

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

**FORM 8-K
CURRENT REPORT**
**Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): May 9, 2024

Biohaven Ltd.

(Exact name of registrant as specified in its charter)

British Virgin Islands
(State or other jurisdiction of incorporation)

001-41477
(Commission File Number)

Not applicable
(IRS Employer Identification No.)

c/o Biohaven Pharmaceuticals, Inc.
215 Church Street
New Haven, Connecticut 06510
(Address of principal executive offices, including zip code)
(203) 404-0410
(Registrant's telephone number, including area code)
Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2024, Biohaven Ltd. (the “**Registrant**”) issued a press release announcing its financial results for the first quarter ended March 31, 2024. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Press Release, dated May 9, 2024, "Biohaven Reports First Quarter 2024 Financial Results and Recent Business Developments."
104	The cover page of this Current Report on Form 8-K formatted as Inline XBRL.

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 hereunto duly authorized.

Date: May 9, 2024

Biohaven Ltd.

By: /s/ Matthew Buten
Matthew Buten
Chief Financial Officer

Biohaven Reports First Quarter 2024 Financial Results and Recent Business Developments

- Cash, cash equivalents, marketable securities and restricted cash totaled approximately \$287.6 million on March 31, 2024, which excludes the net proceeds of approximately \$247.8 million from Biohaven's public offering completed on April 22, 2024
- Completed public offering of 6,451,220 Biohaven Ltd. 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
- Reported preliminary summary of data from ongoing single ascending dose (SAD) study with the lead asset from Biohaven's Molecular Degradator of Extracellular Proteins (MoDE™) platform, BHV-1300
- FDA granted rare pediatric disease designation for the Company's anti-myostatin, taldefgrobep alfa, providing potential to receive priority review voucher (PRV) if ultimately approved for the indication of spinal muscular atrophy (SMA)
- Completed a "buy-back" of partial royalty and milestone considerations from Knopp for the BHV-7000 and other Kv7 pipeline programs, replacing up to low teens royalty obligations with a flat mid-single digit royalty along with certain reduced future milestones
- Phase 2 and 3 programs in epilepsy, major depressive disorder (MDD) and bipolar disorder initiated with selective Kv7 activator, BHV-7000
- Phase 1 studies with brain-penetrant Tyrosine Kinase 2/Janus Kinase 1 (TYK2/JAK1) inhibitor, BHV-8000, and Transient Receptor Potential Melastatin 3 (TRPM3) antagonist, BHV-2100, programs advancing
- Total of three late stage, pivotal clinical trials ongoing with taldefgrobep alfa in SMA and trilorizole in OCD
- 20 abstracts, including 8 oral presentations and 12 posters, featured at the American Academy of Neurology (AAN) Annual Meeting, including recognition of BHV-2100 (TRPM3 antagonist) as AAN Abstract of Distinction in the pain category; breadth of presentations highlights Biohaven's leadership in neuroscience and immunoscience as well as extensive development programs evaluating novel therapies to treat neurological diseases, with abstracts covering programs including Kv7 ion channel modulation, MoDEs™, TYK2/JAK1 inhibition, glutamate modulation, myostatin inhibition, and TRPM3 antagonism

NEW HAVEN, Conn., May 9, 2024 /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 to treat a broad range of rare and common diseases, today reported financial results for the first quarter ended March 31, 2024, and provided a review of recent accomplishments and anticipated upcoming developments.

Vlad Coric, M.D., Chairman and Chief Executive Officer of Biohaven, commented, "We are excited about the clinical progress we are making across our entire portfolio and in particular, the recent initiation of the first-in-human study of BHV-1300 using our Molecular Degradator of Extracellular Protein (MoDE™) technology. We were pleased to report preliminary safety and target engagement data showing degradation of IgG from the initial two low-dose cohorts of the ongoing BHV-1300 study. Thus far, BHV-1300 has also been well-tolerated with no significant adverse effects and no clinically significant lab abnormalities or ECG changes observed to date. We remain enthusiastic about the emerging profile of BHV-1300 and have multiple IND-enabling activities planned for several additional MoDEs directed at autoantibody-mediated disease targets over the next couple of years. MoDEs represent a transformative technology to modulate the immune system and specifically degrade extracellular targets known to cause disease. INDs from our MoDE platform planned for later this year include drug candidates that target autoantibodies against β -1AR for the potential treatment of dilated cardiomyopathy and galactose deficient IgA for IgA nephropathy."

