to be made in cash.

The Company has not recorded any of the remaining contingent consideration payments as a liability in the accompanying condensed consolidated balance sheet as none of the future events which would trigger a milestone payment were considered probable of occurring at September 30, 2024.

During the first quarter of 2024, the Company recorded \$5,689 of R&D expense in the condensed consolidated statement of operations and comprehensive loss for a developmental milestone which became due under the Pyramid Agreement, to be paid in 98,129 common shares of the Company. See Note 6, "Shareholders' Equity" for discussion of common shares issued to as part of the Pyramid Agreement.

# 11. Commitments and Contingencies

# Lease Agreements

The Company leases certain office and laboratory space. Other than the Pittsburgh Centre Avenue Lease described below, there have been no material changes to the lease obligations from those disclosed in Note 11, "Commitments and Contingencies" to the consolidated financial statements included in the 2023 Form 10-K.

# Pittsburgh Centre Avenue Lease Agreement

In March 2024, the Company entered into a lease agreement in Pittsburgh, Pennsylvania for lab space (the "Pittsburgh Centre Avenue Lease"), which will be used to support the research and development of the Company's ion channel platform and replace the Company's current operating lease in Pittsburgh. The lease is expected to commence in mid 2025 after substantial completion of building improvements, and has a term of 122 months, with an option to extend for one additional period of 60 months. The Company expects to record the Pittsburgh Centre Avenue Lease as an operating lease. The Company has annual commitments relating to the Pittsburgh Centre Avenue Lease ranging from \$1,859 to \$2,373, excluding any additional tenant improvement allowance that would increase the base rent.

# Research Commitments

The Company has agreements with several contract manufacturing organizations ("CMOs") and contract research organizations ("CROs") to provide products and services in connection with the Company's preclinical studies and clinical trials. As of September

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 11. Commitments and Contingencies (Continued)

30, 2024, the Company had no remaining maximum research commitments in excess of one year.

# **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 and executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service. 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 condensed consolidated financial statements as of September 30, 2024 or December 31, 2023.

# License, Acquisition and Other Agreements

The Company has entered into licensing, developmental and acquisition agreements with various parties under which it is obligated to make contingent and non-contingent payments (see Note 10, "License, Acquisitions and Other Agreements").

# Other Agreements

# Moda Agreement

On January 1, 2021, the Company entered into a consulting services agreement (the "Moda Agreement") with Moda Pharmaceuticals LLC ("Moda") to further the scientific advancement of technology, drug discovery platforms (including the technology licensed under the Yale MoDE Agreement), product candidates and related intellectual property owned or controlled by the Company.

Under the Moda Agreement, the Company paid Moda an upfront cash payment of \$2,700 and 37,836 shares of the Former Parent valued at approximately

\$3,243. In addition, Moda will be eligible to receive additional development, regulatory, and commercial milestone payments of up to \$111,783. The Moda Agreement has a term of four years and may be terminated earlier by the Company or Moda under certain circumstances including, for example, the Company's discontinuation of research on the MoDE platform or default. In August 2023, the Company entered into an amendment to the Moda Agreement with Moda. Under the amendment, Moda will be eligible to receive development, regulatory, and commercial milestone payments of up to \$48,200, in addition to the milestones noted above.

The Company did not record any material milestone payments related to the Moda Agreement for the three months ended September 30, 2024. For the nine months ended September 30, 2024, the Company recorded research and development expense of \$850 related to developmental milestones under the Moda Agreement. For the three and nine months ended September 30, 2023, the Company did not record any material milestone payments related to the Moda Agreement.

# Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. As of September 30, 2024, there were no matters which would have a material impact on the Company's financial results.

# 12. Income Taxes

The following table provides a comparative summary of the Company's income tax provision and effective income tax rate for the three and nine months ended September 30, 2024 and 2023:

	Three Mo Septe		Nin		nded 30,	September
	2024	2023		2024		2023
Income tax (benefit) provision	\$ (59)	\$ (3,287)	\$	687	\$	(171)
Effective income tax rate	— %	(3.1)%	ó	0.1 %		(0.1)%

The change in income tax provisions for the three months ended September 30, 2024 as compared to the same period in 2023 was primarily attributable to the Company adopting the guidance contained in a Notice of

# NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

# 12. Income Taxes (Continued)

Proposed Rule Making issued during the third quarter of 2023 by the United States Internal Revenue Service ("the Notice"). The Notice allows the Company to immediately deduct certain R&D expenditures which were incurred in the US and reimbursed by the Company's foreign parent. Previously, these expenditures were required to be capitalized under the Tax Cuts and Jobs Act, which was effective for tax years beginning on or after January 1, 2022.

The change in income tax provisions for the nine months ended September 30, 2024 as compared to the same period in 2023 was primarily attributable to an increase in income in the US, partially offset by windfall tax deductions arising from non-cash share-based compensation.

# 13. Related Party Transactions

# Relationship with the Former Parent

Upon the effectiveness of the Separation on October 3, 2022, the Former Parent ceased to be a related party of the Company.

On October 3, 2022, the Company entered into agreements with the Former Parent in connection with the Separation, including a Transition Services Agreement. For a full discussion of agreements entered into with the Former Parent, refer to Note 14, "Related Party Transactions" to the consolidated financial statements included in the 2023 Form 10-K. The Company did not record any material income for transition services provided to the Former Parent during the three and nine months ended September 30, 2024. For the three and nine months ended September 30, 2023, the Company recorded \$1,233 and \$6,753, respectively, in other income reflecting transition services provided to the Former Parent.

# Related Party Agreements

# License Agreement with Yale University

On September 30, 2013, the Company entered into the Yale Agreement with Yale University (see Note 10). The Company's Chief Executive Officer is one of the inventors of the patents that the Company has licensed from Yale University and, as such, is entitled to a specified share of the glutamate product-related royalty revenues that may be received by Yale University under the Yale Agreement.

In January 2021, the Company entered into the Yale MoDE Agreement with Yale University (see Note 10 for details). Under the license agreement, the Company acquired exclusive, worldwide rights to Yale University's

intellectual property directed to its MoDE platform. Under the Yale MoDE Agreement, the Company entered into the Yale MoDE SRA (see Note 10 for details), which included funding of up to \$4,000 over the life of the agreement. In May 2023, the Company entered into an additional sponsored research agreement with Yale University (the "2023 Yale SRA"), which includes funding of up to \$612 over the life of the agreement.

For the three and nine months ended September 30, 2024, the Company recorded \$422 and \$1,449, respectively, in R&D expense, including certain administrative expenses, related to the Yale MoDE Agreement, the Yale Agreement, and the 2023 Yale SRA (collectively, the "Yale Agreements"). For the three and nine months ended September 30, 2023, the Company recorded \$614 and \$2,313, respectively, in research and development expense, including certain administrative expenses, related to the Yale Agreements. As of September 30, 2024, the Company did not owe any amounts to Yale University.

# Item 2. 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 condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 Form 10-K") filed with the Securities and Exchange Commission (the "SEC"). 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 (the "Exchange Act"). We have based these forwardlooking statements on our current expectations and projections about future events. The following information and any forwardlooking statements should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q 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, among other things, 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 biopharmaceutical company focused on the discovery, development, and commercialization of life-changing treatments in key therapeutic areas, including immunology, neuroscience, and oncology. We are advancing our innovative portfolio of therapeutics, leveraging our proven drug development experience and multiple proprietary drug development platforms. Our extensive clinical and preclinical programs include Kv7 ion channel modulation for epilepsy and mood disorders; extracellular protein degradation for immunological diseases; Transient Receptor Potential Melastatin 3 ("TRPM3") antagonism for migraine and neuropathic pain; Tyrosine Kinase 2/Janus Kinase 1 ("TYK2/JAK1") inhibition for neuroinflammatory disorders: glutamate modulation for obsessive-compulsive disorder ("OCD") and spinocerebellar ataxia ("SCA"); myostatin inhibition for neuromuscular and metabolic diseases, including spinal muscular atrophy ("SMA") and obesity; and antibody recruiting bispecific molecules ("ARMs") and antibody drug conjugates ("ADCs") for cancer.

# Separation from Biohaven Pharmaceutical Holding Company Ltd.

On October 3, 2022, Biohaven Pharmaceutical Holding Company Ltd. (the "Former Parent") completed the distribution (the "Distribution") to holders of its common shares of all of the outstanding common shares of Biohaven Ltd. and the spin-off of Biohaven Ltd. from the Former Parent (the "Spin-Off") described in Biohaven's Information Statement attached as Exhibit 99.1 to Biohaven's Registration Statement on Form 10, as amended (Reg. No. 001-41477). Collectively, we refer to the Distribution and Spin-Off throughout this Quarterly Report on Form 10-Q as the "Separation." As a result of the Separation, Biohaven Ltd. became an independent, publicly traded company as of October 3, 2022, and commenced regular way trading under the symbol "BHVN" on the New York Stock Exchange (the "NYSE") on October 4, 2022. Where we describe historical business activities in this report, we do so as if the Former Parent's activities related to such assets and liabilities had been performed by the Company.

# **Clinical-Stage Milestones**

Our clinical-stage milestones include the following:

		1H 2024	2H 2024
	Obsessive-Compulsive Disorder	Phase 3 Interim Analysis	
	2 ongoing trials		Phase 3 Interim Analysis
Troriluzole   BHV-4157	Spinocerebellar Ataxia		Topline Results – RWE protoco
	i i		NDA Submission
Table for all and Alfa I DUNA 0000	Spinal Muscular Atrophy		Phase 3 Topline
Taldefgrobep Alfa   BHV-2000	Obesity		Initiate Phase 2
	Focal Epilepsy	Initiate Phase 2/3	
Kv7 Activator   BHV-7000	Generalized Epilepsy	Initiate Phase 2/3	
	Bipolar Disorder	Initiate Phase 2/3	
	Major Depressive Disorder	Initiate Phase 2	
TDDM0.A. (	Migraine		Initiate Phase 2
TRPM3 Antagonist   BHV-2100	Neuropathic Pain		Initiate POC
TYK2/JAK1   BHV-8000 (brain-penetrant)	Neurodegenerative Disorders		Initiate Phase 2
lgG Degrader   BHV-1300	Rheumatoid Arthritis	Phase 1 lgG Interim Data	SAD & MAD data update
lgG Degrader   BHV-1310	Myasthenia Gravis		Initiate Phase 1
lgA Degrader   BHV-1400	IgA Nephropathy		Initiate Phase 1
β1-AR AAB Degrader   BHV-1600	Dilated Cardiomyopathy		Initiate Phase 1
Trop2   BHV-1510	Advanced or Metastatic Epithelial Tumors	Initiate Phase 1	
B Autoantihody			

AAB, Autoantibody

Milestone achieved

# Glutamate Modulation Platform

The most advanced product candidate from our glutamate receptor antagonist platform is troriluzole (previously referred to as trigriluzole and BHV-4157), which is currently in two Phase 3 trials in OCD and, for which, we plan to submit a new drug application ("NDA") in Spinocerebellar Ataxia ("SCA") to the U.S. FDA and have submitted a marketing authorisation application ("MAA") in SCA Type 3 ("SCA3") to the European Medicines Agency ("EMA"). Troriluzole is also being evaluated by the Global Coalition for Adaptive Research ("GCAR") as part of Glioblastoma Adaptive Global Innovative Learning Environment - NCT03970447 ("GBM AGILE"), a revolutionary patient-centered, adaptive platform trial for registration that tests multiple therapies for patients with newly-diagnosed and recurrent glioblastoma ("GBM"). Other product candidates include BHV-5500, which is an antagonist of the glutamate N-methyl-D-aspartate ("NMDA") receptor and its oral prodrug BHV-5000.

