



Biohaven Reports Recent Business Developments and Third Quarter 2026 Financial Results

October 29, 2026

- The US Food and Drug Administration (FDA) accepted new drug application resubmission for Vyglxia (troriluzole) in spinocerebellar ataxia (SCA), user fee goal date 1Q27.
- Announced exclusive global license with SK Biopharmaceuticals Co., Ltd. for Kv7 ion channel platform, including opakalim (BHV-7000); providing \$400 million in near-term cash consideration to Biohaven.
- Entered into exclusive license with Ono Pharmaceutical Co., Ltd. for Biohaven's MoDE pan IgG degrader portfolio, led by BHV-1300 in Phase 3 for Graves' disease, in Japan, South Korea, Taiwan and the ASEAN region; up to \$100 million in near-term payments to Biohaven, including \$80 million upfront received to date and eligible to receive another \$20 million upon a milestone achievement anticipated within a year, plus royalties of approximately twenty percent on net sales in the licensed territory.
- Enrollment ongoing in pivotal Phase 3 trial of BHV-1300, a MoDE™ extracellular degrader targeting IgG, in Graves' disease. More than 50 sites have been activated for enrollment in the US and Canada, with additional site openings expected in Japan, Australia, the UK and the EU.
- On track to initiate the pivotal Phase 3 trial of BHV-1400, a TRAP™ extracellular degrader targeting galactose-deficient IgA1 (Gd-IgA1), in IgA nephropathy (IgAN) during 4Q 2026. Planned regions include Japan and other Asia-Pacific regions (Australia, China, India, Taiwan and South Korea), United States, Europe (EU and UK), and Latin America.
- BHV-1530 FGFR3-directed ADC to be featured in oral presentation at ENA 2026; combination cohort with LIBTAYO® (cemiplimab-rwlc) now enrolling under clinical supply agreement with Regeneron.

NEW HAVEN, Conn., Oct. 29, 2026 /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 for the third quarter ended September 30, 2026.



Vlad Coric, M.D., Chairman and Chief Executive Officer of Biohaven, commented, "This quarter marked important progress in executing our strategy of building differentiated platforms and partnering them to create both near-term and long-term value. We are excited to have entered into the first ever regional collaboration for an extracellular protein degrader with Ono Pharmaceutical to develop and commercialize our MoDE IgG degrader portfolio, led by BHV-1300, in Japan, South Korea, Taiwan and the ASEAN region. The agreement provides up to \$100 million in near-term payments, preserves our rights in the U.S., Europe and China, and further validates the potential of our MoDE and TRAP platforms. Additionally, our announced agreement with SK Biopharmaceuticals provides for \$400 million in near-term, non-dilutive capital upon closing and positions opakalim for success with a leading epilepsy company as a partner. Establishing these unique collaborations with two leading global drug development and commercialization companies is a testament to the impressive potential and versatility of our portfolio."

Dr. Coric continued, "Beyond these partnerships, we continue to advance a diverse and innovative pipeline. We are making meaningful progress with the first degraders from our MoDE and TRAP platforms, with BHV-1300 now in a pivotal Phase 3 trial in Graves' disease and BHV-1400 expected to begin its next stage of clinical development in IgA nephropathy in the second half of 2026. A number of innovative new degraders are planned to follow in 2027. In epilepsy, RISE 3 topline data for our Kv7 activator opakalim remain on track for the second half of 2026, and we are working to complete an additional nonclinical safety package and look forward to closing our transaction with SK Biopharmaceuticals. We are also advancing taldefgrobep alfa for body recomposition, our TYK2/JAK1 inhibitor for Parkinson's disease and intranasal oxytocin for tinnitus. In oncology, our clinical programs are led by FGFR3- and TROP2-directed antibody-drug conjugates. We believe the breadth of our pipeline positions Biohaven well heading into a pivotal period for the company."

Third Quarter 2026 and Recent Business Highlights

Spinocerebellar Ataxia (SCA) Program

- The FDA has informed Biohaven that the company's new drug application resubmission for Vyglxia (troriluzole) in SCA has been accepted for review. The resubmission included new positive supportive analyses.
- The FDA communicated that it considers the resubmission a complete response to the November 4, 2025 action

letter, and has assigned a user fee goal date in the first quarter of 2027. The FDA plans to convene a meeting of the Peripheral and Central Nervous System Advisory Committee to obtain input from external stakeholders. The anticipated date of the advisory committee meeting will be forthcoming in the near term.

