

**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): March 3, 2025

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 March 3, 2025, Biohaven Ltd. (the “**Registrant**”) issued a press release announcing its financial results for the fourth quarter and full year ended December 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 March 3, 2025, "Biohaven Reports Recent Business Developments and Fourth Quarter and Full Year 2024 Financial Results."
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: March 3, 2025

Biohaven Ltd.

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

Biohaven Reports Recent Business Developments and Fourth Quarter and Full Year 2024 Financial Results

- Announced acceptance and Priority Review by the United States Food and Drug Administration (FDA) of the new drug application (NDA) for troriluzole in all-genotype spinocerebellar ataxia; expected Prescription Drug User Fee Act (PDUFA) date in 3Q 2025.
- Cash, cash equivalents, marketable securities and restricted cash as of December 31, 2024 totaled approximately \$489 million.
- Reported positive degrader data with multiple doses of BHV-1300 achieving up to 84% reduction of total IgG, with a median reduction of 80%, after subcutaneous weekly 1000 mg dosing in the ongoing Phase 1 study.
 - Optimized subcutaneous administration of BHV-1300 achieved rapid, deep and sustained lowering of total IgG, differentiating Biohaven's new small-molecule class of degraders from the monoclonal antibody FcRn-targeting competition
 - Doses up to 2000 mg have been safe and well-tolerated. Dose escalation is ongoing with the optimized subcutaneous formulation of BHV-1300 to explore full range of IgG lowering and Phase 1 study completion expected in 1H 2025. Expect to initiate Phase 2 study in Graves' disease in mid-2025.
- Accelerating clinical development and operational execution across five innovative platforms including more than 10 assets in 6 therapeutic areas spanning immunology & inflammation, neuroscience, and oncology:
 - Portfolio targeting large indications including obesity, epilepsy, depression, obsessive-compulsive disorder (OCD), migraine, pain, Alzheimer's disease, Parkinson's disease, Graves' disease, multiple sclerosis (MS), rheumatoid arthritis, and cancer.
 - Also advancing treatments for rare diseases including myasthenia gravis, peripartum cardiomyopathy, spinal muscular atrophy, and IgA nephropathy.
- Pursuing targeted, patient-directed, immune-modulating treatment with next generation and selective TRAP™ degraders:
 - **IgA Nephropathy (IgAN) program:** First-in-human dosing with BHV-1400, a next generation Targeted Removal of Aberrant Proteins (TRAP™) degrader, achieved rapid, deep, and selective lowering of only aberrant galactose-deficient IgA1 (Gd-IgA1), the antibody causing IgA nephropathy, while sparing normal IgA. The first and lowest dose tested (125 mg) of BHV-1400 in the ongoing Phase 1 trial achieved rapid lowering of Gd-IgA1 with a median reduction of 60% within four hours of administration after a single dose. Maximal reduction exceeding 70% was observed within eight hours. Reductions were sustained for days even after a single dose. Additional SAD and MAD cohorts with BHV-1400 have been completed and will be presented at an upcoming conference.
 - **Peripartum cardiomyopathy (PPCM) program:** First-in-human dosing with BHV-1600, a TRAP degrader of β 1AR autoantibodies, was initiated and has been well-tolerated to date after the first two dosing cohorts without clinically significant changes in innate or adaptive immunity, including white blood cells and immunoglobulins IgG, IgA, IgE, and IgM. Additional SAD and MAD cohorts with BHV-1600 have been completed and will be presented at an upcoming conference.
 - Both compounds have been safe and well tolerated and Phase 1 studies with BHV-1400 and BHV-1600 are expected to be completed in 1H 2025.
 - Additional degraders advancing including IgG4 degrader, PLA2R autoantibody degrader, insulin autoantibody degrader, and TSH receptor autoantibody degrader.
- Pivotal clinical data and other developmental milestones expected across balance of portfolio:
 - **Troriluzole** (*novel glutamate modulator*): Following FDA acceptance and Priority Review grant for troriluzole NDA, the Company is preparing for commercial launch in SCA in 2025, if approved. Topline data from Phase 3 OCD trial in 1H 2025.
 - **BHV-7000** (*selective activator of Kv7.2/7.3 potassium channels*): Registrational Phase 2/3 studies ongoing in major depressive disorder, focal epilepsy, and generalized epilepsy. Bipolar mania 3-week study did not statistically separate from the comparator on the Young Mania Rating Scale primary outcome measure and analyses are ongoing with results expected to be presented at an upcoming conference. Major depressive disorder topline results expected in 2H 2025. Focal epilepsy study topline results expected in 1H 2026.
 - **BHV-2100** (*oral, selective TRPM3 antagonist offering novel, non-addictive treatment for migraine and neuropathic pain*): Topline data from the laser-evoked potential study in 1H 2025; proof-of-concept in migraine ongoing.