# Troriluzole

# Spinocerebellar Ataxia

SCAs are a group of ultra-rare, dominantly inherited neurodegenerative disorders predominantly characterized by atrophy of the cerebellum, brainstem, and spinal cord. The disease course of SCA is one of relentless progression over years and inevitably leads to clinical deterioration of motor function, gait imbalance with frequent falling, severe speech impairment,

swallowing difficulties, and premature death. SCAs are thought to be pathogenetically related but disease course and brain region involvement are known to vary between the different genotypes. SCA affects approximately 15,000 people in the United States and 24,000 in Europe and the United Kingdom. SCA3, also known as Machado-Joseph disease, is the most common genotype, and accounts for approximately 30% to 50% of SCAs worldwide. Currently, there are no approved symptomatic or neuroprotective treatments for SCA.

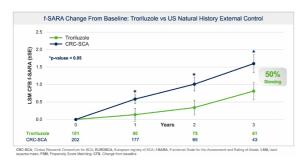
In May 2022, the Company announced top-line results from the Phase 3 clinical trial (Study BHV4157-206) evaluating the efficacy and safety of its investigational therapy, troriluzole, in patients with SCA. The primary endpoint, change from baseline to week 48 on the modified functional Scale for the Assessment and Rating of Ataxia ("f-SARA"), did not reach statistical significance in the overall SCA population as there was less than expected disease progression in the placebo arm over the course of the study. Preliminary post hoc analysis of efficacy measures by genotype suggested a treatment effect in patients with the SCA3 genotype (p=0.045, LSM difference from placebo). A risk reduction in falls was also observed in the SCA3 population, as well as across all SCA genotypes. Troriluzole was well tolerated with an adverse event profile similar to placebo.

Based on the findings of further analyses performed and the debilitating nature of SCA, in May 2023 we announced that we submitted a New Drug

Application ("NDA") to the FDA for troriluzole for the treatment of SCA3. In July 2023, the FDA informed us that it would not review the recently submitted NDA application for troriluzole given that the study's primary endpoint was not met and thus, would not permit a substantive review. In followup to the regulatory decision on the NDA application, we held followup meetings with the FDA regarding the SCA data.

In October, 2023, the EMA informed us that our Marketing Authorization Application ("MAA") for troriluzole (Dazluma) in the treatment of SCA3 has been validated and is now under review by EMA's Committee for Medicinal Products for Human Use ("CHMP"). In the fourth quarter of 2024, we completed a clarification meeting with the CHMP Rapporteurs. The MAA documents are now being updated with a broader indication to include all SCA genotypes, in light of the new positive BHV4157-206-RWE study data (discussed below).

In September 2024, we announced positive topline results from pivotal Study BHV4157-206-RWE (NCT06529146) demonstrating the efficacy of troriluzole on the mean change from baseline in the f-SARA after 3 years of treatment. The study achieved the primary endpoint and showed statistically significant improvements on the f-SARA at years 1 and 2 and 3 (see figure below).

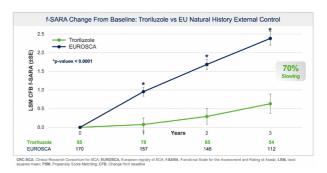


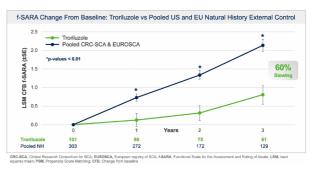
Collectively, data across multiple analyses demonstrate a robust and clinically meaningful slowing of disease progression in SCA patients. These treatment benefits translate into a 50-70% slower rate of decline compared to untreated patients, representing 1.5-2.2 years delay in disease progression over the 3-year study period. Additionally, in a responder sensitivity analysis, disease progression when defined by a 2 point or greater worsening on the f-SARA at 3 years showed an odds ratio ("OR") of 4.1 (95% CI: 2.1, 8.1) for the untreated external control arm versus troriluzole treated subjects (p < 0.0001; pooled analysis).

Study BHV4157-206-RWE was designed, in discussion with the FDA, to assess the effectiveness of troriluzole in SCA after 3 years of treatment as measured by the change from baseline in the f-SARA. The study utilized Phase 3 data and an external control of matched, untreated SCA subjects from the US Clinical Research Consortium for the Study of Cerebellar Ataxia ("CRC-SCA") in accordance with FDA's Guidance on

Real-World Evidence ("RWE") of effectiveness. All endpoints were prespecified, and both the study protocol and statistical analysis plan were submitted to, and reviewed by, FDA prior to topline data analysis. The new analysis doubled the previously available 3 year data with 63 subjects now completing 3 years of treatment with troriluzole and matched to the external control arm. Propensity Score Matching ("PSM") was used to ensure that untreated patients from the CRC-SCA study were rigorously matched to treated patients from Study BHV4157-206 on baseline characteristics. The primary objective was to examine the treatment effects of troriluzole for up to 3 years, by comparing data on the f-SARA from patients treated with troriluzole in Study BHV4157-206 to untreated patients from the natural history study. Troriluzole-treated patients demonstrated statistically significant and sustained benefits at years 1, 2 and 3 on the f-SARA compared to a rigorously matched natural history control.

Additionally, prespecified analyses in the protocol employed a separate, independent natural history control from the European SCA natural history study ("EUROSCA") for global regulatory purposes. Results using the EUROSCA patients, in addition to a pooled analysis using both CRC-SCA and EUROSCA patients, as the external controls were also statistically significant and consistent with the primary efficacy analysis at all timepoints (see figures below). The addition of EUROSCA data increased the external control sample size and added to the robustness of the statistically significant treatment differences at years 1, 2, and 3, favoring troriluzole.





Based upon the topline data from Study BHV4157-206-RWE, and previous safety and efficacy data from the troriluzole development program in SCA,

we plan to submit an NDA to the FDA in the fourth quarter of 2024. The troriluzole development program has generated the largest clinical trial dataset in SCA and now has follow-up in some patients treated with troriluzole for over 5 years. We previously received both Fast-Track and Orphan drug designation ("ODD") from the FDA, and ODD from the European Medicines Agency ("EMA"), for troriluzole in SCA. An NDA with ODD is eligible for priority FDA review. We will be prepared to commercialize SCA in the US in 2025, if ultimately approved, based on potential priority review timelines.

# Obsessive Compulsive Disorder

We commenced a Phase 2/3 double-blind, randomized, controlled trial to assess the efficacy of troriluzole in adults with OCD in December 2017. The Phase 2/3 study results were announced in June 2020. Troriluzole 200 mg administered once daily as adjunctive therapy in OCD patients with inadequate response to standard of care treatment showed consistent numerical improvement over placebo on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) at all study timepoints (weeks 4 to 12) but did not meet the primary outcome measure at week 12. Troriluzole treated subjects (n = 111) had a mean Y-BOCS improvement of -3.4 points from baseline versus -2.9 for placebo-treated (n = 115) subjects [difference -0.5 and p-value = 0.451] at week 4, -5.1 points (n = 96) versus -3.6 for placebo-treated (n = 108) subjects [difference -1.5 and p-value = 0.041] at week 8, and -5.9 points (n = 99) versus -4.9 for placebotreated (n = 102) subjects [difference -1.0 and p-value = 0.220] at week 12. Troriluzole's safety profile was generally consistent with past clinical trial experience with its active metabolite, riluzole. Treatment emergent adverse events ("TEAE"s) were mostly reported to be mild in intensity. TEAEs that occurred in at least 5% of patients in the troriluzole group, and more frequently in the troriluzole group than in the placebo group, were headache, dizziness, fatigue, somnolence, nausea and nasopharyngitis.

Given the strong signal in the Phase 2/3 proof of concept study and after receiving feedback from the FDA in an End of Phase 2 meeting, in December 2020 we initiated enrollment in a Phase 3 program. The Phase 3 program will have an estimated total enrollment of up to 700 participants in each trial with a primary endpoint of change from baseline on the Y-BOCS total score at week 4, 8 and 10. The two Phase 3 randomized, double-blind, placebocontrolled trials that make-up our Phase 3 program for OCD are currently ongoing.

In January 2024, we announced plans to conduct a preplanned interim analysis ("IA") to evaluate efficacy in the first of our two Phase 3 studies in OCD. The IA was planned to be conducted by an independent Data Monitoring Committee after approximately 70% of subjects in the primary analysis population reached the primary endpoint. The Data Monitoring Committee convened in the second quarter of 2024 to review the IA and informed the Company that the study may continue. As such, we continue enrolling patients in the first

Phase 3 study in OCD and expect that this study will be fully enrolled in the first quarter of 2025. We expect to report topline data from the first Phase 3 study in OCD in the first half of 2025.

There is a similarly designed pre-planned IA for the second Phase 3 study in OCD, with topline results from this IA anticipated in the fourth quarter of 2024.

# Glioblastoma

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

In July 2022, the Company and GCAR announced that enrollment has commenced in GBM AGILE for the evaluation of troriluzole. The study is currently ongoing.

# **Myostatin Platform**

# Taldefgrobep Alfa (BHV-2000)

In February 2022, we announced a worldwide license agreement with BMS for the development and commercialization rights to taldefgrobep alfa (also known as BMS-986089 and now referred to as BHV-2000), a novel, Phase 3-ready anti-myostatin adnectin. Myostatin is a natural protein that limits skeletal muscle growth, an important process in healthy muscular development that can lead to improvements of lean mass and loss of adipose tissue by acting through the activin receptor type-2B ("ActRIIb"). In patients with neuromuscular diseases, active myostatin can critically limit the growth needed to achieve developmental and functional milestones. Myostatin inhibition is a promising therapeutic strategy for enhancing muscle mass and strength in a range of pediatric and adult neuromuscular conditions. In addition, preclinical and early clinical data suggest that blocking myostatin and downstream signaling through its receptors on skeletal muscle may produce physical and metabolic changes that are important to individuals living with overweight and obesity, including reducing body fat and improving insulin sensitivity while increasing lean muscle mass. Taldefgrobep's novel mode of action inhibiting both myostatin directly and through the ActRIIb and its unique impact on body composition suggest it could be used as monotherapy or in combination with other antiobesity medications.

