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): July 27, 2023

Biohaven Ltd.

(Exact name of registrant as specified in its charter)

British Virgin Islands	**001-41477**	**Not applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 7.01 Regulation FD Disclosure

On July 27, 2023, Biohaven Ltd. issued a press release providing preliminary EEG data updates for its Kv7 platform, a regulatory update on Troriluzole, and other corporate updates. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be 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 July 27, 2023, "Biohaven Provides Preliminary EEG Data Update for Kv7 Platform, Regulatory Update on Troriluzole and Other Corporate Updates."
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: July 28, 2023

Biohaven Ltd.

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

Exhibit 99.1

Biohaven Provides Preliminary EEG Data Update for Kv7 Platform, Regulatory Update on Troriluzole and Other Corporate Updates

NEW HAVEN, Conn., July 27, 2023 /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 announced multiple updates on key programs including: preliminary EEG data from its lead investigational agent, BHV-7000, from the Kv7 activator program; Phase 1 update on its brain-penetrant dual TYK2/JAK1 inhibitor, BHV-8000; development update on its IgG degrader, BHV-1300, from the bispecific platform; and a regulatory update on troriluzole.

Biohaven reported positive, interim data from an electroencephalogram (EEG) biomarker study with the initial, low-dose of BHV-7000 studied in healthy volunteers. Preliminary Phase 1 data confirmed evidence of target engagement in the central nervous system for subjects with projected therapeutic concentrations of BHV-7000 (based on the EC50 from preclinical models), measured by changes from baseline in EEG spectral power that occurred after dosing. These pharmacodynamic (PD) effects were similar to those reported in the literature for antiseizure medicines (ASMs), including Kv7 activators in development that are clinically effective in treating epilepsy. BHV-7000's PD effects were also differentiated from those reported for other Kv7 activators including, specifically, the absence of increases in EEG spectral power in frequency bands associated with drowsiness and somnolence. While additional, higher-dose groups of BHV-7000 are still being evaluated in the EEG analysis, the results from the low-dose group validate the preclinical hypothesis, confirm the Phase 1 SAD/MAD clinical data, and provide strong support for Biohaven's plans to initiate pivotal studies with BHV-7000 in focal epilepsy and bipolar disorder in the second half of 2023. The preliminary data highlight BHV-7000's differentiation and potentially favorable clinical profile compared to other ASMs, and Biohaven expects to present the complete EEG results by the end of the year. Additionally, new pharmacokinetic data from multiple clinical formulations being studied has now confirmed a once daily extended-release formulation that will be used in the Phase 2/3 clinical programs.

Michael Bozik, M.D., President, Ion Channel Research & Development at Biohaven, commented, "These EEG data provide further evidence of the paradigm changing potential of BHV-7000 to deliver robust antiseizure efficacy, without the burdensome CNS adverse effects typical of antiseizure medicines. While other Kv7 modulators have exhibited clear efficacy in the clinic, they have been limited by CNS effects such as somnolence, speech disorder, and memory impairment. Demonstrating target engagement without affecting the power spectra of low frequency bands in the EEG is consistent with the absence of somnolence and fatigue seen in the Phase 1 SAD/MAD studies of BHV-7000. We are extremely pleased that BHV-7000 continues to demonstrate an exceptional and differentiated clinical profile."

Biohaven has now successfully dosed three dose cohorts with single ascending doses of its brain penetrant TYK2/JAK1 agent, BHV-8000, in the ongoing Phase 1 study. The ongoing Phase 1 study is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple ascending doses of BHV-8000 in healthy volunteers. Based on the preliminary data that are available, projected therapeutic concentrations of BHV-8000 were achieved, and BHV-8000 was well tolerated with only mild adverse events reported. These data support further development of BHV-8000, and Biohaven anticipates beginning a Phase 2 clinical trial with BHV-8000 in Parkinson's disease and potentially other neuroinflammatory diseases in 2024.