- **Taldefgrobep alfa** (*novel myostatin inhibitor*): Expect FDA meeting to discuss SMA registrational path in 1H 2025; separately initiating taldefgrobep alfa Phase 2 study in obesity in 1H 2025.
- **BHV-8000** (*highly selective, oral, brain-penetrant, TYK2/JAK1 inhibitor; broad potential for neurodegenerative and neuroinflammatory disorders*): Initiating BHV-8000 Phase 2/3 study in Parkinson's disease in 1H 2025 and advancing Alzheimer's disease, MS and ARIA programs in 2025.
- **Advancing oncology next-generation antibody drug conjugate (ADC) portfolio**: Milestones with novel ADC technology and strategic collaborations driving next-generation cancer therapies include: preliminary Phase 1 data with BHV-1510, and ongoing dose optimization as monotherapy and combination therapy with Libtayo® in epithelial tumors, with interim Phase 1 data anticipated in 2H 2025; Phase 1 trial initiation of the novel FGFR3-directed ADC, BHV-1530, planned in 1H 2025; and advancing additional ADC programs through collaborations with Merus and GeneQuantum.

NEW HAVEN, Conn., March 3, 2025 /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 provided a review of recent accomplishments and anticipated upcoming developments and reported financial results for the fourth quarter and full year ended December 31, 2024.

Vlad Coric, M.D., Chairman and Chief Executive Officer of Biohaven, commented, “We have made considerable progress this past year in advancing our innovative and diversified portfolio. Most notably, we oversaw the advent of our groundbreaking degrader or MoDE™ technology continue to advance into the clinic, with today’s added news that multiple doses of BHV-1300 lowered serum IgG by up to 84% from baseline. Modulation of IgG has proven to be an exciting and growing market in the treatment of autoimmune disease, and BHV-1300 has the potential to further advance the field. Our next generation TRAP™ degraders offer the additional advantage of selectively removing antigen-specific targets while sparing off-target effects to allow continued healthy immune functioning. The selectivity of MoDE and TRAP degraders demonstrated to date has the potential to redefine the immune-modulating treatment paradigm. The implications and applications of this selective targeting could be multi-organ, multi-disease and we are eager to continue unlocking the vast potential afforded by our innovative degrader technology.”

Dr. Coric continued, “Thanks to focused execution across the balance of our portfolio, we believe we are poised to deliver important milestones in 2025 and beyond, starting with the FDA accepting our troriluzole NDA filing resubmission and granting Priority Review. An approval in this indication could profoundly impact the outlook for nearly 40,000 patients living with spinocerebellar ataxia across the globe and we are making commercial plans in earnest as we await final regulatory outcomes; we separately await the results of critical Phase 3 data in each of our 2 identical ongoing studies in OCD. Our ion channel platform expects to report topline pivotal results with our Kv7.2/7.3 potassium channel activator, BHV-7000, in major depressive disorder in 2H 2025 and in focal epilepsy in 1H 2026. Furthering our expansion of knowledge for our ion channel platform, we expect to report data from the laser-evoked hyperalgesia and proof-of-concept migraine studies with TRPM3 antagonist, BHV-2100, in 1H 2025. With taldefgrobep alfa, our anti-myostatin agent, we likewise look forward to working with appropriate regulatory bodies to establish a potential path forward in spinal muscular atrophy as we work in tandem to initiate our Phase 2 study in obesity. Regarding our brain-penetrant TYK2/JAK1 Inhibitor, we are eager to initiate our Phase 2/3 study in Parkinson’s disease in the first half of the year as we advance programs in Alzheimer’s, MS, and ARIA in parallel. Finally, we are significantly advancing our ADC portfolio as new strategic collaborations and ongoing clinical and non-clinical work has invigorated our oncology franchise, with several milestones anticipated in 2025, including interim Phase 1 data with our lead clinical Trop-2 ADC program, BHV-1510 and a Phase 1 initiation with our novel FGFR3 ADC, BHV-1530, for patients with urothelial cancer & other tumors; we are also advancing multiple ADCs through our newly announced collaborations with Merus and GeneQuantum.”