# Spinal Muscular Atrophy

In July 2022, we commenced enrollment in a Phase 3 clinical trial of BHV-2000 assessing the efficacy and safety of taldefgrobep alfa in Spinal Muscular Atrophy ("SMA"). SMA is a rare, progressively debilitating motor neuron disease in which development and growth of muscle mass are compromised, resulting in progressive weakness and muscle atrophy, reduced motor function, impaired quality of life and often death. The Phase 3 placebo-controlled, double-blind trial is designed to evaluate the efficacy and safety of taldefgrobep as an adjunctive therapy for participants who are already taking a stable dose of nusinersen or risdiplam or have a history of treatment with onasemnogene abeparvovec-xioi (Zolgensma), compared to placebo. The study is neither restricted nor limited to patients based on ambulatory status or classification of SMA and is designed to randomize approximately 180 patients in this randomized, double-blind, placebo-controlled global trial. Baseline characteristics of the population enrolled in the ongoing Phase 3 study in SMA were reported and confirmed to be well matched to the target clinical population. The

primary endpoint of the study, the 32 Item Motor Function Measurement, is a reliable and validated endpoint for measuring clinically meaningful benefit in SMA. We expect to report topline data from our Phase 3 study in the fourth quarter of 2024.

In February 2023, we received Fast Track designation from the FDA for taldefgrobep alfa for the treatment of SMA. In December 2022, we received orphan drug designation from the FDA for taldefgrobep in the treatment of SMA. In July 2023, we received orphan drug designation from the European Commission for taldefgrobep alfa in the treatment of SMA.

In April 2024, we announced that the FDA granted "rare pediatric disease" designation for taldefgrobep alfa. The designation provides for the potential for taldefgrobep to receive a priority review voucher ("PRV") if ultimately approved for the indication of SMA prior to September 30, 2026. The rare pediatric disease PRV program will begin to sunset in December of 2024 and will not apply for approvals after September 30, 2026.

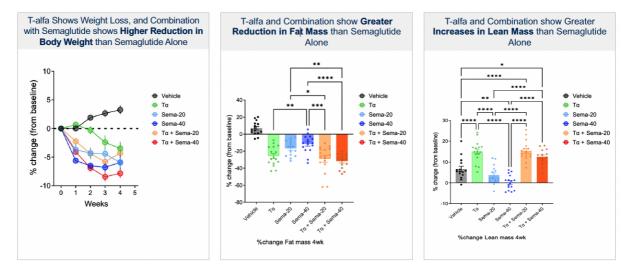
# Metabolic Disorders

Obesity is a disease of excess and/or abnormal deposits of adipose tissue and a current global public health crisis. By 2030, it is expected that nearly one billion people will be living with obesity, including 50% of the adult and 25% of the adolescent US population. The primary driver of obesity-related morbidity and mortality is metabolically active visceral adipose tissue and associated deposits of adipose tissue in and around organs such as the heart, liver, kidneys, and muscle.

Preclinical and clinical data have demonstrated the potential for anti-myostatin therapies to produce physical and metabolic changes that are highly relevant to individuals living with overweight and obesity, including reducing total body fat and visceral adiposity, and improving insulin sensitivity and bone mineral density, while increasing lean muscle mass.

In October 2023, we announced preclinical data demonstrating the ability of taldefgrobep alfa to significantly reduce fat mass while increasing lean mass in an obese mouse model. In a mouse model of diet-induced obesity, untreated mice exhibited an increase in fat mass of 31%, while the mice treated with taldefgrobep alfa demonstrated increases in lean mass of 25% from baseline (p≤.0.001) and lost 11% of their baseline fat (p≤.0.001) compared to vehicle (placebo) treated mice. Insulin and leptin levels were consistently lower in mice treated with taldefgrobep alfa compared to the untreated mice. There was no difference in food intake over time across the taldefgrobep alfa and untreated mice, counter to what has been observed with incretin mimetics (e.g., semaglutide) which are consistently associated with a reduction in energy intake.

In May 2024, we announced preclinical data from a diet induced obesity mouse model, which showed treatment with taldefgrobep alfa together with a glucagon-like peptide-1 ("GLP-1") agonist produced greater reductions in body weight and fat mass, and a larger increase in lean muscle mass, compared to treatment with GLP-1 alone (see figure below).



We plan to initiate a Phase 2 clinical trial of taldefgrobep in the management of metabolic disease in the fourth quarter of 2024 or early 2025. The study will evaluate the ability of taldefgrobep to maintain lean mass muscle as an adjunctive to standard of care GLP-1 therapy in adults living with overweight and obesity. We are evaluating and have not yet finalized potential clinical trial designs, including size and primary and secondary endpoints.

#### Ion Channel Platform

# Kv7

# BHV-7000

In April 2022, we closed the acquisition from Knopp Biosciences LLC ("Knopp") of Channel Biosciences, LLC, a wholly owned subsidiary of Knopp owning the assets of Knopp's Kv7 channel targeting platform, pursuant to a Membership Interest Purchase Agreement, dated February 24, 2022 (the "Purchase Agreement"). The acquisition of the Kv7 channel targeting platform added the latest advances in ion-channel modulation to our growing neuroscience portfolio. BHV-7000 (formerly known as KB-3061), the lead asset from the Kv7 platform is an activator of Kv7.2/Kv7.3, a key ion channel involved in neuronal signaling and in regulating the hyperexcitable state in epilepsy.

In the second quarter of 2022, our Clinical Trial Application for BHV-7000 was approved by Health Canada, and we subsequently began Phase 1 clinical development. First-in-human single ascending dose ("SAD") and multiple ascending dose ("MAD") studies have now been completed. BHV-7000 was well-tolerated at all dose levels in both studies with no SAEs and no dose-limiting toxicities.

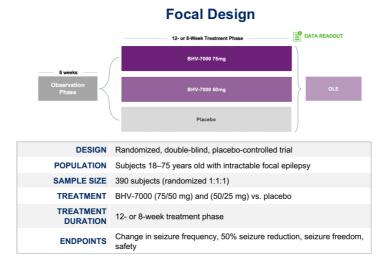
In 2023, we initiated a Phase 1 open-label electroencephalogram ("EEG") study designed to evaluate the effects of BHV-7000 on changes from baseline in EEG spectral power after administration of single doses of BHV-7000 (10, 25, or 50 mg) to healthy adult volunteers. BHV-7000 was well-tolerated at all doses studied and EEG data showed dose-dependent increases in brain spectral power, with minimal power increase in the delta frequency band and the highest spectral power increases in the alpha, beta, and gamma frequency bands. The minimal impact of BHV-7000 on slower frequencies (i.e., delta) is consistent with the low incidence of central nervous system ("CNS") adverse events, in particular somnolence, seen in the BHV-7000 Phase 1 SAD/MAD studies, and the study results confirm the CNS activity of BHV-7000 at projected therapeutic concentrations.

Based on the results from the EEG study and the safety profile in SAD/MAD trials, along with PK data from a new once-daily extended-release ("ER") formulation, Biohaven plans on exploring three oral dose levels of once-daily BHV-7000 (25 mg, 50 mg, and 75 mg) in the Phase 2/3 clinical trials in epilepsy and mood disorders. This dosing approach with a Kv7 activator will allow for assessment of distinct target concentrations over a wide range, above and below EC50 drug concentrations efficacious in nonclinical models, not previously feasible with drugs in this class.

# **Epilepsy**

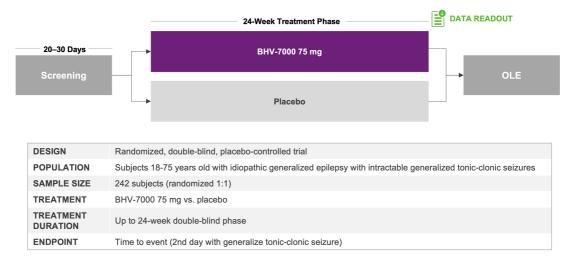
Epilepsy affects approximately 3.5 million Americans, or more than 1.2% of adults and 0.6% of children in the U.S., and more than 50 million patients worldwide, according to the World Health Organization ("WHO"). It is the fourth most common neurological disorder, and many patients struggle to achieve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

In January 2024, we completed our End-of-Phase 2 meeting with the FDA to advance to Phase 3 trials and announced that more than 110 global clinical sites have been selected in the first of two focal epilepsy trials. Enrollment in our Phase 2/3 program commenced in the first quarter of 2024. The two pivotal studies evaluating the efficacy of BHV-7000 in refractory focal epilepsy are planned as randomized, double-blind, placebo-controlled, 8- and 12-week trials with a primary endpoint of change from baseline in 28-day average seizure frequency in adults with focal epilepsy. One of the focal epilepsy studies will evaluate 25 mg and 50 mg doses of BHV-7000 and the second study will evaluate 50 mg and 75 mg doses of BHV-7000 (see figure below).



In addition to the focal epilepsy program, we initiated a Phase 2/3 study of BHV-7000 in idiopathic generalized epilepsy ("IGE") in the second quarter of 2024. The pivotal study evaluating the efficacy of BHV-7000 with IGE is planned

as a randomized, double-blind, placebo-controlled 24-week time-to-event trial with a primary endpoint of time to second generalized seizure in adults and adolescents with IGE (see figure below).

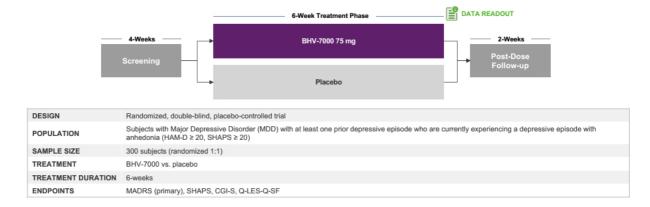


#### **Mood Disorders**

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

# Major Depressive Disorder

We initiated a Phase 2 clinical trial with BHV-7000 for the treatment of MDD in the second quarter of 2024. The study is a 6 week, randomized, double-blind, placebo-controlled trial in approximately 300 subjects, with a primary endpoint of measurement on the Montgomery-Asberg Depression Rating Scale ("MADRS"). See figure below for trial design.



