Biohaven Ltd. Reports Third Quarter 2022 Financial Results and Reports Recent Business Developments

November 9, 2022

- Biohaven Ltd. launched post-closing of the Biohaven Pharmaceutical Holding Company Ltd. sale to Pfizer on October 4, 2022, and completed a public offering of 28,750,000 Biohaven Ltd. common shares at a price of $10.50 per share on October 25, 2022, with a total initial capitalization and net cash proceeds from offering of approximately $541 million, and no debt.
- Advancing multiple late-stage clinical programs including innovative drug candidates targeting Kv7 modulation for epilepsy and neuropsychiatric disorders, glutamate modulation in Obsessive-Compulsive Disorder (OCD) and spinocerebellar ataxia (SCA), and myostatin in spinal muscular atrophy (SMA).
- Key industry executives added to leadership team, including:
    - Bruce Car, Ph.D. as Chief Scientific Officer;
    - Irfan Qureshi, M.D. as Chief Medical Officer, and
    - Tanya Fischer, M.D., Ph.D. as Chief Development Officer and Head of Translational Medicine.

NEW HAVEN, Conn., Nov. 9, 2022 /PRNewswire/ -- Biohaven Ltd. (NYSE: BHVN) ("Biohaven" or the "Company"), a global clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of life-changing therapies for people with debilitating neurological and neuropsychiatric diseases, including rare disorders, today reported financial results for the third quarter ended September 30, 2022, and provided a review of recent accomplishments and anticipated upcoming milestones. The reported financial results present, on a historical basis, the combined assets, liabilities, expenses and cash flows directly attributable to the Company, which have been prepared from Biohaven Pharmaceutical Holding Company Ltd., the former parent, consolidated financial statements and accounting records, and are presented on a stand-alone basis as if the operations had been conducted independently from the former parent.

Vlad Coric, M.D., Chairman and Chief Executive Officer of Biohaven, commented, "Just weeks after launching in October as a new publicly traded company and separate independent entity as part of the merger agreement with Pfizer, we continued to advance our late stage clinical development programs and substantially enhanced our resources by raising gross proceeds of approximately $301.9 million in a public financing that drew support from a breadth of longstanding and new Biohaven investors. We are well positioned with an outstanding drug development team, a deep late-stage pipeline and a strong capital position to favorably position us to accelerate development across our portfolio."

Dr. Coric continued, "Our Kv7 platform, with its vast potential to address epilepsy and neuropsychiatric indications, is being prioritized by the team with the goal of at least one Phase 2/3 study start in 2023. We also continue to make progress with our Phase 3 study evaluating taldefgrobep alfa in patients with spinal muscular atrophy, as well as with our Phase 3 study evaluating troriluzole in patients with OCD. Finally, our discovery efforts remain a key pillar of our pipeline formation strategy; with IND-enabling studies underway across several programs, we expect to provide updates on programs like TRPM3, a potential breakthrough, non-opioid treatment option for pain, and other earlier stage protein degrader programs in the coming months and years. Our unwavering commitment to patients continues propelling us forward and we cannot wait to deliver additional therapeutic breakthrough medicines to drive outcomes for patients, shareholders and employees."

Third Quarter and Recent Business Highlights:

- **Company launch** - On October 3, 2022, Biohaven Ltd. began operating as a separate independent entity in connection with the merger agreement entered into with Pfizer Inc. in May 2022. As of October 4, 2022, Biohaven Ltd. commenced regular way trading under the symbol "BHVN" on the New York Stock Exchange as an independent, publicly traded company focused on delivering innovative life-changing treatments for neurological and neuropsychiatric diseases, including rare disorders, and leveraging its proven drug development capabilities and proprietary technology platforms to advance a pipeline of best-in-class therapies. The Company, led by Vlad Coric, M.D. as Chairman and Chief Executive Officer, launched with approximately $257.8 million in cash and no debt.
- **Public offering** - On October 25, 2022, the Company closed its previously announced underwritten public offering of 28,750,000 of its common shares, which includes the full exercise of the underwriters' option to purchase 3,750,000 additional shares, at the public offering price of $10.50 per share. The gross proceeds raised in the offering, before

deducting underwriting discounts and estimated expenses of the offering payable by the Company, were approximately $301.9 million. As of November 7, 2022, we had 68,160,979 common shares, without par value per share, outstanding.