Extracellular Protein Degraders (MoDE and TRAP degrader platform)

- **Exclusive license with Ono Pharmaceutical Co., Ltd. for MoDE IgG degrader portfolio.** In October 2026, Biohaven entered into a strategic licensing and collaboration agreement with Ono Pharmaceutical Co., Ltd. (Ono), under which Ono obtained an exclusive license to develop and commercialize Biohaven's MoDE pan IgG degrader portfolio, led by BHV-1300 and including next-generation follow-on degraders BHV-1310 and BHV-1320, in Japan, South Korea, Taiwan and the countries of the Association of Southeast Asian Nations (ASEAN). Highlights of the agreement include:
 - **Financial terms.** Biohaven will receive up to \$100 million in near-term payments, consisting of an \$80 million upfront payment received to date and a \$20 million milestone payment upon achievement of a milestone anticipated within a year of signing, and is eligible to receive royalties of approximately 20 percent on net sales by Ono in the licensed territory.
 - **Retained rights.** Biohaven retains all rights to the MoDE IgG degrader portfolio outside the licensed territory, including in the U.S., Europe and China.
 - **Lead program.** BHV-1300 is an investigational small-molecule extracellular IgG degrader in Phase 3 development for Graves' disease. In a Phase 1b study in patients with Graves' disease, BHV-1300 produced deep reduction in the pathogenic autoantibody to the TSH receptor, rapid normalization of free T3 and free T4, and improvement in patient symptoms, with selective sparing of IgG3 and patient-friendly autoinjector self-administration.
 - **Strategic rationale.** The collaboration pairs Biohaven's clinically validated MoDE platform, which originated in research at Yale University, with Ono's development and commercial capabilities across Japan, South Korea, Taiwan and ASEAN. Ono has stated that the collaboration is intended to strengthen its late-stage pipeline in immunology and inflammation.
- **BHV-1300:** Continue enrolling patients in ongoing Phase 3 study in Graves' disease following June 2026 study initiation.
- **BHV-1400:** Pivotal study initiation in IgAN study targeted for 2H 2026.

Kv7 Ion Channel Platform and Opakalim (BHV-7000)

- **Exclusive global license with SK Biopharmaceuticals.** In August 2026, Biohaven entered into a license agreement with SK Biopharmaceuticals Co., Ltd. (SKBP). Upon closing, SKBP will have an exclusive, royalty-bearing, worldwide license to Biohaven's Kv7 ion channel platform, including opakalim (BHV-7000) as well as other Kv7 compounds and products covered by the license agreement.
 - The terms of the agreement provide for Biohaven receiving \$400 million in cash consideration, consisting of \$350 million payable at closing and \$50 million payable one year after closing, and Biohaven is eligible to receive up to \$150 million in development and regulatory milestone payments.
 - Biohaven is also eligible to receive tiered royalties ranging from the mid-teens to low twenties on U.S. net sales of opakalim and a mid-single digit royalty on net sales outside the U.S.
 - SKBP will assume responsibility for Kv7 program costs going forward, including certain specified milestone and royalty obligations to Knopp Biosciences and for future Kv7 programs.
 - The applicable HSR waiting period for the license agreement with SKBP expired on October 28, 2026, next allowing for completion of remaining closing conditions.
- **Partial clinical hold on new enrollment.** As part of the nonclinical characterization of certain metabolites of opakalim observed in rodent testing, an update was provided to global regulatory authorities regarding these ongoing studies. It was determined that there was insufficient information related to a specific metabolite to assess its risk to human subjects. The FDA instructed Biohaven to pause new enrollment until additional clarifying nonclinical studies are completed and issued a partial clinical hold letter on September 4, 2026. The partial clinical hold applies to new patient enrollment only. Until additional nonclinical data are available, specific near-term implications regarding the development program are as follows:
 - Dosing of already randomized patients, more than 600 across the program, is allowed to continue while the additional nonclinical data are generated.
 - There is no impact to RISE 3 timelines. The study is fully enrolled and randomized, dosing is ongoing, and topline data remains on track for the second half of 2026.
 - RISE 2 (BHV7000-302) will continue dosing, but new enrollment is paused pending nonclinical data expected in the coming weeks. The open-label extension study also continues dosing.
 - Biohaven voluntarily instituted this plan at its global sites outside the U.S.
 - The significance of the nonclinical metabolite findings to humans is uncertain. The findings may be specific to rodents and not relevant to human safety or there may be sufficient safety exposures and the additional nonclinical studies underway are intended to address those questions.
 - Opakalim has generally been safe and well tolerated in clinical studies, with more than 1,200 participants dosed to

date.