“An exciting year awaits us to be sure, and as we move forward, I’m confident our strong momentum will continue thanks to the unwavering dedication of our talented team, underpinned by our relentless desire to innovate, serve patients, and generate value in lockstep.”

Full Year and Recent Business Highlights

Glutamate Modulation Platform - Milestones and Next Steps:

Troriluzole is a novel glutamate modulator currently in Phase 3 development for all-genotype spinocerebellar ataxia (SCA) and obsessive-compulsive disorder (OCD). The FDA has accepted for review the Company's NDA for troriluzole for the treatment of adult patients with SCA and has granted Priority Review; troriluzole

previously received Orphan Drug and Fast-Track designations. EU marketing authorization application is also under review for troriluzole in all SCA genotypes. There are no FDA-approved treatments for SCA. Additionally, two Phase 3 trials with troriluzole in OCD are ongoing.

- **Announced FDA acceptance and Priority Review of troriluzole NDA for the treatment of spinocerebellar ataxia:** The FDA's decision regarding the NDA is expected within 6 months of filing (during 3Q 2025). Based on FDA Priority Review timelines and, if ultimately approved, Biohaven is prepared to commercialize troriluzole for SCA in the US in 2025.
 - The Company had previously achieved positive topline results in a pivotal study of troriluzole in SCA. Troriluzole 200 mg dosed orally, once daily, in patients with SCA met the study's primary endpoint on the change from baseline in the modified functional Scale for the Assessment and Rating of Ataxia (f-SARA) at 3 years in all study population genotypes. Troriluzole also showed statistically significant superiority after both 1 and 2 years of treatment. Troriluzole achieved statistically significant superiority on 9 consecutive, prespecified primary and secondary endpoints. SCA patients treated with troriluzole showed a 50-70% slowing of disease progression, representing 1.5-2.2 years delay in disease progression over the 3-year study period.

Upcoming milestones:

- Following FDA acceptance of the troriluzole all-genotype SCA NDA filing resubmission with Priority Review status and a 3Q 2025 PDUFA date, the Company is preparing for commercial launch in SCA in 2025, pending approval.
- Topline data from two Phase 3 OCD trials in 1H 2025 and 2H 2025, respectively.

Inflammation and Immunology Platform - Milestones and Next Steps:

Targeted Extracellular Protein Degradation

Biohaven's novel immune-modulating extracellular degrader platform harnesses selectivity, rapidity, and patient-friendly self-administration to remove disease-causing proteins from the body to potentially treat a wide range of diseases; MoDEs™ (Molecular Degradors of Extracellular Proteins) uniquely harness the hepatic asialoglycoprotein receptor (ASGPR) for efficient and safe removal of circulating pathogenic targets. BHV-1300 and BHV-1310 are IgG degraders; Biohaven introduced next generation TRAP™ (Targeted Removal of Aberrant Protein) degraders, which are highly selective, each targeting a specific disease-causing protein for proteolysis; BHV-1400 is a TRAP degrader targeting Gd-IgA1. BHV-1600 is a TRAP degrader targeting β 1-AR autoantibodies.