- **Advanced Phase 1 studies for BHV-7000** - As previously reported, in the second quarter of 2022, the Company's Clinical Trial Application for BHV-7000 was approved by Health Canada, and the Company subsequently began clinical development. BHV-7000, 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.
- **Advanced development of extracellular target degrader platform technology (MoDEs™) for therapies across a variety of diseases including neuroscience, immunology and oncology** - In October, Biohaven announced advancements in the development of its MoDE extracellular target degrader platform technology licensed from Yale University for various disease indications, including, but not limited to, neurological disorders, cancer, infectious and autoimmune diseases. Biohaven made further innovations in this ground-breaking technology with new patent applications covering additional targets and functionality.
- **Operationalized fully-equipped Biohaven Cambridge laboratory** - In October, the Company expanded its footprint to include new laboratory space in Cambridge, Massachusetts.
- **Commenced enrollment in Phase 3 SMA study** - In July, the Company commenced enrollment in a Phase 3 clinical trial assessing the efficacy and safety of taldefgrobep alfa in SMA. Taldefgrobep targets myostatin, a natural protein that limits skeletal muscle growth, through two mechanisms: lowering myostatin directly and blocking key downstream signaling mechanisms. The Company expects to enroll approximately 180 patients in this randomized, double-blind, placebo-controlled global trial.
- **Global Coalition for Adaptive Research (GCAR) commenced enrollment in Glioblastoma Adaptive Global Innovative Learning Environment (GBM Agile) Phase 2-3 adaptive platform trial for patients with glioblastoma** - In July, GCAR announced the activation of Biohaven's troriluzole in GBM AGILE, a patient-centered, adaptive platform trial for registration that tests multiple therapies for patients with newly-diagnosed and recurrent glioblastoma (GBM). GBM AGILE is an international, innovative platform trial designed to more rapidly identify and confirm effective therapies for patients with glioblastoma through response adaptive randomization. The new interventions are opening first at Henry Ford Health Cancer in Detroit under Henry Ford site Principal Investigator Dr. Tom Mikkelsen and will subsequently open at more than 40 trial sites across the United States with additional global sites to follow.

Upcoming Milestones:

Biohaven is progressing its product candidates through clinical programs in a number of common and rare disorders. The Company expects to reach significant pipeline milestones in the coming periods. Biohaven expects to:

- **Complete Phase 1 studies of BHV-7000 in the first half of 2023:** If the Phase 1 studies are successfully completed, Biohaven expects to initiate at least one pivotal trial in patients with epilepsy in the second half of 2023.
- **Complete enrollment in Phase 3 study of troriluzole in OCD in 2023:** Two Phase 3 randomized, double-blind, placebo-controlled studies are expected to enroll approximately 1,300 patients across nearly 200 global study sites. The Company anticipates completing enrollment in 2023.
- **Provide an update on troriluzole in SCA:** The Company had previously reported top-line results from a Phase 3 clinical trial evaluating the efficacy and safety of its investigational therapy, troriluzole, in patients with SCA in May of 2022. While the primary endpoint, change from baseline to Week 48 on the modified functional Scale for the Assessment and Rating of Ataxia did not reach statistical significance in the overall SCA population, as there was less than expected disease progression over the course of the study, post hoc analysis of efficacy measures by genotype suggested a treatment effect in patients with the SCA Type 3 (SCA3) genotype, which represents the most common form of SCA and accounted for 41 percent of the study population. The Company intends to interact with the FDA and/or EMA in the first half of 2023. We have not yet decided on the format of such a regulatory interaction but we could seek advice through various formal or informal interactions with regulatory agencies or we could choose to submit a New Drug Application (NDA) if we believe that is warranted from the results of our ongoing post-hoc analyses.
- **Continue advancing Phase 3 clinical studies of taldefgrobep alfa in SMA:** The Company expects to enroll approximately 180 patients in the study.
- **Continue advancing early discovery portfolio across multiple neuroscience and immunoscience indications:** The Company's preclinical pipeline includes molecular degraders of extracellular proteins, CD38 targeting antibody recruiting molecules (ARMs), TRP channels, TDP-43 targeting small molecules, and other undisclosed targets, including those with disease-modifying potential.
- **Continue pursuing formulation development work with BHVN-5500 for use in combination studies with Kv7 platform:** The Company is developing BHV-5500 (lanicemine), a low-trapping NMDA receptor antagonist. One potential target indication includes Complex Regional Pain Syndrome. Other disorders of interest include post-herpetic neuralgia and diabetic peripheral neuralgia. Current work is focused on formulation development.

Capital Position:

Cash as of September 30, 2022 was $50.7 million, excluding $0.8 million of restricted cash, compared to $76.1 million as of December 31, 2021. On October 3, 2022, in connection with the closing of the acquisition of Biohaven Pharmaceutical Holding Company Ltd. by Pfizer, Biohaven Ltd. launched with a cash balance of approximately $257.8 million. On October 25, 2022, the Company closed its previously announced public offering, which resulted in net proceeds to the Company of approximately $282.8 million.