Oncology

- **BHV-1530 combination cohorts initiated:** In July 2026, Biohaven announced plans to initiate combination cohorts evaluating BHV-1530 with the anti-PD-1 antibody Libtayo (cemiplimab-rwlc). These cohorts began enrolling in the third quarter of 2026. In connection with these plans, Biohaven entered into a clinical supply agreement with Regeneron Pharmaceuticals, Inc. under which Biohaven will sponsor and fund the combination clinical trial and Regeneron will provide Libtayo. The agreement builds on the existing clinical supply agreement for BHV-1510, Biohaven's next-generation TROP2-directed ADC.
- Early clinical activity of BHV-1530 has been observed, including confirmed partial responses in heavily pretreated patients, with no dose-limiting toxicities and no FGFR inhibitor class toxicities such as hyperphosphatemia, nail disorders, stomatitis or retinopathy.
- **BHV-1530 selected for oral presentation at EORTC-NCI-AACR:** In September 2026, Biohaven announced that Phase 1 data for BHV-1530, its FGFR3-directed antibody-drug conjugate with a novel topoisomerase I (Topolx) payload, were selected for an oral presentation at the 38th EORTC-NCI-AACR Symposium (ENA 2026), to be held November 18 to 20, 2026, in Barcelona, Spain (presentation scheduled for November 19).
- **BHV-1510: endometrial expansion cohort is ongoing, with anticipated enrollment completion in late 2026 to early 2027.**

Additional Pipeline Updates

- **Phase 2 obesity study with taldefgrobep alfa remains ongoing:** Taldefgrobep alfa targets the myostatin-activin pathway with the goal of producing high-quality changes in body composition (including increases in lean mass while reducing fat mass) that can translate into greater metabolic health and improved wellness. The ongoing Phase 2 study, being conducted in overweight adults and adults living with obesity, is exploring subcutaneous administration of taldefgrobep alfa once-weekly and once-monthly. The study is being amended to include an assessment of taldefgrobep alfa in combination with a GLP-1-based therapy. As a result of the amended study design, we now anticipate topline data from the monotherapy and combination therapy portions of the trial in 2H 2027.
- **Parkinson's disease program:** BHV-8000 is an orally-administered, brain-penetrant, selective TYK2/JAK1 inhibitor designed to modulate neuroinflammation and peripheral immune dysregulation present in neurodegenerative disease. BHV-8000 is currently being evaluated as a disease-modifying therapy in a global Phase 2/3 study being conducted in people living with early-stage Parkinson's disease.
- **BHV-8100:** First-in-human study ongoing with BHV-8100, an oral, brain-penetrant pyruvate kinase M2 (PKM2) modulator targeting the bioenergetic and immunometabolic basis of systemic and central nervous system disorders.

Corporate Updates

- **AI-enabled candidate selection and translational strategy.** Biohaven is collaborating with Bexorg's NeuroLens AI platform, together with whole-human-brain data generated on Bexorg's BrainEx platform, to help select neuroscience candidates and guide translational strategy. NeuroLens evaluates assets against a data lake built from approximately 500 human brains, with datasets enriched for Biohaven programs, and showed high positive and negative predictive values across 43 recently studied CNS programs. In scoring Biohaven's neuroscience portfolio, BHV-8100 showed a particularly high NeuroLens score and platform fit, and BrainEx data showed optimal blood-brain barrier penetrance and a clear dose-response relationship that informed dose projection. The same approach has supported the selection of lead candidate BHV-8200 and the generation of brain and cerebrospinal fluid data supporting the translational strategy for BHV-8000.
- In August 2026, the U.S. District Court for the District of Delaware entered judgment confirming the jury's July 2026 finding that RA Capital and Avilar Therapeutics willfully and maliciously misappropriated a Yale trade secret relating to the MoDE platform, formalizing a combined \$4 million award to Yale and Biohaven. Post-trial motions on a number of topics have been filed.
- In August 2026, the Company announced the appointment of technology investor John Yetimoglu to the Board of Directors. His appointment reflects Biohaven's conviction that the next wave of breakthroughs in medicine will be driven by the convergence of biology, data, and computation. As the company expands its use of artificial intelligence, machine learning, and advanced computational methods across discovery, translational science, and clinical development, Mr. Yetimoglu's perspective on frontier technology and AI infrastructure is expected to strengthen the Board's strategic oversight in these areas.