Dr. Coric continued, "The Biohaven R&D team continues to make impressive progress across our broader pipeline, with enrollment having begun in our BHV-7000 epilepsy program. In addition, dosing is now complete in Phase 1 SAD and MAD cohorts of BHV-8000, our TYK2/JAK1 inhibitor, paving the way for multiple clinical trial initiations in 2024, such as Parkinson's disease, Alzheimer's disease and prevention of Amyloid-Related Imaging Abnormalities (ARIA) associated with amyloid lowering agents. Additionally, Phase 3 trials are underway in OCD (obsessive-compulsive disorder), and in SMA, with data anticipated in both studies later this year. Further, multiple Phase 2 and Phase 2/3 studies initiated in Q2 in MDD, Bipolar Disorder and Generalized Epilepsy, and Phase 2 studies are projected to start in the second half of the year in migraine and obesity. And finally, important updates are expected with our burgeoning antibody drug conjugate (ADC) platform, with our recent initiation of enrollment in the TROP2 Phase 1 study, multiple INDs and 5–7 new ADC targets projected in the next two years. We excitedly await a steady cascade of anticipated upcoming milestones and were pleased to

complete a public offering to further advance our development plans and research efforts. We look forward to unveiling further updates across our clinical programs and future development plans at our annual R&D Day at the Yale Innovation Summit on May 29, 2024 in New Haven, CT.”

First Quarter 2024 and Recent Business Highlights

- **Reported preliminary safety and IgG lowering data from ongoing SAD study with BHV-1300** — In April 2024, the Company provided preliminary safety and IgG lowering data from its ongoing SAD study of BHV-1300. In the study, 16 subjects completed two dosing cohorts to date. All cohorts have proceeded as initially planned without any cohort expansion or interruption.
 - To date, BHV-1300 has been safe and well-tolerated with no serious adverse events (SAEs) or moderate or severe adverse events (Aes) observed. Only mild Aes have been observed, which were deemed not to be related to BHV-1300 with most resolving spontaneously. No clinically significant laboratory abnormalities (including liver function tests and albumin) or electrocardiogram (ECG) changes have been observed to date.
 - Preliminary IgG lowering data is consistent with modeling based on non-clinical experience, with dose- and time-dependent IgG lowering observed even in initial low dose cohorts. Reductions were greater for IgG1, IgG2 and IgG4 subclasses compared to IgG3; BHV-1300 was designed to spare IgG3.
 - Based on initial findings, the Company plans to accelerate development across additional autoantibody-mediated targets.
- **Phase 2/3 program with BHV-7000 underway in epilepsy** - Also initiated a Phase 2 study in MDD and Phase 2/3 studies in Bipolar Disorder and Generalized Epilepsy with BHV-7000.
- **Taldefgrobep alfa awarded "rare pediatric disease" designation** - In April 2024, the Company announced that the Food and Drug Administration (FDA) granted "rare pediatric disease" designation for taldefgrobep alfa. The designation provides the potential for taldefgrobep to receive a PRV if ultimately approved for the indication of SMA.
- **Oral and poster presentations at AAN showcased breadth of development work across the platform** - In April 2024, the Company delivered 8 oral presentations and 12 posters at the AAN Annual Meeting, showcasing development programs including Kv7 ion channel modulation, MoDEs, TRPM3 antagonism, TYK2/JAK1 inhibition, glutamate modulation, and myostatin inhibition.
 - AAN Abstract of Distinction awarded to BHV-2100, which demonstrated potent reversal of pain in preclinical models and favorable initial safety and pharmacokinetic data in Phase 1 studies, highlighting the potential for TRPM3 antagonism as a novel nonopioid target to treat pain and migraine.
 - Biohaven's first-in-class Molecular Degradator of Extracellular Proteins (MoDE™) technology targeting IgG removal, BHV-1300, was selected for an oral presentation at AAN highlighting its novel mechanism of action and the latest preclinical data demonstrating rapid, robust, and selective target removal.
- **Public offering** - On April 22, 2024, the Company closed its previously announced underwritten public offering of 6,451,220 of its common shares, which included the full exercise of the underwriters' option to purchase 841,463 additional shares, at the public offering price of \$41.00 per share. The net proceeds raised in the offering, after deducting underwriting discounts and estimated expenses of the offering payable by the Company, were approximately \$247.8 million. As of May 6, 2024, we had 88,291,909 common shares outstanding.