Announced multiple advancements across MoDE and TRAP platforms:

- **IgA Nephropathy (IgAN) program:** First-in-human (FIH) dosing with BHV-1400 achieved rapid, deep, and selective lowering of only aberrant galactose-deficient IgA1 (Gd-IgA1). The first and lowest dose tested (125 mg) of BHV-1400 in the ongoing Phase 1 trial achieved rapid lowering of Gd-IgA1 with a median reduction of 60% within four hours of administration after a single dose. Maximal reduction exceeding 70% was observed within eight hours. Reductions were sustained for days even after a single dose. BHV-1400 has been safe and well-tolerated in the Phase 1 study to date and demonstrated no clinically significant changes in innate or adaptive immunity.
- **Peripartum cardiomyopathy (PPCM) program:** FIH dosing with BHV-1600 was initiated and has been well-tolerated to date after the first two dosing cohorts without clinically significant changes in innate or adaptive immunity. Held INTERACT meeting with FDA in 4Q 2024.
- **IgG degrader programs:** BHV-1300: Advanced optimized subcutaneous formulation with deep reductions of total IgG exceeding 80% with 1,000 mg weekly dosed over four weeks in the ongoing Phase 1 study. Doses of up to 2,000 mg have been safe and well-tolerated. There were no clinically significant reductions in IgG3, IgA, IgE, IgM, or albumin, nor clinically significant increases in AST, ALT, bilirubin, or cholesterol.

Upcoming milestones:

- IgG MoDE Degradors (1300/1310): BHV-1300 Phase 1 with the optimized subcutaneous formulation expected completion in 1H 2025. BHV-1310 completion of preclinical testing prior to anticipated first-in-human study initiating 1H 2025. Phase 2 study in Graves' disease expected

- to initiate mid-2025 and additional programs in rheumatoid arthritis and myasthenia gravis continue to be pursued.
- Phase 1 study with BHV-1400 and BHV-1600 expected to be completed in 1H 2025.
- Four additional degraders advancing including: IgG4 degrader, PLA2R autoantibody degrader, insulin autoantibody degrader, and TSH receptor autoantibody degrader.

TYK2/JAK1 Inhibition

BHV-8000 is an oral, brain-penetrant, selective TYK2/JAK1 inhibitor with broad potential for neuroinflammatory and neurodegenerative disorders.

- Completed Phase 1 study with BHV-8000:** In the Phase 1 SAD/MAD study in healthy participants, BHV-8000 was generally safe and well-tolerated while producing significant reductions in inflammatory biomarkers relative to placebo. Biohaven completed interactions with FDA enabling registrational programs for Parkinson's disease and the prevention of ARIA.

Upcoming milestones:

- Initiate BHV-8000 Phase 2/3 study in Parkinson's disease in 1H 2025.
- Advance Alzheimer's, MS and ARIA programs in 2025.

Ion Channel Platform - Milestones and Next Steps:

Kv7 Activation: Epilepsy & Neuropsychiatric Indications

BHV-7000, the lead asset from the Kv7 platform, is a selective activator of Kv7.2/Kv7.3 potassium channels. Kv7 activation is a clinically validated target for treating mood disorders and epilepsy. Four registrational studies are ongoing in major depressive disorder, focal epilepsy, and generalized epilepsy.

- BHV-7000 once-daily extended-release formulation data presented:** Reported expanded safety results from BHV-7000 Phase 1 MAD studies at the American Epilepsy Society (AES) 2024 Annual Meeting, including the once-daily extended-release formulation being evaluated in ongoing Phase 2 and 3 clinical studies, demonstrating excellent tolerability at all doses evaluated without central nervous system (CNS) adverse effects typically associated with other anti-seizure medications (ASMs), such as somnolence and cognitive/mood disturbances. BHV-7000 was safe and well-tolerated at dose levels up to 120 mg daily for 15 days with no dose-limiting toxicities; 120 mg exceeds the doses being evaluated in ongoing Phase 2 and 3 clinical studies of up to 75 mg daily in focal epilepsy, idiopathic generalized epilepsy, and major depressive disorder.
- Completed a focused topline analysis of treatment with BHV-7000 in the acute treatment of manic episodes associated with bipolar disorder in a 3-week trial:** BHV-7000 did not statistically differentiate from the comparator arm on the primary efficacy endpoint of improvement from Baseline to Day 21 on the Young Mania Rating Scale. Additional analyses are ongoing, and complete study results will be presented at an upcoming scientific meeting. BHV-7000 75 mg once daily, the highest dose of BHV-7000 being evaluated in Phase 2/3 trials, was safe and well-tolerated in this study. No adverse trends in vital signs, ECGs, or labs were noted. There were no treatment emergent serious adverse events. Most adverse events were mostly mild in intensity and resolved spontaneously. This offers a highly favorable and differentiated profile compared to other antiseizure medicines and is consistent with lack of GABA effects.