Expected Upcoming Milestones

Vyglxia (troriluzole) in SCA:

- FDA advisory committee meeting (date to be announced); user fee goal date in 1Q 2027.

Selective Kv7 Ion Channel Activator (Opakalim):

- Topline results for Phase 2/3 study expected in 2H 2026.

Myostatin-Activin Pathway Inhibitor (Taldefgrobep alfa):

- Phase 2 study in obesity remains ongoing with planned addition of GLP-1 combination cohort; topline data expected in 2H 2027.

Lead TRAP and MoDE Extracellular Protein Degraders (BHV-1400 and BHV-1300):

- **BHV-1300:** Continue enrollment of patients in ongoing Phase 3 study in Graves' disease.
- **BHV-1400:** Pivotal study initiation in IgAN targeted for 2H 2026.

Capital Position:

Cash, cash equivalents, marketable securities and restricted cash as of September 30, 2026, totaled approximately \$164.0 million. On October 20, 2026, Biohaven received \$80.0 million from Ono Pharmaceuticals and will receive an additional \$350.0 million from SKBP upon the closing of the SKBP Agreement.

Third Quarter 2026 Financial Highlights:

Research and Development (R&D) Expenses: R&D expenses, including non-cash share-based compensation costs, were \$101.9 million for the three months ended September 30, 2026, compared to \$141.2 million for the three months ended September 30, 2025. The decrease of \$39.3 million was primarily due to decreases in direct program spend and preclinical spend in 2026 as compared to the same period in the prior year. The decrease in direct program spend was largely due to our strategic reprioritization of programs, which was implemented in the fourth quarter of 2025. Non-cash share-based compensation expense was \$12.1 million for the three months ended September 30, 2026, a decrease of \$1.9 million as compared to the same period in 2025.

General and Administrative (G&A) Expenses: G&A expenses, including non-cash share-based compensation costs, were \$24.6 million for the three months ended September 30, 2026, compared to \$28.2 million for the three months ended September 30, 2025. The decrease of \$3.6 million was primarily due to decreased employee costs, including non-cash share-based compensation expense. Non-cash share-based compensation expense was \$6.6 million for the three months ended September 30, 2026, a decrease of \$1.0 million as compared to the same period in 2025.

Other (Expense) Income, Net: Other (expense) income, net was other expense, net of \$2.9 million for the three months ended September 30, 2026, compared to other expense, net of \$3.8 million for the three months ended September 30, 2025. The decrease in expense of \$0.9 million was primarily due to decreased non-cash losses during the three months ended September 30, 2026 related to changes in fair value of our notes payable liability under the Note Purchase Agreement with Beetlejuice SA LLC, an affiliate of Oberland Capital Management LLC, entered into during the second quarter of 2025 (the NPA), which were partially offset by gains recorded during the three months ended September 30, 2025 for the non-cash changes in fair value of our forward contracts and derivative liabilities recorded in connection with the amendment to our Membership Interest Purchase Agreement with Knopp Biosciences LLC in May 2024, and decreased investment income.

Net Loss: Biohaven reported a net loss for the three months ended September 30, 2026 of \$129.3 million, or \$0.86 per share, compared to \$173.4 million, or \$1.64 per share, for the same period in 2025. Non-GAAP adjusted net loss for the three months ended September 30, 2026 was \$110.7 million, or \$0.73 per share, compared to \$155.9 million, or \$1.47 per share, for the same period in 2025. 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 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 news 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, obesity, 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; MoDE™ and TRAP™ extracellular protein degradation for immunological diseases; and myostatin inhibition for neuromuscular and metabolic diseases, including obesity.