Biohaven's first-in-class bispecific IgG degrader, BHV-1300, is demonstrating a highly competitive safety, manufacturable and pharmacodynamic profile as it advances to IND in 2H2023. BHV-1300 sits atop a deep pipeline of partially derisked, follow-on IgG degraders as well as antigen-specific degraders providing both optionality and a sustainable output of drug candidates for several years. Currently approved FcRn inhibitors are limited by the need for healthcare provider administration and some have the potential for effects on albumin and cholesterol. Additionally, FcRn inhibitors preclude the

coadministration of biologic immunosuppressive therapies – this mechanism clears all Fc containing drugs – while BHV-1300 dosage regimens will allow coadministration of existing standards of care.

Biohaven anticipates completing enrollment in a Phase 3 study of troriluzole in OCD by the end of the year. Two Phase 3 randomized, double- blind, placebo-controlled studies are expected to enroll up to 700 patients (in each trial) across nearly 200 global study sites.

On its SCA program, the FDA informed Biohaven that it would not review the recently submitted NDA application for troriluzole given that the study's primary endpoint was not met and thus, would not permit a substantive review. The communication from the FDA indicated that the Company may request a Type A meeting within 30 days. Biohaven is committed to working closely with the FDA to bring troriluzole to people with SCA3 as quickly as possible given no therapy is currently approved for this ultra-rare genetic disorder and is requesting a Type A meeting to comprehensively address FDA's concerns cited in the refusal to file letter. Any updates regarding the Type A meeting will be provided subsequent to the upcoming regulatory interaction.

Vlad Coric, M.D. CEO and Chairman commented, "As a physician, I am deeply disappointed by the FDA's decision not to review the submitted NDA, and not to give complete consideration of all available data that we believe show disease modifying effects for this genetic disorder that has no approved treatments. Troriluzole's active metabolite has a known safety profile and is well-tolerated; and, troriluzole was submitted under a 505(b)(2) application with data suggesting an 80% reduction or 7-month benefit in disease progression over the 1-year study period. The risk-benefit profile for troriluzole warranted careful consideration by the FDA for this ultra-rare disorder. SCA is clearly a severely debilitating, life-threatening disease with substantial unmet need. The approximately 6,000 patients in North America at least deserved a thorough review of the data package submitted.

Approximately 200 patients have been treated with troriluzole for up to 3 years (whose diagnosis has been confirmed with genetic testing), and the troriluzole treated cohorts have remained stable compared to the untreated natural history cohorts who clearly show marked disease progression over that similar time period." Dr. Coric added, "We stand committed to serving people suffering from SCA and will continue to work with the FDA to request further consideration of all the available data. We believe the NDA package is compelling and shows that treatment with troriluzole leads to clinically meaningful treatment benefits, including significantly delaying disease progression and reduction in falls. We stand by these data and analyses."

About Biohaven
Biohaven is 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. Biohaven's experienced management team brings with it a track record of delivering new drug approvals for products for diseases such as migraine, depression, bipolar disorder and schizophrenia. Biohaven is advancing a pipeline of therapies for diseases with little or no treatment options, leveraging its proven drug development capabilities and proprietary platforms, including Kv7 ion channel modulation for epilepsy and neuronal hyperexcitability, glutamate modulation for obsessive-compulsive disorder and spinocerebellar ataxia, myostatin inhibition for neuromuscular diseases, and brain-penetrant TYK2/JAK1 inhibition for immune-mediated brain disorders. Biohaven's portfolio of early- and late-stage product candidates also includes discovery research programs focused on TRPM3 channel activation for neuropathic pain, CD-38 antibody recruiting, bispecific molecules for multiple myeloma, antibody drug conjugates (ADCs), and targeted extracellular protein degrader platform technology (MoDEs™ platform) with potential application in neurological disorders, cancer, and autoimmune diseases. For more information, visit www.biohaven.com.

Forward-looking Statements
This news release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The use of certain words, including "continue", "plan", "will", "believe", "may", "expect", "anticipate" and similar expressions, is intended to identify forward-looking statements. Investors are cautioned that any forward-looking statements, including statements regarding the future

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

MoDEs is a trademark of Biohaven Therapeutics Ltd.

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