### Bipolar disorder

We also initiated a Phase 2/3 clinical trial with BHV-7000 for the treatment of bipolar disorder in the second quarter of 2024. The study is a 3 week, randomized, double-blind, placebo-controlled trial in approximately 256 subjects, with a primary endpoint of measurement on the Young Mania Rating Scale ("YMRS"). See figure below for trial design.



DESIGN	Randomized, double-blind, placebo-controlled trial
POPULATION	Subjects with Bipolar Disorder I with at least one prior mood episode who are currently experiencing a manic episode (YMRS ≥ 20)
SAMPLE SIZE	256 subjects (randomized 1:1)
TREATMENT	BHV-7000 vs. placebo
TREATMENT DURATION	3-weeks
ENDPOINTS	YMRS (primary), CGI-S

# KCNQ2 Developmental Epileptic Encephalopathy

We are currently exploring BHV-7000 as a potential treatment for KCNQ2 developmental epileptic encephalopathy ("KCNQ2-DEE"), a rare pediatric epileptic encephalopathy first described in 2012 resulting from dominant-negative mutations in the KCNQ2 gene. BHV-7000 has been granted Rare Pediatric Disease Designation by the United States Food and Drug Administration (the "FDA") for the treatment of KCNQ2-DEE.

#### Neuropathic Pain

We are currently evaluating the activity of BHV-7000 and other compounds from our proprietary series of selective Kv7.2/7.3 activators in multiple preclinical models of neuropathic pain.

#### Migraine

We are currently exploring BHV-7000 as a potential treatment for migraine. Kv7.2/7.3 openers have shown significant activity in cortical spreading depression models of migraine.

#### **TRPM3 Ion Channel Antagonists**

In January 2022, we entered into an Exclusive License and Research Collaboration Agreement with Katholieke Universiteit Leuven ("KU Leuven") to develop and commercialize TRPM3 antagonists to address the growing proportion of people worldwide living with chronic pain disorders (the "KU Leuven Agreement"). The TRPM3 antagonist platform was discovered at the Centre for Drug Design and Discovery and the Laboratory of Ion Channel Research at KU Leuven. Under the KU Leuven Agreement, we receive exclusive global rights to develop, manufacture and commercialize KU Leuven's portfolio of small-molecule TRPM3 antagonists. The portfolio includes the lead candidate, henceforth known as BHV-2100.

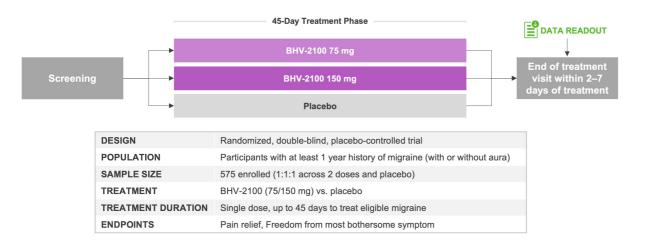
## **BHV-2100**

BHV-2100 is an orally-bioavailable small molecule antagonist of TRPM3. TRPM3 is expressed in the relevant human tissue types for pain and migraine, and both preclinical models and human genetics implicate TRPM3 in pain and migraine.

In May 2024, we reported positive pharmacokinetic and safety data from the completed Phase 1 study with BHV-2100. The results demonstrated rapid absorption with therapeutic concentrations achieved by 20 minutes. The favorable tolerability profile at single doses up to 500 mg exceeds the anticipated therapeutic dose and is well above the EC90 concentration. Based on these findings, we have initiated a Phase 2 study of BHV-2100 in the acute treatment of migraine and a proof-of-concept study in pain in the fourth quarter of 2024.

### Migraine

In September 2024, we announced that we have initiated a Phase 2 study evaluating BH-2100 in the acute treatment of migraine. The study is a 45-day, randomized, double-blind, placebo-controlled trial in approximately 575 subjects, with primary endpoints of freedom from pain at two hours post-dose and freedom from most bothersome symptom at two hours post-dose. See figure below for trial design.



#### Neuropathic Pain

BHV-2100 is also being developed as a potential non-opioid treatment for neuropathic pain. We are evaluating the ability of BHV-2100 to reduce pain behaviors across several preclinical models of neuropathic pain, including chemotherapy induced neuropathy, diabetic neuropathy, and nerve injury. The Company initiated a proof of concept study for neuropathic pain in the fourth quarter of 2024.

The study is a Phase-1b, randomized, double-blind, placebo and active reference controlled, crossover trial to assess the anti-nociceptive and anti-hyperalgesic effects of single oral doses of BHV-2100 (25 mg, 75 mg, and 150 mg) vs. placebo, in a cohort of approximately 24 healthy male volunteer participants, utilizing a laser-evoked potential experimental pain paradigm.

# Additional research on TRPM3-mediated disorders

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

# Inflammation and Immunology Platform

# TYK2/JAK1

# Agreement with Hangzhou Highlightll Pharmaceutical Co. Ltd.

In March 2023, we entered into an exclusive, worldwide (excluding People's Republic of China and its territories and possessions) license agreement with Hangzhou Highlightll Pharmaceutical Co. Ltd. ("Highlightll"), pursuant to which we obtained the right to research, develop, manufacture and commercialize Highlightll's brain penetrant dual TYK2/JAK1 inhibitor program (the "Highlightll Agreement").

#### **BHV-8000**

Dysregulation of the immune system has been implicated in several neurodegenerative and neuroinflammatory disorders including Parkinson's disease, multiple sclerosis, Alzheimer's disease, amyotrophic lateral sclerosis and autoimmune encephalitis. Over-active immune cells and microglia driving chronic neuroinflammation resulting in release of cytokines with activation of leukocytes that are thought to contribute to neuronal injury, death, gliosis, and demyelination. The TYK2 and JAK1 signal transduction pathways mediate highly complementary immune and inflammatory signaling events. Targeted, small-molecule therapies that inhibit TYK2 or JAK kinases have separately demonstrated robust efficacy in autoimmune, dermatologic and gastrointestinal disorders. TYK2 is a validated immune target as evidenced by a recent peripheral program that gained FDA approval, and there are multiple additional peripheral non-CNS programs in clinical development. Brain penetrant inhibitors of TYK2/JAK1 have the potential to bring this validated immune target to brain disorders.

There are currently no brain penetrant, selective, dual TYK2/JAK1 inhibitors approved for brain disorders. In May 2023, we began dosing with BHV-8000 (previously TLL-041), in a Phase 1 study in normal healthy volunteers. In May 2024, we reported positive results from the Phase 1 single and multiple ascending dose study with BHV-8000 in healthy subjects, including evidence of target engagement along with a safe and well tolerated profile. The Phase 1 study also confirmed cerebrospinal fluid ("CSF") exposures of BHV-8000 and evidence of biomarker target engagement within the CNS. We also announced the successful completion of two FDA meetings with favorable feedback enabling registrational programs for Parkinson's disease and for the prevention of amyloid-related imaging abnormalities ("ARIA"), a novel indication.

We anticipate beginning Phase 2/3 clinical trials with BHV-8000 in the first half of 2025 targeting

neuroinflammatory conditions, potentially including Amyloid-Related Imaging Abnormalities ("ARIA") in Alzheimer's disease, Alzheimer's disease, Parkinson's disease and multiple sclerosis. We are evaluating and have not yet finalized potential clinical trial designs, including size and primary and secondary endpoints.

# **MoDE Degraders**

# Bispecific Molecular Degraders of Extracellular Proteins

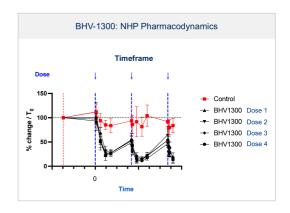
Molecular Degraders of Extracellular Proteins ("MoDEs") are bispecific molecules that target pathologic circulating proteins and direct them to the liver for degradation by the endolysosomal pathway. Our MoDE platform is being explored for use in a wide range of therapeutic areas, including indications in immune-mediated diseases, cancer and other diseases. We are planning for MoDEs to be administered as intravenous or subcutaneous formulations. We expect to initiate a total of 4 Investigational New Drug Applications or the foreign equivalent ("IND") for the degrader program in 2024.

#### BHV-1300

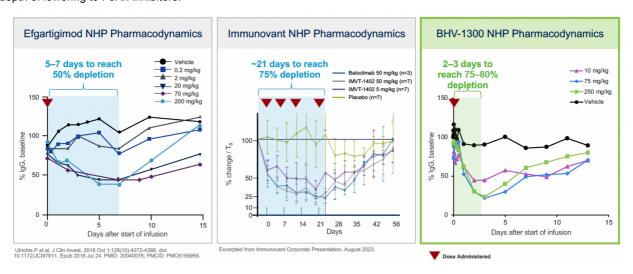
BHV-1300 is an IgG degrader which we are initially developing for the treatment of rheumatoid arthritis

("RA"). RA is a chronic autoimmune disease estimated to affect 1 to 2% of the global population. RA primarily affects the joints, causing pain, swelling, stiffness, and loss of function.

We evaluated the effect of single and multiple doses of BHV-1300 in cynomolgus monkeys. In September 2023, we reported data from confirmatory studies that showed a 75-80% reduction of IgG levels two days after a single dose and over 90% of IgG lowering after three doses.

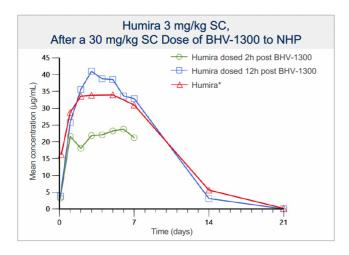


Maximal lowering across FcRn inhibitors is 60-80% within approximately 7 to 21 days after initiation of single or multiple doses, respectively, in cynomolgus. In contrast, a single dose of BHV-1300 lowers IgG by approximately 75 to 80% after approximately 2 days, and after three rapid doses to greater than 90% lowering. The length of significant exposure to BHV-1300 is approximately one day within the dosage interval compared to continuous exposure required of the FcRn inhibitors. Mechanism related liabilities of FcRn inhibitors seen in animals and man, including hypoalbuminemia and hypercholesterolemia, are not expected and do not occur with BHV-1300 in cynomolgus. See figures below comparing the speed and depth of lowering to FcRn inhibitors.



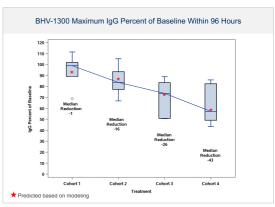
In January 2024, we reported preclinical pharmacodynamic single dose data with BHV-1300 which demonstrated the Biohaven IgG degrader technology allows for co-administration with Fccontaining biologics. The PK of Humira® was unaltered

after being dosed 12 hours after BHV-1300 administration (see figure below).