Third Quarter 2022 Financial Highlights:

Research and Development ("R&D") Expenses: R&D expenses, including non-cash share-based compensation costs, were $52.8 million for the three months ended September 30, 2022, compared to $47.0 million for the three months ended September 30, 2021. The increase of $5.9 million was primarily due to increased expenses relating to our clinical programs partially offset by decreases in our program expenses for verdiperstat. Non-cash share-based compensation expense was $9.7 million for the three months ended September 30, 2022, a decrease of $0.5 million as compared to the same period in 2021.

General and Administrative ("G&A") Expenses: G&A expenses, including non-cash share-based compensation costs, were $14.8 million for the three months ended September 30, 2022, compared to $8.5 million for the three months ended September 30, 2021. The increase of $6.3 million was primarily due to increased expenses related to accounting, legal and other professional fees associated with the Pfizer acquisition and spin-off of Biohaven Ltd. as an independent, publicly traded company. Non-cash share-based compensation expense was $7.3 million for the three months ended September 30, 2022, an increase of $2.1 million as compared to the same period in 2021.

Net Loss: Biohaven reported a net loss for the three months ended September 30, 2022, of $68.9 million, or $1.75 per share, compared to $54.4 million, or $1.38 per share, for the same period in 2021. Non-GAAP adjusted net loss for the three months ended September 30, 2022 was $49.2 million, or $1.25 per share, compared to $39.0 million, or $0.99 per share for the same period in 2021. These non-GAAP adjusted net loss and non-GAAP adjusted net loss per share measures, more fully described below under "Non-GAAP Financial Measures," exclude non-cash share-based compensation charges and gains or losses from equity method investment. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the tables below. Net loss per share and Non-GAAP adjusted net loss per share were calculated based on the 39,368,042 shares of Biohaven Ltd. common stock distributed to Biohaven Pharmaceutical Holding Company Ltd. shareholders at the time of the Distribution, including common shares issued in connection with Biohaven Pharmaceutical Holding Company Ltd. stock options that were exercised on October 3, 2022 and common shares issued in connection with Biohaven Pharmaceutical Holding Company Ltd. restricted stock units that vested on October 3, 2022. The same number of shares is being utilized for the calculation of basic and diluted earnings per share for all periods presented prior to the Spin-Off.

Non-GAAP Financial Measures

This press release includes financial results prepared in accordance with accounting principles generally accepted in the United States (GAAP), and also certain non-GAAP financial measures. In particular, Biohaven has provided non-GAAP adjusted net loss and adjusted net loss per share, adjusted to exclude the items below. Non-GAAP financial measures are not an alternative for financial measures prepared in accordance with GAAP. However, Biohaven believes the presentation of non-GAAP adjusted net loss, when viewed in conjunction with GAAP results, provides investors with a more meaningful understanding of ongoing operating performance. These measures exclude (i) non-cash share-based compensation, which is substantially dependent on changes in the market price of common shares, (ii) gains or losses from equity method investment, which are non-cash and based on the financial results and valuation of another company that we did not manage or control, and (iii) transaction-related costs incurred relating to the Company's spin-off from Biohaven Pharmaceutical Holding Company Ltd., which are limited to a specific period of time and related to Biohaven Ltd. being established as a standalone public company.

Biohaven believes the presentation of these non-GAAP financial measures provides useful information to management and investors regarding Biohaven's results of operations. When GAAP financial measures are viewed in conjunction with these non-GAAP financial measures, investors are provided with a more meaningful understanding of Biohaven's ongoing operating performance and are better able to compare Biohaven's performance between periods. In addition, these non-GAAP financial measures are among those indicators Biohaven uses as a basis for evaluating performance, and planning and forecasting future periods. These non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP financial measures. A reconciliation between these non-GAAP measures and the most directly comparable GAAP measures is provided later in this press release.

About Biohaven

Biohaven is a global clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of life-changing therapies for people with debilitating neurological and neuropsychiatric diseases, including rare disorders. The company is advancing a pipeline of best-in-class therapies for diseases with little or no treatment options, leveraging its proven drug development capabilities and proprietary platforms, including Kv7 ion channel modulation for epilepsy and neuronal hyperexcitability; glutamate modulation for obsessive-compulsive disorder and spinocerebellar ataxia and myostatin inhibition for neuromuscular diseases. Biohaven's portfolio of early- and late-stage product candidates also includes discovery research programs focused on TRPM3 channel activation for neuropathic pain and CD-38 antibody recruiting, bispecific molecules for multiple myeloma.