Upcoming milestones:

- Pivotal major depressive disorder topline results expected in 2H 2025. Focal epilepsy study topline results expected in 1H 2026.

TRPM3 Ion Channel Antagonism: Migraine & Neuropathic Pain

BHV-2100 is an oral, selective TRPM3 antagonist potentially offering a novel, non-addictive treatment for migraine and neuropathic pain

- Phase 1 study data supports evaluation in migraine and pain:** Based on favorable PK and safety data from Phase 1 studies in healthy subjects, a Phase 1b laser-evoked hyperalgesia trial completed and a proof-of-concept in the acute treatment of migraine is ongoing. Preliminary data from the laser-evoked hyperalgesia study demonstrated that BHV-2100 reduced laser heat-

induced pain and brain evoked potentials in healthy volunteers, providing the first indication of potential clinical efficacy in pain with the novel TRPM3 mechanism recapitulating antinociceptive preclinical efficacy across a spectrum of pain models.

Upcoming milestones:

- Data from the laser-evoked potential study and migraine proof-of-concept in 1H 2025.

Myostatin Platform - Milestones and Next Steps:

Taldefgrobep is a novel myostatin inhibitor that is optimized to block signaling of myostatin and other activin II receptor ligands, key regulators of muscle and fat metabolism. Biohaven is studying taldefgrobep in a global Phase 3 expansion study in Spinal Muscular Atrophy (SMA), as an adjunctive therapy to enhance muscle mass and function in patients treated with standard-of-care therapies.

- **Provided update on Phase 3 taldefgrobep alfa program for spinal muscular atrophy:** In November 2024, the Company presented analyses of prespecified subgroups by race and ethnicity demonstrating that the largest study population (87% Caucasian; n=180) showed clinically meaningful improvements on the MFM-32 at all timepoints, including Week 48, compared to the corresponding placebo+SOC group ($p < 0.05$), though the overall primary endpoint was not met. Additionally, robust target engagement (myostatin reduction) and beneficial impacts on body composition parameters (fat mass, lean muscle mass, and bone density) were noted, offering a potential paradigm shift in the treatment of obesity with opportunity to improve quality of weight loss; lower total body weight by specifically reducing fat mass while also preserving or increasing lean muscle mass.

Upcoming milestones:

- Expect FDA meeting to discuss SMA registrational path in 1H 2025
- Initiate taldefgrobep Phase 2 study in obesity in 1H 2025

Next-Generation ADC Platform - Milestones and Next Steps:

Biohaven's antibody drug conjugate (ADC) technology is focused on novel, modular site-specific conjugation chemistry approaches, with the potential to drive superior clinical profiles compared to current industry standard maleimide and lipophilic click chemistries.