\* Adapted from BLA 761154, IND 116471, Study no. r-fkb327-01

The Phase 1 study examining BHV-1300 was initiated in the first quarter of 2024 and remains ongoing. In May 2024, we reported preliminary results from our Phase 1 study of BHV-1300. These results in healthy subjects reported that BHV-1300 rapidly and selectively lowers IgG in a dose-dependent manner in the first 4 cohorts completed to date (see figure below). Preliminary IqG lowering data is consistent with modeling, with dose- and timedependent IgG lowering observed even in initial low-dose cohorts. Some subjects experienced IgG reductions as low as 50 to 70% of baseline. BHV-1300 demonstrated reduction of IgG without significantly impacting LFTs, albumin, LDL cholesterol or other serum labs. BHV-1300 has been safe and well tolerated to date, with no serious or severe adverse events. Most AEs were mild, deemed unrelated to study drug and resolved spontaneously. As expected from the selectivity of the molecule for IgG, when compared to placebo, there were no meaningful reductions in average IgA, IgM or IgE levels during the week after dosing. No adverse trends have been observed in vital signs or ECGs. Modeling suggests additional cohorts in the Phase 1 study will achieve greater than 70% lowering of IgG utilizing doses compatible with subcutaneous administration.



Preliminary data from ongoing Phase 1 Study (as of May 28, 2024).

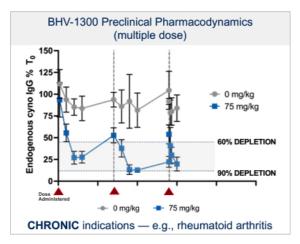
The Phase 1 study has also compared intravenous and subcutaneous administration of BHV-1300. Subcutaneous administration of BHV-1300 demonstrated an average of approximately 44% higher than expected exposure compared to the dose-equivalent intravenous formulation without injection site reactions. This new human data confirms the feasibility of the Company's plan for convenient dosing of BHV-1300 with a patient self-administered subcutaneous auto-injector. The Company expects to provide an update from our SAD/MAD study by the end of 2024.

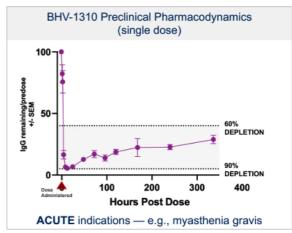
#### BHV-1310

BHV-1310 is a next generation bispecific IgG degrader with the same specificity as BHV-1300 for IgG1, IgG2 and IgG4 which is initially being developed for the treatment of rare disorders including conditions like generalized myasthenia gravis ("gMG") and potentially other acute or chronic conditions, or chronic conditions with acute exacerbations or flares.

MG is a neuromuscular disorder that is estimated to affect approximately 36,000 to 60,000 people in the United States. Patients with gMG develop antibodies that attack critical signaling receptor proteins at the junction between nerve and muscle cells, inhibiting communication between nerves and muscle and resulting in weakness of the skeletal muscles.

In January 2024, we demonstrated optimization of degrader technology with BHV-1310 which allows for deeper reductions in IgG after single dose (see figure below). The deep and rapid reductions observed suggest that BHV-1310 could have potential application in acute settings. We expect to initiate Phase 1 studies of BHV-1310 in the fourth quarter of 2024. We are evaluating and have not yet finalized potential clinical trial designs, including size and primary and secondary endpoints.





#### BHV-1400

BHV-1400 is a selective MoDE which is being developed to target Gd-IgA1 for the treatment of IgA Nephropathy. Specific removal of pathogenic Gd-IgA1 and associated circulating immune complexes with preservation of normal IgA potentially permits disease remission without incurring an infection risk. We shared preliminary data demonstrating the chimeric antibody-ASGPR ligand conjugate specifically mediated endocytosis of Gd-IgA1, as opposed to normal IgA1 and IgA2, in an endocytosis assay with ASGPR-expressing cell lines, and that MoDE degraders successfully internalize and degrade these immune-complexes. We expect to initiate Phase 1 studies of BHV-1400 in the fourth quarter of 2024. We are evaluating and have not yet finalized potential clinical trial designs, including size and primary and secondary endpoints.

#### BHV-1600

BHV-1600 is a selective MoDE designed to remove circulating agonistic antibodies of all isotypes and subclasses directed against myocardial beta-1 adrenergic receptor (" $\beta$ -1 AR") through hepatic ASGPR binding and hepatocellular degradation. This molecule was created using a peptide that mimics the antigenic epitope common to most patients with autoantibodies directed to  $\beta$ -1 AR. This peptide mimics the native sequence such that circulating antibodies are efficiently trapped and subsequently removed by hepatic endocytosis through the ASGPR receptor.

We are developing BHV-1600 for the treatment of dilated cardiomyopathy. Dilated cardiomyopathy is a condition where the cardiac muscle contracts less effectively, the chambers of the heart are enlarged and thinning of cardiac walls results. This can lead to cardiac valvular incompetency, arrhythmias, thrombosis, and

heart failure. We expect to initiate Phase 1 studies of BHV-1600 in the fourth quarter of 2024. We are evaluating and have not yet finalized potential clinical trial designs, including size and primary and secondary endpoints.

# Additional Degraders

We are currently developing additional MoDE degraders which will advance to INDs in 2025. These include potential treatments for Type 1 diabetes with our degrader targeting anti-insulin and anti-proinsulin autoantibodies, kidney disease with our degrader targeting phospholipase A2 receptor ("PLA2R") antibodies for idiopathic membranous nephropathy, an IgG4 specific degrader to target IgG4-mediated rare diseases, and gene therapy administration optimization with our degrader to target neutralizing antibodies to Adeno-Associated Virus Serotype 9 ("AAV9").

# **Oncology Platform**

#### **CD-38**

# BHV-1100

In the fourth quarter of 2021, we initiated a Phase 1a/1b trial in multiple myeloma patients using its antibody recruiting molecule BHV-1100 in combination with autologous cytokine induced memory-like natural killer cells and immune globulin to target and kill multiple myeloma cells expressing the cell surface protein CD38. BHV-1100 is the lead clinical asset from Biohaven's Antibody Recruiting Molecule ("ARM™") Platform developed from a strategic alliance with PeptiDream Inc. ("PeptiDream") (TYO: 4587). This open-label single center Phase 1a/1b study will assess the safety and tolerability as well as exploratory efficacy endpoints in newly diagnosed multiple myeloma patients who have tested positive for minimal residual disease

("MRD+") in first or second remission prior to autologous stem cell transplant ("ASCT"). We plan to enroll 30 newly diagnosed multiple myeloma patients. The primary outcome measures are dose limiting toxicities following combination product administration (time frame: 100 days post-combination product administration) and incidence and severity of side effects related to the combination product (time frame: 90 to 100 days post-combination product administration).

# **Antibody Drug Conjugates**

#### **BHV-1510**

In January 2024, we acquired BHV-1510 through our acquisition of Pyramid Biosciences, Inc. ("Pyramid"). BHV-1510 is a next-generation Trophoblast Cell Surface Antigen 2 ("TROP-2") directed ADC employing an optimized next-generation construct with novel linker-payload and enzymatic, site-specific conjugation, targeting TROP2-expressing carcinomas. Carcinoma refers to a malignant neoplasm of epithelial origin. Carcinomas account for 80 to 90 percent of all cancer cases and several examples have been successfully treated with ADCs. Abundant TROP-2 expression has been described for many carcinoma subtypes.

In preclinical TROP-2 expressing tumor models, BHV-1510 has shown improved antitumor activity versus other TROP-2 directed ADCs, in addition to improved plasma stability, more potent in vitro cytotoxicity, superior bystander effect, and greater immunogenic cell death with the novel Topolx payload. Improved and differentiated safety has been seen in cynomolgus monkey GLP toxicology studies, suggesting a wide therapeutic index. BHV-1510 has similar favorable characteristics to our proprietary MATE conjugation technology, which should allow highly stable site-specific conjugation, resulting in a favorable PK, toxicity and manufacturability profile.

The IND for BHV-1510 was approved by the FDA in January 2024. The First-in Human. Phase 1/2 trial evaluating BHV-1510 in patients with advanced solid tumors commenced in the second quarter of 2024. This trial consists of two parts; Phase 1 dose escalation and Phase 2 dose expansion, in patients with advanced incurable cancer that have progressed on or are intolerant to standard therapy. The trial will also evaluate BHV-1510 in combination with the anti-PD1 cemiplimab. The primary objective of Phase 1 is safety, to identify a recommended dose for expansion ("RDE") or maximum tolerated dose. Phase 1 dose escalation will be implemented based on a Bayesian optimal interval design, with the lowest dose initiated as a single patient cohort. Patients are expected to be dosed in escalating cohorts, with dosing regimens administered intravenously every two or three weeks. The Phase 2 dose expansion part of the study will consist of non-randomized efficacy finding expansion cohorts, defined by specific tumor types that will be treated at the RDE to estimate the anti-tumor activity of BHV-1510. Up to approximately 220 subjects are planned to be evaluated

Preclinically, BHV-1510 has shown enhanced cellular cytotoxicity, bystander killing, and immunogenic cell death resulting in improved efficacy as monotherapy, and synergistic efficacy in combination with anti-PD-1 therapy. In IND-enabling studies, BHV-1510 also showed a broader therapeutic margin relative to more advanced Trop-2 ADCs, including a lack of lung toxicity, that may translate to an improved clinical efficacy and safety profile. In May 2024, we announced that we entered into a clinical supply agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron") under which we will sponsor and fund the planned combination clinical trial and Regeneron will provide Libtayo®. Libtayo® is a fully-human monoclonal antibody targeting the immune checkpoint receptor programmed cell death protein-1 ("PD-1").

#### BHV-1500

BHV-1500 is a next-generation CD30-directed ADC employing a Biohaven proprietary site-specific conjugation (MATE reagent), targeting CD30-expressing tumors such as Hodgkin's and other lymphoma and the MMAE payload. Hodgkin's disease and other CD30-expressing lymphoma are characterized by the uncontrolled growth of malignant lymphocytes or lymphoblasts. Adcetris has demonstrated effectiveness in the treatment of Hodgkin's Lymphoma.

In preclinical CD30 expressing murine tumor models, BHV-1500 has shown improved antitumor activity versus Adcetris (brentuximab vedotin), and substantially improved safety, plasma stability and pharmacokinetics in monkeys. We expect to submit an IND for BHV-1500 in 2025.

