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): September 4, 2026

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 8.01 Other Events.

Biohaven Ltd. (the "Company," "we" or "our") is providing updates to the BHV-7000 program. We refer you to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2026 for a description of the BHV-7000 program.

In January 2024, we completed our End-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") to advance to Phase 3 trials and announced that more than 110 global clinical sites have been selected in the first of two focal epilepsy trials (BHV7000-302 and BHV7000-303). Enrollment in our Phase 2/3 program commenced in the first quarter of 2024. The two pivotal studies evaluating the efficacy of BHV-7000 in refractory focal epilepsy are randomized, double-blind, placebo-controlled, 8- and 12-week trials with a primary endpoint of change from baseline in 28-day average seizure frequency in adults with focal epilepsy. BHV7000-303 is evaluating 50 mg and 75 mg doses of BHV-7000. BHV7000-201 is the associated open-label extension ("OLE") study. The clinical safety profile of BHV-7000 has generally been safe and well-tolerated to date with over 1,200 participants dosed with BHV-7000 across the development program.

In June 2026, we announced that enrollment in BHV7000-303 was complete. Dosing continues and topline data readout remains on timeline for the second half of 2026.

As part of the nonclinical characterization of certain metabolites of BHV-7000 observed in rodent testing, an update was provided to global regulatory authorities regarding these ongoing nonclinical studies. It was determined that there was insufficient information related to a specific metabolite to assess risks of that metabolite to human subjects at this time. Thus, FDA instructed the Company to pause new enrollment until additional clarifying nonclinical studies are completed, and issued a partial clinical hold letter on September 4, 2026 that pauses new patient enrollment pending the results of additional nonclinical data regarding the metabolite. The partial clinical hold applies to new patient enrollment only. Dosing continues for all patients already randomized across the BHV-7000 program, more than 600 patients. BHV7000-303, one of two pivotal studies in refractory focal epilepsy, is fully enrolled and randomized. Dosing continues in BHV7000-303 and topline data remain on track for the second half of 2026.

Until the additional nonclinical data are available in the coming weeks, specific near-term implications regarding the development program are as follows:

- Dosing of already randomized patients is allowed to continue across the BHV-7000 program while waiting for the additional nonclinical data to further characterize this metabolite.
- There is no impact to the BHV7000-303 timelines as study enrollment and randomization was previously completed. Dosing remains ongoing in BHV7000-303 and topline data continues to be on timelines for the second half of 2026.
- BHV7000-302 will also continue dosing but new enrollment is paused pending nonclinical data that is expected in the coming weeks to further elucidate findings related to this metabolite that have uncertain significance in humans. Additionally, the OLE study continues dosing.
- Biohaven voluntarily instituted this plan to its global sites outside of 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, and the additional nonclinical studies underway are intended to address that question. BHV-7000 has generally been safe and well-tolerated in clinical studies with over 1,200 participants dosed to date.

On August 26, 2026, Biohaven Bioscience Ireland Limited ("BBIL"), a wholly owned subsidiary of the Company, entered into a License Agreement (the "License Agreement") with SK Biopharmaceuticals Co., Ltd. ("SKBP"). Pursuant to the License Agreement, effective upon the closing of the transactions contemplated thereby, SKBP will have an exclusive, royalty-bearing, worldwide license, with the right to grant sublicenses subject to the terms of the License Agreement, to Biohaven's Kv7 ion channel platform, including BHV-7000 as well as other Kv7 compounds and products covered by the License Agreement. All clinical and nonclinical data, including those related to the metabolite characterization submitted to global regulatory authorities, was fully disclosed to SKBP prior to the

signing of the License Agreement. Biohaven and SKBP continue to work on the completion of the required Hart-Scott-Rodino ("HSR") submission required for closing.

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: September 9, 2026

Biohaven Ltd.

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