- BHV-1510, a clinical-stage TROP2 directed ADC with a highly differentiated preclinical efficacy and safety profile, has demonstrated early Phase 1 clinical activity and a tolerable safety profile of the novel topoisomerase 1 inhibitor (TopoIx) payload in early cohorts, with no payload associated interstitial lung disease, gastrointestinal toxicities or significant hematological toxicities. Dose escalation and optimization are ongoing as monotherapy and in combination with Libtayo (R) (cemiplimab), an anti-PD1 checkpoint inhibitor, through a clinical supply agreement with Regeneron.
- Based on the preclinical profile and encouraging early results with BHV-1510, Biohaven has entered into an expanded collaboration agreement with GeneQuantum, which provides broad target exclusivity for up to 18 ADC targets incorporating the TopoIx payload
- The next ADC program positioned to enter clinic, BHV-1530, is a novel FGFR3 ADC that incorporates the TopoIx payload. Similar to BHV-1510, this program has demonstrated a differentiated efficacy and safety profile in preclinical studies, including synergistic in vivo efficacy in combination with a checkpoint inhibitor. Potential indications include urothelial cancer and other FGFR3-driven solid tumors.
- In January 2025, Biohaven also announced a multi-target collaboration with Merus N.V. to co-develop three novel dual-targeted ADCs, leveraging Merus' Biclomics® technology platform, and Biohaven's next-generation ADC conjugation and payload technologies.

Expected Upcoming Milestones:

We believe Biohaven is well positioned to achieve significant milestones in 2025 and 2026 across numerous programs:

MoDE™ Platform

- IgG MoDE Degraders (1300/1310): BHV-1300 Phase 1 with the optimized subcutaneous formulation completing in 1H 2025. BHV-1310 completion of preclinical testing prior to anticipated FIH study

initiating 1H 2025. Expect to initiate Phase 2 study in Graves' disease in mid-2025, and additional programs in rheumatoid arthritis and myasthenia gravis continue to be pursued.

- Phase 1 with BHV-1400 and BHV-1600 expected to be completed in 1H 2025.
- Four additional degrader molecules advancing including: IgG4 degrader, PLA2R autoantibody degrader, insulin autoantibody degrader, and TSH receptor autoantibody degrader.

Kv7 Activator (BHV-7000):

- Pivotal major depressive disorder topline results expected in 2H 2025. Focal epilepsy study topline results expected in 1H 2026.

Glutamate Modulator (Troriluzole):

- Preparing for commercial launch in all-genotype SCA in 2025, following FDA filing acceptance and 3Q 2025 PDUFA date.
- Topline data from two Phase 3 OCD trials in 1H 2025 and 2H 2025, respectively.

Myostatin (Taldefgrobep alfa):

- Expect FDA meeting to discuss SMA registrational path in 1H 2025.
- Initiate taldefgrobep Phase 2 study in obesity in 1H 2025.

TRPM3 Antagonist (BHV-2100):

- Continue advancing enrollment in proof-of-concept trial with BHV-2100 in acute migraine; data from the laser-evoked potential study expected in 1H 2025.

TYK2/JAK1 Inhibitor (BHV-8000):

- Initiate BHV-8000 Phase 2/3 study in Parkinson's disease in 1H 2025.
- Advance Alzheimer's, MS and ARIA programs.

Next Generation ADC Platform:

- Interim Phase 1 data with BHV-1510 and dose optimization as monotherapy and combination therapy with Libtayo® in epithelial tumors in 2025.
- Initiate Phase 1 trial of BHV-1530 in 1H 2025.
- Advance Merus collaboration ADCs (undisclosed targets) and TopoI α ADCs in 2025.

Capital Position:

Cash, cash equivalents, marketable securities and restricted cash as of December 31, 2024 totaled approximately \$489 million.

Fourth Quarter 2024 Financial Highlights:

Research and Development (R&D) Expenses: R&D expenses, including non-cash share-based compensation costs, were \$167.5 million for the three months ended December 31, 2024, compared to \$134.8 million for the three months ended December 31, 2023. The increase of \$32.7 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 \$7.1 million for the three months ended December 31, 2024, a decrease of \$2.0 million as compared to the same period in 2023. Non-cash share-based compensation expense was lower in the fourth quarter of 2024 primarily due to our annual equity incentive awards granted in the fourth quarter of 2023 with no new annual equity incentive awards granted in the fourth quarter of 2024.