#### **Recent Developments**

#### Amendment to Knopp Purchase Agreement

In May 2024, we entered into an amendment to the Purchase Agreement with Knopp (the "Knopp Amendment"). Under the Knopp Amendment, the parties thereto agreed to replace the scaled high single digit to low teens royalty payment obligations with a flat royalty payment in the mid-single digits for BHV-7000 and the pipeline programs. The parties also agreed to reduce the success-based payments payable under the Purchase Agreement by removing all commercial sales-based milestones, which were up to \$562.5 million, and reducing the developmental and regulatory milestones, which were up to \$575 million, to up to \$210 million based on regulatory approvals in the United States and EMEA for BHV-7000 (\$25 million of which has already been paid) and up to an additional \$60 million based on regulatory approval in the United States for the other Kv7 pipeline programs. We retain the ability to pay these contingent milestone payments in cash or in Biohaven Shares at our election, subject to the same increases if we elect to pay in Biohaven

In consideration of the revisions to the success-based payment and royalty payment obligations, we agreed to issue to Knopp 1,872,874 Biohaven Shares,

valued at approximately \$75 million, through a private placement within 60 days of the date of execution of the Knopp Amendment (the "2024 Additional Consideration") and additional Biohaven Shares with an approximate value of \$75 million within 60 days of the first anniversary of execution of the Knopp Amendment (the "2025 Additional Consideration"). We also gave Knopp the option to request a one-time cash true-up payment from us in December 2024 in the event that Knopp continues to hold the Biohaven Shares representing the 2024 Additional Consideration and the value of such shares has declined, and a one-time cash true-up payment from us in December 2025 in the event that Knopp continues to hold the Biohaven Shares representing the 2025 Additional Consideration and the value of such shares has declined, in each case, subject to certain conditions. In May 2024, we issued the 2024 Additional Consideration at an approximate value of \$66.0 million.

As further consideration for the revisions to the success-based payment and royalty payment obligations in the Knopp Amendment, we issued to Knopp a warrant (the "Warrant") to purchase 294,195 Biohaven Shares at a purchase price per share of \$67.98, subject to certain specified development milestones and the Company achieving a specified market capitalization.

For further discussion of the Knopp Amendment, refer to Note 4, "Fair Value of Financial Assets and Liabilities", Note 6, "Shareholders' Equity, " and Note 10, " License, Acquisitions and Other Agreements" to the accompanying condensed consolidated financial statements included in this Form 10-Q.

# **Components of Our Results of Operations**

#### Revenue

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

# **Operating Expenses**

## Research and Development Expenses

Research and development ("R&D") expenses consist primarily of costs incurred in connection with the development of our product candidates. We expense research and development costs as incurred. These expenses include:

 expenses incurred under agreements with contract research organizations ("CROs") or contract manufacturing organizations ("CMOs"), as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services:

- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- employee-related expenses, including salaries, benefits, travel and non-cash share-based compensation expense for employees engaged in research and development functions;
- · costs related to compliance with regulatory requirements;
- development milestone payments incurred prior to regulatory approval of the product candidate;
- rent and operating expenses incurred for leased lab facilities and equipment; and
- payments made in cash, equity securities or other forms of consideration under third-party licensing or other agreements prior to regulatory approval of the product candidate.

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

Our external direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs, CMOs, and central laboratories in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees and certain development milestones incurred under license agreements. We do not allocate employee costs, or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee the research and development as well as for managing our preclinical development, process development, manufacturing and clinical development

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will remain significant over the next several years as we increase personnel costs, conduct late-stage clinical trials, and prepare regulatory filings for our product candidates. We also expect to incur additional expenses related to milestones payable to third parties with whom we have entered into license agreements to acquire the rights to our product candidates.

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

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

# General and Administrative Expenses

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

We anticipate that our general and administrative expenses, including payroll and related expenses, will remain significant in the future as we continue to support our research and development activities and prepare for potential commercialization of our product

candidates, if successfully developed and approved. We also anticipate increased expenses associated with general operations, including costs related to accounting and legal services, director and officer insurance premiums, facilities and other corporate infrastructure, and office-related costs, such as information technology costs, as well as ongoing additional costs associated with operating as an independent, publicly traded company.

### Other Income, Net

Other income, net primarily consists of changes in the fair value of our forward contract and derivative liabilities and net investment income.

The fair value of the forward contracts and derivative liabilities recognized in connection with the Knopp Amendment are determined using a Monte Carlo simulation of the Company's stock price over the respective duration and terms of each instrument being valued. Refer to Note 4, "Fair Value of Financial Assets and Liabilities" to the accompanying condensed consolidated financial statements included in this Form 10-Q for detail on valuation inputs and methodology. The fair value of these liabilities are recorded on the condensed consolidated balance sheets with changes in fair value recorded in other income, net in the condensed consolidated statements of operations and comprehensive loss.

Net investment income is comprised of interest income and net accretion and amortization on investments in addition to realized gains and losses. Refer to Note 3, "Marketable Securities," to the accompanying condensed consolidated financial statements included in this Form 10-Q for further detail on our investments.

#### **Provision for Income Taxes**

The income tax expense in the condensed consolidated financial statements was calculated on a separate return method and presented as if the Company's operations were separate taxpayers in the respective jurisdictions up to and including the Separation. Cash tax payments, income taxes receivable and deferred taxes, net of valuation allowance, are reflective of our actual tax balances prior and subsequent to the Separation.

As a company incorporated in the BVI, we are principally subject to taxation in the BVI. Under the current laws of the BVI, the Company and all dividends, interest, rents, royalties, compensation and other amounts paid by the Company to persons who are not resident in the BVI and any capital gains realized with respect to any shares, debt obligations, or other securities of the Company by persons who are not resident in the BVI are exempt from all provisions of the Income Tax Ordinance in the BVI.

We have historically outsourced all of the research and clinical development for our programs under a

master services agreement with Biohaven Pharmaceuticals, Inc. ("BPI"). As a result of providing services under this agreement, BPI was profitable during the three and nine months ended September 30, 2024 and 2023. A similar arrangement is also in place for our subsidiary, Biohaven Biosciences Ireland Limited ("BBIL") also operates under a similar arrangement. Both Companies are subject to taxation in the US and Ireland, respectively. As such, in each reporting period, the tax provision includes the effects of the results of operations of BPI and BBIL.

At September 30, 2024 and December 31, 2023, we continued to maintain a full valuation allowance against our net deferred tax assets, comprised primarily of research and development tax credit carryforwards and net operating loss carryforwards, based on management's assessment that it is more likely than not that the deferred tax assets will not be realized.

Our income tax provisions primarily represent Federal and state taxes related to the profitable operations of our subsidiaries in the United States and Ireland.

# **Results of Operations**

# Comparison of the Three Months Ended September 30, 2024 and 2023

The following tables summarize our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,			
		2024	2023	Change
In thousands				
Operating expenses:				
Research and development	\$	157,607	\$ 95,517	\$ 62,09
General and administrative		20,561	15,030	5,53
Total operating expenses		178,168	110,547	67,62
Loss from operations		(178,168)	(110,547)	(67,62
Other income, net		17,805	4,686	13,11
Loss before (benefit) provision for income taxes		(160,363)	(105,861)	(54,50
(Benefit) provision for income taxes		(59)	(3,287)	3,22
Net loss	\$	(160,304)	\$ (102,574)	\$ (57,73

#### Research and Development Expenses

	Three Months Ended September 30,			
	2024	2023*	Change	
<u>In thousands</u>				
Direct research and development expenses by program:				
BHV-4157 (Troriluzole)	\$ 14,774	\$ 20,028	\$ (5,254)	
BHV-2000 (Taldefgrobep Alfa)	20,186	12,293	7,893	
BHV-7000 & BHV-7010 (Kv7)	44,370	13,316	31,054	
BHV-2100 (TRPM3 Antagonist)	5,386	4,873	513	
BHV-8000 (TYK2/JAK1)	3,064	3,353	(289)	
BHV-1300 (IgG Degrader)	8,745	6,914	1,831	
BHV-1310 (IgG Degrader)	2,461	436	2,025	
BHV-1400 (IgA Degrader)	4,591	_	4,591	
BHV-1600 (β1-AR AAB Degrader)	4,145	_	4,145	
BHV-1510 (Trop2)	3,072	_	3,072	
Other programs	156	1,087	(931)	
Unallocated research and development costs:				
Personnel related (including non-cash share-based compensation)	25,452	18,091	7,361	
Preclinical research programs	13,978	8,587	5,391	
Other	7,227	6,539	688	
Total research and development expenses	\$ 157,607	\$ 95,517	\$ 62,090	

<sup>\*</sup>Certain prior year amounts have been reclassified to conform to current year presentation

R&D expenses, including non-cash share-based compensation costs, were \$157.6 million for the three months ended September 30, 2024, compared to \$95.5 million for the three months ended September 30, 2023. The increase of \$62.1 million was due to additional and advancing clinical trials, including late Phase 3 and Phase 2/3 studies, and preclinical research programs in 2024, as compared to the same period in the prior year.

Non-cash share-based compensation expense was \$7.2 million for the three months ended September 30, 2024, an increase of \$5.0 million as compared to the same period in 2023. Non-cash share-based compensation expense was higher in 2024 primarily due to our annual equity incentive awards granted in the fourth quarter of 2023 and the first quarter of 2024.

## General and Administrative Expenses

General and administrative expenses were \$20.6 million for the three months ended September 30, 2024, compared to \$15.0 million for the three months ended September 30, 2023. The increase of \$5.5 million was partly due to increased non-cash share-based compensation expense, which was \$5.0 million for the three months ended September 30, 2024, an increase of \$2.7 million as compared to the same period in 2023. Non-cash share-based compensation expense was higher in 2024 primarily due to our annual equity incentive awards granted in the fourth quarter of 2023 and the first quarter of 2024.

#### Other Income, Net

Other income, net was a net income of \$17.8 million for the three months ended September 30, 2024, compared to \$4.7 million for the three months ended September 30, 2023. The increase was primarily due to non-cash \$12.1 million related to the changes in the fair value of our forward contract and derivative liabilities recorded in connection with the Knopp Amendment as well as increased investment income. See Note 4, "Fair Value of Financial Assets and Liabilities" and Note 10, "License, Acquisitions and Other Agreements" to the accompanying condensed consolidated financial statements included in this Form 10-Q for discussion of the forward contract and derivative liabilities recorded in connection with the Knopp Amendment.

## Benefit for Income Taxes

We recorded an income tax benefit of \$0.1 million for the three months ended September 30, 2024, compared to a benefit for income taxes of \$3.3 million for the three months ended September 30, 2023. The change in income tax expense for the three months ended September 30, 2024 as compared to 2023 was primarily attributable to our adoption of the guidance contained in a Notice of Proposed Rule Making issued during the third quarter of 2023 by the United States Internal Revenue Service ("the Notice"). See further discussion of the Notice in Note 12, "Income Taxes" to the condensed consolidated financial statements included in this Form 10-Q.