Forward-looking Statements

This news release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding the expected timing and amounts of funding under the NPA. 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, licensing and commercialization of development candidates (including approval of our NDA for Vyglxia (troriluzole) in SCA), regarding the closings under licensing agreements (including our licensing agreement with SK Biopharmaceuticals) and the receipt of payments and royalties thereunder, and regarding reduction in annual direct R&D spend, 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 results of studies, including nonclinical studies, such as the studies regarding certain metabolites of BHV-7000 identified in rodent testing; 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 licensing and commercialization of Biohaven's product candidates and the expected timing thereof, including the closings and the receipt of payments and royalties thereunder; the potential for Biohaven's product candidates to be successful therapies; the effectiveness of restructuring of business priorities; 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 September 30, 2026		Nine Months Ended September 30, 2025	
	2026	2025	2026	2025
Operating expenses:				
Research and development	\$ 101,850	\$ 141,169	\$ 306,491	\$ 513,120
General and administrative	24,570	28,213	75,256	89,524
Total operating expenses	126,420	169,382	381,747	602,644
Loss from operations	(126,420)	(169,382)	(381,747)	(602,644)
Other (expense) income, net	(2,923)	(3,840)	(14,776)	10,468
Loss before (benefit) provision for income taxes	(129,343)	(173,222)	(396,523)	(592,176)
(Benefit) provision for income taxes	(64)	221	599	1,091
Net loss	\$ (129,279)	\$ (173,443)	\$ (397,122)	\$ (593,267)
Net loss per share — basic and diluted	\$ (0.86)	\$ (1.64)	\$ (2.65)	\$ (5.74)
Weighted average common shares outstanding— basic and diluted	151,040,349	105,815,038	149,776,602	103,391,267

BIOHAVEN LTD.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share amounts)

	September 30, 2026 December 31, 2025	
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 95,754	\$ 229,957
Marketable securities	65,371	89,180
Prepaid expenses	27,566	47,022
Other current assets	2,823	2,170
Total current assets	191,514	368,329
Property and equipment, net	14,700	15,964
Intangible assets	18,400	18,400
Goodwill	1,390	1,390
Other non-current assets	37,672	47,364
Total assets	\$ 263,676	\$ 451,447
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 13,534	\$ 11,643
Accrued expenses and other current liabilities	49,233	104,291
Total current liabilities	62,767	115,934
Non-current operating lease liability	31,406	39,958
Notes payable	264,294	238,900
Other non-current liabilities	3,456	4,583
Total liabilities	361,923	399,375
Shareholders' (Deficit) Equity:		
Preferred shares, no par value; 10,000,000 shares authorized, no shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Common shares, no par value; 200,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 151,055,160 and 132,775,113 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	2,139,226	1,934,276

Additional paid-in capital	238,835	193,984
Accumulated deficit	(2,481,658)	(2,084,536)
Accumulated other comprehensive income	5,350	8,348
Total shareholders' (deficit) equity	(98,247)	52,072
Total liabilities and shareholders' equity	\$ 263,676	\$ 451,447

BIOHAVEN LTD.
RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL MEASURES
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30, 2026		Nine Months Ended September 30, 2025	
	2026	2025	2026	2025
Reconciliation of GAAP to Non-GAAP adjusted net loss:				
GAAP net loss	\$ (129,279)	\$ (173,443)	\$ (397,122)	\$ (593,267)
Add: non-cash share-based compensation expense	18,624	21,535	66,074	95,409
Add: (gain) loss from change in fair value of derivatives	—	(3,960)	—	8,800
Non-GAAP adjusted net loss	<u>\$ (110,655)</u>	<u>\$ (155,868)</u>	<u>\$ (331,048)</u>	<u>\$ (489,058)</u>
Reconciliation of GAAP to Non-GAAP adjusted net loss per share — basic and diluted:				
GAAP net loss per share — basic and diluted	\$ (0.86)	\$ (1.64)	\$ (2.65)	\$ (5.74)
Add: non-cash share-based compensation expense	0.12	0.21	0.44	0.92
Add: (gain) loss from change in fair value of derivatives	—	(0.04)	—	0.09
Non-GAAP adjusted net loss per share — basic and diluted	<u>\$ (0.73)</u>	<u>\$ (1.47)</u>	<u>\$ (2.21)</u>	<u>\$ (4.73)</u>

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

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