General and Administrative (G&A) Expenses: G&A expenses were \$22.5 million for the three months ended December 31, 2024, compared to \$18.9 million for the three months ended December 31, 2023. The increase of \$3.6 million was primarily due to increased personnel and legal costs for the three months ended December 31, 2024 as compared to the same period in 2023. Non-cash share-based compensation expense was \$5.6 million for the three months ended December 31, 2024, a decrease of \$1.1 million as compared to the same period in 2023. Non-cash share-based compensation expense was lower in the fourth quarter of 2024 primarily due to our annual equity incentive awards granted in the fourth quarter of 2023 with no new annual equity incentive awards granted in the fourth quarter of 2024.

Other Income, Net: Other income, net was \$3.1 million for the three months ended December 31, 2024, compared to other income, net of \$7.7 million for the three months ended December 31, 2023. The decrease of \$4.6 million was primarily due to non-cash changes in the fair value of our forward contract and derivative liabilities recorded in connection with the amendment to our Membership Interest Purchase Agreement with Knopp Biosciences LLC in May 2024 (the Knopp Amendment) and decreased service revenue from the Transition Service Agreement we entered into with Biohaven Pharmaceutical Holding Company Ltd. (the "Former Parent").

Net Loss: Biohaven reported a net loss for the three months ended December 31, 2024 of \$186.8 million, or \$1.85 per share, compared to \$144.8 million, or \$1.81 per share, for the same period in 2023. Non-GAAP adjusted net loss for the three months ended December 31, 2024 was \$173.3 million, or \$1.71 per share, compared to \$128.9 million, or \$1.61 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 and losses from the change in fair value of derivatives. A reconciliation of the GAAP financial results to non-GAAP financial results is included in the tables below.

Full Year 2024 Financial Highlights

R&D Expenses: R&D expenses, including non-cash share-based compensation, were \$795.9 million for the year ended December 31, 2024, compared to \$373.3 million for the year ended December 31, 2023. The increase was largely due to non-cash expense of \$171.9 million paid to Knopp for a milestone and royalty buyback related to BHV-7000 and the 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. The increase in R&D expenses was also related to advancing our clinical platforms including four Phase 3 study starts and one Phase 2 study start for BHV-7000, follow-on Kv7 assets, preclinical research programs, and increases in direct program spend for additional multiple clinical development programs in 2024, as compared to the same period in the prior year. The increase was also due to a \$40.2 million increase in personnel costs, primarily due to increased non-cash share based compensation expense and increased headcount to support our expanding clinical and preclinical research programs. Non-cash share-based compensation expense was \$42.6 million for the year ended December 31, 2024, an increase of \$26.6 million as compared to the same period in 2023. Non-cash share-based compensation expense was higher in the year ended December 31, 2024 primarily due to our annual equity incentive awards granted in the fourth quarter of 2023 and first quarter of 2024.

G&A Expenses: G&A expenses, including non-cash share-based compensation costs, were \$89.2 million for the year ended December 31, 2024, compared to \$62.8 million for the year ended December 31, 2023. The increase of \$26.5 million was primarily due to increased non-cash share-based compensation costs and increased legal costs. Non-cash share-based compensation expense was \$29.4 million for the year ended December 31, 2024, an increase of \$16.6 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 partially granted in the fourth quarter of 2023 with a greater portion granted in the first quarter of 2024, partially offset by the subsequent year annual equity incentive awards being granted in the first quarter of 2025 and no partial grants from such annual equity incentive awards in the fourth quarter of 2024.

Other Income (Expense), Net: Other income (expense), net was income of \$39.4 million for the year ended December 31, 2024, compared to income of \$26.5 million for the year ended December 31, 2023. The increase of \$12.9 million was primarily due to non-cash 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 in other income recognized during the year ended December 31, 2024 as compared to 2023 related to the Transition Services Agreement entered into with the Former Parent.