# Comparison of the Nine Months Ended September 30, 2024 and 2023

The following tables summarize our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,				
		2024	2023		Change
<u>In thousands</u>					
Operating expenses:					
Research and development	\$	628,398	\$ 238,468	\$	389,930
General and administrative		66,782	43,872		22,910
Total operating expenses		695,180	282,340		412,840
Loss from operations		(695,180)	(282,340)		(412,840)
Other income, net		36,288	18,757		17,531
Loss before provision (benefit) for income taxes		(658,892)	(263,583)		(395,309)
Provision (benefit) for income taxes		687	(171)		858
Net loss	\$	(659,579)	\$ (263,412)	\$	(396,167)

# Research and Development Expenses

Research and Development Expenses				
	Nine Months Ended September 30,			
		2024	2023*	Change
<u>In thousands</u>				
Direct research and development expenses by program:				
BHV-4157 (Troriluzole)	\$	48,937	\$ 57,571	\$ (8,634)
BHV-2000 (Taldefgrobep Alfa)		49,062	30,226	18,836
BHV-7000 & BHV-7010 (Kv7)		268,423	31,089	237,334
BHV-2100 (TRPM3 Antagonist)		14,278	6,899	7,379
BHV-8000 (TYK2/JAK1)		9,988	4,514	5,474
BHV-1300 (IgG Degrader)		25,328	11,389	13,939
BHV-1310 (IgG Degrader)		9,660	436	9,224
BHV-1400 (IgA Degrader)		16,295	_	16,295
BHV-1600 (β1-AR AAB Degrader)		8,784	_	8,784
BHV-1510 (Trop2)		25,701	_	25,701
Other programs		1,678	4,867	(3,189)
Unallocated research and development costs:				
Personnel related (including non-cash share-based compensation)		91,017	55,050	35,967
Preclinical research programs		40,056	22,390	17,666
Other		19,191	14,037	5,154
Total research and development expenses	\$	628,398	\$ 238,468	\$ 389,930

<sup>\*</sup>Certain prior year amounts have been reclassified to conform to current year presentation

R&D expenses, including non-cash share-based compensation costs, were \$628.4 million for the nine months ended September 30, 2024, compared to \$238.5 million for the nine months ended September 30, 2023. The increase of \$389.9 million was largely due to non-cash expense of \$171.9 million paid to Knopp for a milestone and royalty buyback related to the BHV-7000 and broader Kv7 platform that was recognized during the three months ended June 30, 2024 (the buyback reduced our potential future milestone payments by \$867.5 million, and replaced the scaled high single digit to low teens royalty payment obligations with a flat royalty payment in the mid-single digits for the Kv7 programs). See further discussion of the Knopp Amendment included in Note 10, "License, Acquisitions and Other Agreements" to the condensed consolidated financial statements included in this Form 10-Q. The increase in expense was also related to advancing our 6 clinical platforms including 5 phase 3 starts for BHV-7000, follow-on Kv7 assets, preclinical research programs, and increases in direct program spend for additional and advancing multiple clinical development programs in 2024, as compared to the same period in the prior year. The \$25.7 million increase in expense for BHV-1510 was primarily due to the Pyramid Acquisition, which resulted in \$10.9 million (non-cash) of expense recorded to R&D during the nine months ended September 30, 2024, a \$1.5 million milestone payment which became due during the first quarter of 2024, and a \$5.7 million non-cash milestone payment which became due during the first quarter of 2024.

Non-cash share-based compensation expense was \$35.5 million for the nine months ended September 30, 2024, an increase of \$28.6 million as compared to the same period in 2023. Non-cash share-based compensation expense was higher in the 2024 primarily due to our annual equity incentive awards granted in the fourth quarter of 2023 and first quarter of 2024.

# General and Administrative Expenses

G&A expenses, including non-cash share-based compensation costs, were \$66.8 million for the nine months ended September 30, 2024, compared to \$43.9 million for the nine months ended September 30, 2023. The increase of \$22.9 million was primarily due to increased non-cash share-based compensation expense. Non-cash share-based compensation expense was \$23.7 million for the nine months ended September 30, 2024, an increase of \$17.7 million as compared to the same period in 2023. Non-cash share-based compensation expense was higher in 2024 primarily due to our annual equity incentive awards being granted in the fourth quarter of 2023 and the first quarter of 2024.

### Other Income, Net

Other income, net was \$36.3 million for the nine months ended September 30, 2024, compared to \$18.8 million for the nine months ended September 30, 2023. The increase was primarily due to noncash \$21.2 million related to the changes in the fair value of our forward contract and derivative liabilities recorded in

connection with the Knopp Amendment as well as increased investment income. The increases were partially offset by a decrease of \$6.8 million in other income recognized during the nine months ended September 30, 2024 as compared to the same period in 2023 related to the Transition Services Agreement entered into with the Former Parent. See Note 4, "Fair Value of Financial Assets and Liabilities" and Note 10, "License, Acquisitions and Other Agreements" to the accompanying condensed consolidated financial statements included in this Form 10-Q for discussion of the forward contract and derivative liabilities recorded in connection with the Knopp Amendment.

# Provision (Benefit) for Income Taxes

We recorded an income tax provision of \$0.7 million for the nine months ended September 30, 2024, compared to an income tax benefit of \$0.2 million for the nine months ended September 30, 2023. The increase in income tax expense for the nine months ended September 30, 2024 as compared to 2023 was primarily attributable higher income in the US.

# **Liquidity and Capital Resources**

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

Historically, we have funded our operations primarily with the cash contribution received from the Former Parent at the Separation and proceeds from the sale of our common shares. We have incurred recurring losses since our inception and expect to continue to generate operating losses for the foreseeable future.

As of September 30, 2024, we had cash and cash equivalents of \$84.4 million and marketable securities of \$294.4 million, which excludes approximately \$269.9 million of net proceeds from an October 2, 2024 underwritten public offering (see 2024 Public Offerings). Cash in excess of immediate requirements is invested in marketable securities and money market funds with a view to liquidity and capital preservation. We continuously assess our working capital needs, capital expenditure requirements, and future investments or acquisitions.

#### **Cash Flows**

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

Nine Months Ended September 30,						
		2024		2023		Change
In thousands						
Net cash used in operating activities	\$	(411,711)	\$	(216,844)	\$	(194,867)
Net cash (used in) provided by investing activities		(157,298)		133,744		(291,042)
Net cash provided by (used in) financing activities		404,921		(33,327)		438,248
Effect of exchange rate changes on cash, cash equivalents and restricted cash		(13)		(187)		174
Net (decrease) in cash, cash equivalents and restricted cash	\$	(164,101)	\$	(116,614)	\$	(47,487)

#### **Operating Activities**

Net cash used in operating activities was \$411.7 million for the nine months ended September 30, 2024 and \$216.8 million for the nine months ended September 30, 2023. The \$194.9 million increase in net cash used in operating activities for the nine months ended September 30, 2024 was primarily due to an increase in R&D spending to advance our 6 clinical platforms including 5 phase 3 starts for BHV-7000, follow-on Kv7 assets, preclinical research programs, and increases in direct program spend for additional and advancing multiple clinical development programs in 2024, as compared to the same period in the prior year.

# Investing Activities

Net cash used in investing activities was \$157.3 million for the nine months ended September 30, 2024, compared to net cash provided by investing activities of \$133.7 million for the nine months ended September 30, 2023. The \$291.0 million increase in net cash used in investing activities for the nine months ended September 30, 2024 was primarily driven by an increase in purchases of marketable securities with cash in excess of immediate requirements, partially offset by an increase in maturities of marketable securities (see Note 3, "Marketable Securities," to the Condensed Consolidated Financial Statements for additional details), as compared to the same period in the prior year.

# Financing Activities

Net cash provided by financing activities was \$404.9 million for the nine months ended September 30, 2024 compared to net cash used in financing activities of \$33.3 million for the nine months ended September 30, 2023. The \$438.2 million increase in net cash provided by financing activities for the nine months ended September 30, 2024 was primarily driven by an increase in proceeds from the issuance of common shares from our April 2024 public equity offering and at-the-market sales of common shares in connection with our Equity Distribution Agreement both in 2024, as compared to the same period in the prior year.

# 2024 Public Offerings

On April 22, 2024, we closed an underwritten public offering of 6,451,220 of its common shares, which included the exercise in full of the underwriters' option to purchase additional shares, at a price to the public of \$41.00 per share. The net proceeds raised in the offering, after deducting underwriting discounts and expenses of the offering payable by us, were approximately \$247.8 million. We intend to use the net proceeds received from the offering for general corporate purposes.

On October 2, 2024, we closed an underwritten public offering of 6,052,631 of our common shares, which included the exercise in full of the underwriters' option to purchase additional shares, at a price of \$47.50 per share. The net proceeds raised in the offering, after deducting underwriting discounts and expenses of the offering payable by us, were approximately \$269.9 million. We intend to use the net proceeds received from the offering for general corporate purposes.

#### **Equity Distribution Agreement**

In October 2023, we entered into an equity distribution agreement pursuant to which we may offer and sell common shares having an aggregate offering price of up to \$150.0 million from time to time through or to the sales agent, acting as our agent or principal (the "Equity Distribution Agreement"). Sales of our common shares, if any, will be made in sales deemed to be "at-the-market offerings". The sales agent is not required to sell any specific amount of securities but will act as our sales agent using commercially reasonable efforts consistent with its normal trading and sales practices, on mutually agreed terms between the sales agent and us. We currently plan to use the net proceeds from any at-the-market offerings of our common shares for general corporate purposes.

In August 2024, we entered into an amendment to the Equity Distribution Agreement pursuant to which we may offer and sell common shares having an aggregate offering price of up to \$450.0 million from time to time through or to the sales agent, acting as its agent or principal.

As of September 30, 2024, we have sold and issued 4,248,588 common shares under the Equity Distribution Agreement, as amended, for total net proceeds of approximately \$146.3 million. As of September 30, 2024, additional common shares having an aggregate offering price of up to \$300.0 million remain available to be issued.

#### **Knopp Amendment**

In May 2024, we entered into the Knopp Amendment which reduced our potential future milestone payments by \$867.5 million, and replaced the scaled high single digit to low teens royalty payment obligations with a flat royalty payment in the mid-single digits for our Kv7 programs. As consideration, we agreed to issue to Knopp the 2024 Additional Consideration and 2025 Additional Consideration, both non-cash common share payments, as well as agreed to one-time cash-true ups for both the 2024 Additional Consideration and 2025 Additional Consideration. See Recent Developments elsewhere in this Current Report on Form 10-Q for additional information on the Knopp Amendment.