Expected Upcoming Milestones:

We believe Biohaven is well positioned to achieve significant, value-creating milestones in 2024 across numerous programs:

Selective Kv7 Activator:

- Continue to advance Phase 2/3 programs in focal epilepsy, idiopathic generalized epilepsy, MDD and bipolar disorder

Troriluzole:

- Continue two Phase 3 trials with troriluzole in OCD

Taldefgrobep alfa:

- Initiate taldefgrobep Phase 2 study in obesity in 2H 2024
- Report taldefgrobep Phase 3 topline results in SMA in 2H 2024

First-in-class TRPM3 Antagonist:

- Initiate BHV-2100 Phase 2 study in acute migraine in 2H 2024
- Conduct BHV-2100 proof of concept (POC) study for neuropathic pain in 2H 2024

TYK2/JAK1 Inhibitor:

- Complete SAD/MAD studies with BHV-8000 and advance to Phase 2 in 2H 2024

Extracellular protein degradation platform

- A total of 4 Investigational New Drug Applications (INDs) are expected for the degrader program in 2024
- Provide progress updates regarding ongoing Phase 1 SAD study with BHV-1300 at annual R&D Day on May 29, 2024 followed up with a MAD update in 2H24

Next Generation ADC Platform:

- Advance Phase 1 TROP2 directed ADC program with BHV-1510 in multiple tumor types

Capital Position:

Cash, cash equivalents, marketable securities and restricted cash totaled approximately \$287.6 million on March 31, 2024, which excludes the net proceeds of approximately \$247.8 million from Biohaven's public offering completed on April 22, 2024.

First Quarter 2024 Financial Highlights:

Research and Development (R&D) Expenses: R&D expenses, including non-cash share-based compensation costs, were \$156.0 million for the three months ended March 31, 2024, compared to \$63.5 million for the three months ended March 31, 2023. The increase of \$92.5 million was primarily due to increases in direct program spend for additional and advancing clinical trials, including late Phase 2/3 studies, and preclinical research programs, as well as \$16.6 million in common shares associated with the acquisition of Pyramid Biosciences, Inc., including a milestone payment for BHV-1510, and increased non-cash share-based compensation expense. Non-cash share-based compensation expense was \$21.3 million for the three months ended March 31, 2024, an increase of \$19.1 million as compared to the same period in 2023. Non-cash share-based compensation expense was higher in the first quarter of 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 (G&A) Expenses: General and administrative expenses were \$27.3 million for the three months ended March 31, 2024, compared to \$14.3 million for the three months ended March 31, 2023. The increase of \$12.9 million was primarily due to increased non-cash share-based compensation expense. Non-cash share-based compensation expense was \$13.6 million for the three months ended March 31, 2024, an increase of \$12.1 million as compared to the same period in 2023. Non-cash share-based compensation expense was higher in the first quarter of 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 \$4.3 million for the three months ended March 31, 2024, compared to a net income of \$8.2 million for the three months ended March 31, 2023. The decrease of \$3.9 million was primarily due to a decrease of \$3.9 million in other income recognized during the three months ended March 31, 2024 as compared to the same period in 2023 related to the Transition Services Agreement entered into with Biohaven Pharmaceutical Holding Company Ltd. (the Former Parent).