Forward-looking Statements

This news release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The use of certain words, including "continue", "plan", "will", "believe", "may", "expect", "anticipate" and similar expressions, is intended to identify forward-looking statements. Investors are cautioned that any forward-looking statements, including statements regarding the future development, timing and potential marketing approval and commercialization of development candidates are not guarantees of future performance or results and involve substantial risks and uncertainties. Actual results, developments and events may differ materially from those in the forward-looking statements as a result of various factors including: the expected timing, commencement and outcomes of Biohaven's planned and ongoing clinical trials; the timing of planned interactions and filings with the Food and Drug Administration; the timing and outcome of expected regulatory filings; complying with applicable U.S. regulatory requirements; the potential commercialization of Biohaven's product candidates; the potential for Biohaven's product candidates to be first in class or best in class therapies; and the effectiveness and safety of Biohaven's product candidates. Additional important factors to be considered in connection with forward-looking statements are described in Biohaven's filings with the Securities and Exchange Commission, including within the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations". The forward-looking statements are made as of the date of this new release, and Biohaven does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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CONDENSED COMBINED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 52,845	$ 46,973	$ 300,028	$ 139,668
General and administrative	14,792	8,519	54,492	28,349
Total operating expenses	67,637	55,492	354,520	168,017
Loss from operations	(67,637)	(55,492)	(354,520)	(168,017)
Other income (expense):				
Gain from equity method investment	—	—	—	5,261
Other expense, net	—	(5)	(71)	(245)
Total other (expense) income, net	—	(5)	(71)	5,016
Loss before provision (benefit) for income taxes	(67,637)	(55,497)	(354,591)	(163,001)
Provision (benefit) for income taxes	1,216	(1,132)	14,581	(1,091)
Net loss and comprehensive loss attributable to common shareholders of Biohaven Ltd.	$ (68,853)	$ (54,365)	$ (369,172)	$ (161,910)
Net loss per share attributable to common shareholders of Biohaven Ltd. — basic and diluted	$ (1.75)	$ (1.38)	$ (9.38)	$ (4.11)
Common shares outstanding—basic and diluted	39,368,042	39,368,042	39,368,042	39,368,042

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CONDENSED COMBINED BALANCE SHEETS

(Amounts in thousands)

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash	$ 50,668	$ 76,057
Prepaid expenses	17,910	6,734
Other current assets	11,972	12,032
Total current assets	80,550	94,823
Property and equipment, net	17,423	13,010
Intangible assets	18,400	18,400
Goodwill	1,390	1,390
Other non-current assets	17,883	14,438
Total assets	$ 135,646	$ 142,061
Liabilities and Equity		
Current liabilities:		
Accounts payable	$ 4,731	$ 4,775
Accrued expenses and other current liabilities	23,704	37,160
Total current liabilities	28,435	41,935
Other non-current liabilities	6,995	5,435
Total liabilities	35,430	47,370
Contingently redeemable non-controlling interests	—	60,000
Equity:		
Net investment from Former Parent	100,216	34,691
Total equity	100,216	34,691
Total liabilities and equity	$ 135,646	$ 142,061

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RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL MEASURES

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

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Reconciliation of GAAP to Non-GAAP adjusted net loss:				
GAAP net loss	$ (68,853)	$ (54,365)	$ (369,172)	$ (161,910)
Add: non-cash share-based compensation expense	16,997	15,393	77,927	52,671
Less: Gain from equity method investment	—	—	—	(5,261)
Add: Transaction-related costs	2,641	—	5,863	—
Non-GAAP adjusted net loss	$ (49,215)	$ (38,972)	$ (285,382)	$ (114,500)
Reconciliation of GAAP to Non-GAAP adjusted net loss per share — basic and diluted:				
GAAP net loss per share attributable to Biohaven Ltd. — basic and diluted	$ (1.75)	$ (1.38)	$ (9.38)	$ (4.11)
Add: non-cash share-based compensation expense	0.43	0.39	1.98	1.34
Less: Gain from equity method investment	—	—	—	(0.13)
Add: Transaction-related costs	0.07	—	0.15	—
Non-GAAP adjusted net loss per share attributable to Biohaven Ltd. — basic and diluted	$ (1.25)	$ (0.99)	$ (7.25)	$ (2.91)

MoDEs is a trademark of Biohaven Therapeutics Ltd.

Investor Contact:

Jennifer Porcelli
Vice President, Investor Relations
jennifer.porcelli@biohavenpharma.com
+1 (201) 248-0741

Media Contact:

Mike Beyer, Media Relations Counselor
Sam Brown Inc.
mikebeyer@sambrown.com
+1 (312) 961-2502

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