On May 30, we issued 1,872,874 common shares valued at \$66.0 million to Knopp to settle the forward contract liability related to the 2024 Additional Consideration and recognized a non-cash gain of \$9.2 million on settlement. We expect to issue the common shares representing the 2025 Additional Consideration on or before June 30, 2025, in accordance with the Knopp Amendment.

In the event that Knopp continues to hold the shares of the Company's common shares representing the 2025 Additional Consideration on December 1, 2025 and the Market Price declines relative to the respective Reference Price, both as defined in the agreement, we would be responsible for a cash payment equal to the difference.

# **Knopp Warrant**

As further consideration under the Knopp Amendment, we issued to Knopp a warrant to purchase 294,195 of the Company's common shares with a purchase price of \$67.98, subject to certain specified development milestones and the Company achieving a specified market capitalization.

As of September 30, 2024, the vesting conditions have not been met and the warrant is still outstanding.

# **Funding Requirements**

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

- continue to advance and expand the development of our discovery programs and clinical-stage assets;
- continue to initiate and progress other supporting studies required for regulatory approval of our product candidates, including long-term safety studies, drug-drug interaction studies, preclinical toxicology and carcinogenicity studies;

- initiate preclinical studies and clinical trials for any additional indications for our current product candidates and any future product candidates that we may pursue;
- continue to build our portfolio of product candidates through the acquisition or in-license of additional product candidates or technologies;
- continue to develop, maintain, expand and protect our intellectual property portfolio;
- pursue regulatory approvals for our current and future product candidates that successfully complete clinical trials;
- establish and support our sales, marketing and distribution infrastructure to commercialize any future product candidates for which we may obtain marketing approval;
- hire additional clinical, medical, commercial, and development personnel.

We expect that our cash, cash equivalents and marketable securities, as of the date of this Quarterly Report on Form 10-Q, will be sufficient to fund operating and financial commitments and other cash requirements for more than one year. We expect we will need to raise additional capital until we are profitable. If no additional capital is raised through either public or private equity financings, debt financings, strategic relationships, alliances and licensing agreements, or a combination thereof, we may delay, limit or reduce discretionary spending in areas related to research and development activities and other general and administrative expenses in order to fund our operating costs and working capital needs.

We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional capital to pursue in-licenses or acquisitions of other product candidates. If we receive regulatory approval for our product candidates, we expect to incur commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize or whether we commercialize jointly or on our own.

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

 the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials:

- the costs, timing and outcome of regulatory review of our product candidates;
- the 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 timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any; and
- other capital expenditures, working capital requirements, and other general corporate activities.

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 thirdparty funding, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinguish 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.

## **Contractual Obligations and Commitments**

Except as discussed in Note 11, "Commitments and Contingencies" to our Condensed Consolidated Financial Statements included in Item 1, "Unaudited Condensed Consolidated Financial Statements," of this Quarterly Report on Form 10-Q, there have been no material changes to our contractual obligations and commitments as included in our audited consolidated financial statements included in the 2023 Form 10-K.

# Critical Accounting Policies and Significant Judgments and Estimates

We have prepared our condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States

("GAAP"). Our preparation of our condensed consolidated financial statements requires us to make estimates, assumptions, and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosures at the date of the condensed consolidated financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

Excluding the discussion below, during the nine months ended September 30, 2024, there were no material changes to our critical accounting policies as reported in our annual consolidated financial statements included in the 2023 Form 10-K.

#### Valuation of Forward Contract and Derivative Liabilities

We have accounted for certain consideration agreed to in connection with the Knopp Amendment as forward contracts and derivative liabilities. The fair value of these liabilities have been determined based on Monte Carlo simulations of Biohaven's share price, which requires judgment and assumptions on the volatility of our share price, discounted to present value using a risk-free rate plus Biohaven specific credit risk as they are payable in either cash or a variable number of shares.

Our expectations of the volatility of Biohaven's share price at the reporting date could be materially different than our actual future volatility, and if so, would mean the estimated fair value could be significantly higher or lower than the fair value determined.

#### **Recently Issued Accounting Pronouncements**

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

# Item 3. Quantitative and Qualitative Disclosures about Market Risks

# **Foreign Currency Translation**

Our operations include activities in countries outside the U.S. As a result, our financial results are impacted by factors such as changes in foreign currency exchange rates or weak economic conditions in the foreign markets where we operate. Our monetary exposures on our balance sheet are currently immaterial to our financial position as of September 30, 2024.

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

#### **Interest Rate Risk**

As of September 30, 2024, we invest our excess cash balances in marketable securities of highly rated financial institutions and investment-grade debt instruments. We seek to diversify our investments and limit the amount of investment concentrations for individual institutions, maturities and investment types. Most of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Based on the type of securities we hold, we do not believe a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 1.00%, the fair value of our investment portfolio would (decrease) increase by approximately \$(0.5) million and \$0.5 million, respectively.

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

#### **Credit Risk**

Financial instruments that potentially expose the Company to concentrations of credit risk consist of cash, cash equivalents, and short-term debt securities. The Company maintains a portion of its cash deposits in government insured institutions in excess of government insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts. The Company's cash management policy permits investments in U.S. federal government and federal agency securities, corporate bonds or commercial paper, supranational and sovereign obligations, certain qualifying money market mutual funds, certain repurchase agreements, and places restrictions on credit ratings, maturities, and concentration by type and issuer. The Company is exposed to credit risk in the event of a default by the financial institutions holding its cash in excess of government insured limits and in the event of default by corporations and governments in which it holds investments in cash equivalents and short-term debt securities, to the extent recorded on the condensed consolidated balance sheet.

We have not experienced any credit losses or recorded any allowance for credit losses related to our cash, cash equivalents, and short-term debt securities.

# 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 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 costbenefit 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 September 30, 2024, our Chief Executive Officer and Chief Financial Officer have concluded that, as of September 30, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

# Changes in Internal Controls over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2024 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

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Our risk factors have not changed materially from those described in "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 29, 2024.

# Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

# **Pyramid Agreement**

In January 2024, we acquired Pyramid Biosciences, Inc. ("Pyramid"), pursuant to an Agreement and Plan of Merger, dated January 7, 2024 (the "Pyramid Agreement"). In consideration for the Pyramid acquisition we made an upfront payment of 255,794 of our common shares. As of September 30, 2024, 253,838 of these common shares have been issued by the Company, including 428 common shares that were issued in the third guarter of 2024. We also agreed to make additional success-based payments upon the achievement of certain regulatory milestones, which we may elect to pay in cash or our common shares. In January 2024, a payment became due to Pyramid related to achievement of a developmental milestone under the Pyramid Agreement, which we elected to pay in 98,129 of our common shares. As of September 30, 2024, 97,387 of these common shares have been issued by the Company, including 154 common shares that were issued in the third guarter of 2024. The shares related to both of these payments were not registered under the Securities Act upon issuance, and a portion of the shares were subsequently registered under our Registration Statement on Form S-3.

Pyramid represented that, among other things, it is an institutional accredited investor as defined in Rule 501(a) of Regulation D of the Securities Act. The foregoing shares shall be issued in reliance on the private offering exemption provided by Section 4(a)(2) of the Securities Act. See Note 10, "License, Acquisitions and Other Agreements," to the Condensed Consolidated Financial Statements appearing elsewhere in this report for additional details on this transaction.

# Amendment to Knopp Purchase Agreement

In May 2024, we entered into an amendment (the "Knopp Amendment") to our existing Membership Interest Purchase Agreement, dated as of February 24, 2022, with Knopp Biosciences LLC ("Knopp") in order to make certain changes to the royalty payment obligations and success-based payments. See Item 5, "Other Information" for additional information related to the Knopp Amendment.

In connection with the Knopp Amendment, we issued to Knopp 1,872,874 of our common shares, valued at approximately \$75.0 million as of the effective date, through a private placement within 60 days of the date of execution of the Knopp Amendment (the "2024 Additional Consideration"). We also agreed to issue additional shares of our common shares, valued at approximately \$75.0 million, within 60 days of the first anniversary of execution of the Knopp Amendment (the "2025 Additional Consideration"). In addition, we issued to Knopp a warrant (the "Warrant") to purchase 294,195 of our common shares at a purchase price per share of \$67.98, subject to certain specified development milestones and achieving a specified market capitalization.

The foregoing issuance and sale of our common shares in connection with the execution of the Knopp Amendment and the Warrant have not been registered under the Securities Act of 1933 (the "Securities Act") or any state securities laws. We have relied on the exemption from the registration requirements of the Securities Act under Section 4(a)(2) thereof, for a transaction by an issuer not involving any public offering.

# Item 5. Other Information

# Rule 10b5-1 Trading Plans

During the quarter ended September 30, 2024, none of our directors or officers adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

# Item 6. Exhibits

Exhibit No.	Description
31.1	Certification of Principal Executive Officer under Section 302 of the Sarbanes-Oxley Act.
31.2	Certification of Principal Financial Officer under Section 302 of the Sarbanes-Oxley Act.
32.1‡	Certifications of Principal Executive Officer and Principal Financial Officer under Section 906 of the Sarbanes-Oxley Act.
101	The following materials from the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2024 are formatted in iXBRL (Inline eXtensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations and Comprehensive Loss, (iii) the Condensed Consolidated Statements of Cash Flows and (iv) the Notes to Condensed Consolidated Financial Statements, tagged as blocks of text and including detailed tags.
104	Cover Page Interactive Data File (formatted in iXBRL in Exhibit 101).

# Portions of this exhibit (indicated by asterisks) have been omitted as such information is (i) not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

‡ 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.

BIOHAVEN LTD.

Dated: November 12, 2024

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/ Matthew Buten

Matthew Buten Chief Financial Officer (Principal Financial Officer)

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

#### I, Vlad Coric, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Biohaven Ltd. (the "registrant");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared:
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

/s/ VLAD CORIC, M.D.

Vlad Coric, M.D.

President and Chief Executive Officer
(principal executive officer)

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

#### I, Matthew Buten, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Biohaven Ltd. (the "registrant");
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report:
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e)) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2024

/s/ MATTHEW BUTEN

Matthew Buten Chief Financial Officer (principal financial officer)

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

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

- 1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2024, 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 12 day of November 2024.

/s/ VLAD CORIC, M.D.

Vlad Coric, M.D.

President and Chief Executive Officer
(principal executive officer)

/s/ MATTHEW BUTEN

Matthew Buten

Chief Financial Officer
(principal financial officer)

<sup>\*</sup> This certification accompanies the Form 10-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.