Net Loss: Biohaven reported a net loss for the three months ended March 31, 2024, of \$179.5 million, or \$2.20 per share, compared to \$70.5 million, or \$1.03 per share, for the same period in 2023. Non-GAAP adjusted net loss for the three months ended March 31, 2024 was \$144.6 million, or \$1.77 per share, compared to \$66.7 million, or \$0.98 per share for the same period in 2023. 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. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the tables below.

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, which are adjusted to exclude non-cash share-based compensation, which is substantially dependent on changes in the market price of common shares. 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 and adjusted net loss per share, when viewed in conjunction with GAAP results, provides investors with a more meaningful understanding of ongoing operating performance and can assist investors in comparing 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 news release.

About Biohaven

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; TRPM3 antagonism for migraine and neuropathic pain; TYK2/JAK1 inhibition for neuroinflammatory disorders; glutamate modulation for OCD and SCA (spinocerebellar ataxia); myostatin inhibition for neuromuscular and metabolic diseases, including SMA and obesity; antibody recruiting bispecific molecules and antibody drug conjugates for cancer.

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 FDA; 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 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 news 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.

BIOHAVEN LTD.**CONSOLIDATED STATEMENTS OF OPERATIONS****(Amounts in thousands, except share and per share amounts)****(Unaudited)**

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 155,972	\$ 63,461
General and administrative	27,268	14,321
Total operating expenses	183,240	77,782
Loss from operations	(183,240)	(77,782)
Other income, net	4,305	8,229
Loss before provision for income taxes	(178,935)	(69,553)
Provision for income taxes	569	939
Net loss	<u>\$ (179,504)</u>	<u>\$ (70,492)</u>
Net loss per share — basic and diluted	<u>\$ (2.20)</u>	<u>\$ (1.03)</u>
Weighted average common shares outstanding— basic and diluted	81,601,826	68,206,879

BIOHAVEN LTD.

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands, except share amounts)

	March 31, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 182,705	\$ 248,402
Marketable securities	100,713	133,417
Prepaid expenses	46,214	35,242
Income tax receivable	8,433	13,252
Other current assets	10,679	12,133
Total current assets	348,744	442,446
Property and equipment, net	16,693	17,191
Intangible assets	18,400	18,400
Goodwill	1,390	1,390
Other non-current assets	33,305	33,785
Total assets	\$ 418,532	\$ 513,212
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 36,385	\$ 15,577
Accrued expenses and other current liabilities	50,203	39,846
Total current liabilities	86,588	55,423
Non-current operating lease liabilities	27,086	27,569
Other non-current liabilities	3,411	2,245
Total liabilities	117,085	85,237
Shareholders' Equity:		
Preferred shares, no par value; 10,000,000 shares authorized, no shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common shares, no par value; 200,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 81,807,221 and 81,115,723 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	910,964	887,528
Additional paid-in capital	69,385	39,804
Accumulated deficit	(678,796)	(499,292)
Accumulated other comprehensive loss	(106)	(65)
Total shareholders' equity	301,447	427,975
Total liabilities and shareholders' equity	\$ 418,532	\$ 513,212

BIOHAVEN LTD.

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL MEASURES

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

(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Reconciliation of GAAP to Non-GAAP adjusted net loss:		
GAAP net loss	\$ (179,504)	\$ (70,492)
Add: non-cash share-based compensation expense	34,877	3,765
Non-GAAP adjusted net loss	<u>\$ (144,627)</u>	<u>\$ (66,727)</u>
Reconciliation of GAAP to Non-GAAP adjusted net loss per share — basic and diluted:		
GAAP net loss per share — basic and diluted	\$ (2.20)	\$ (1.03)
Add: non-cash share-based compensation expense	0.43	0.05
Non-GAAP adjusted net loss per share — basic and diluted	<u>\$ (1.77)</u>	<u>\$ (0.98)</u>

MoDEs is a trademark of Biohaven Therapeutics Ltd.

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