Net Loss: The Company reported a net loss attributable to common shareholders for the year ended December 31, 2024 of \$846.4 million, or \$9.28 per share, compared to \$408.2 million, or \$5.73 per share for the same period in 2023. Non-GAAP adjusted net loss for the year ended December 31, 2024 was \$790.6 million, or \$8.67 per share, compared to \$379.4 million, or \$5.33 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 and losses from the change in fair value of derivatives. 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 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, and changes in the fair value of derivative liabilities, which do not correlate to actual cash payment obligations in the relevant periods. 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; 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 and the expected timing thereof; the potential for Biohaven's product candidates to be successful 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 December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 167,473	\$ 134,813	\$ 795,871	\$ 373,281
General and administrative	22,458	18,898	89,240	62,770
Total operating expenses	189,931	153,711	885,111	436,051
Loss from operations	(189,931)	(153,711)	(885,111)	(436,051)
Other income, net	3,136	7,743	39,424	26,500
Loss before provision (benefit) for income taxes	(186,795)	(145,968)	(845,687)	(409,551)
Provision (benefit) for income taxes	48	(1,212)	735	(1,383)
Net loss	\$ (186,843)	\$ (144,756)	\$ (846,422)	\$ (408,168)
Net loss per share — basic and diluted	\$ (1.85)	\$ (1.81)	\$ (9.28)	\$ (5.73)
Weighted average common shares outstanding— basic and diluted	101,054,895	79,929,910	91,234,337	71,200,527

BIOHAVEN LTD.

CONSOLIDATED BALANCE SHEETS

(Amounts in thousands, except share amounts)

	December 31, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 99,134	\$ 248,402
Marketable securities	386,857	133,417
Prepaid expenses	49,376	35,242
Income tax receivable	2,597	13,252
Other current assets	508	12,133
Total current assets	538,472	442,446
Property and equipment, net	17,320	17,191
Intangible assets	18,400	18,400
Goodwill	1,390	1,390
Other non-current assets	39,525	33,785
Total assets	\$ 615,107	\$ 513,212
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 18,029	\$ 15,577
Accrued expenses and other current liabilities	51,487	39,846
Forward contract and derivative liability	84,710	—
Total current liabilities	154,226	55,423
Non-current operating lease liabilities	32,782	27,569
Other non-current liabilities	4,663	2,245
Total liabilities	191,671	85,237
Shareholders' Equity:		
Preferred shares, no par value; 10,000,000 shares authorized, no shares issued and outstanding as of December 31, 2024 and December 31, 2023	—	—
Common shares, no par value; 200,000,000 shares authorized as of December 31, 2024 and 2023; 101,221,989 and 81,115,723 shares issued and outstanding as of December 31, 2024 and 2023, respectively	1,656,702	887,528
Additional paid-in capital	112,369	39,804
Accumulated deficit	(1,345,714)	(499,292)
Accumulated other comprehensive income (loss)	79	(65)
Total shareholders' equity	423,436	427,975
Total liabilities and shareholders' equity	\$ 615,107	\$ 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 December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Reconciliation of GAAP to Non-GAAP adjusted net loss:				
GAAP net loss	\$ (186,843)	\$ (144,756)	\$ (846,422)	\$ (408,168)
Add: non-cash share-based compensation expense	12,695	15,871	71,963	28,787
Add: (gain) loss from change in fair value of derivatives	890	—	(16,140)	—
Non-GAAP adjusted net loss	<u>\$ (173,258)</u>	<u>\$ (128,885)</u>	<u>\$ (790,599)</u>	<u>\$ (379,381)</u>
Reconciliation of GAAP to Non-GAAP adjusted net loss per share — basic and diluted:				
GAAP net loss per share — basic and diluted	\$ (1.85)	\$ (1.81)	\$ (9.28)	\$ (5.73)
Add: non-cash share-based compensation expense	0.13	0.20	0.79	0.41
Add: (gain) loss from change in fair value of derivatives	0.01	—	(0.18)	—
Non-GAAP adjusted net loss per share — basic and diluted	<u>\$ (1.71)</u>	<u>\$ (1.61)</u>	<u>\$ (8.67)</u>	<u>\$ (5.33)</u>

MoDEs and TRAP are trademarks of Biohaven Therapeutics Ltd.
Libtayo is a registered trademark of Regeneron Pharmaceuticals, Inc.

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