August 10, 2022

Division of Corporation Finance Office of Life Sciences Securities and Exchange Commission 100 F Street, N.E. Washington, D.C. 20549-9303

Attention: Julie Sherman

Mary Mast Tyler Howes Jason Drory

Re: Biohaven Research Ltd.

Draft Registration Statement on Form 10 Confidentially Submitted on July 1, 2022

CIK No. 0001935979

Ladies and Gentlemen:

This letter responds to the comment letter from the Staff of the Securities and Exchange Commission (the "Staff"), dated July 28, 2022, regarding the Registration Statement on Form 10 of Biohaven Research Ltd. (the "Company") confidentially submitted by the Company on July 1, 2022. The Company's response to the comment letter follows.

Registration Statement on Form 10

Draft Information Statement, Exhibit 99.1

Questions and Answers About the Distribution Agreement Q: What conditions must be satisfied to complete the Spin-Off?, page 3

1. Please revise this Q&A to discuss any material consequences to shareholders if any of the listed conditions are waived and Biohaven Pharmaceutical Holding proceeds with the spin-off. In addition, please revise to identify the conditions that are subject to waiver.

<u>Company Response</u>: In response to the Staff's comment, the Registrant has revised the disclosure on pages 3–4 and 61 of the Information Statement to clarify that each of the listed conditions may be waived.

The Registrant respectfully submits that, prior to waiving any condition, the applicable party would consider the consequences of such waiver, which will vary depending on the particular condition and the facts and circumstances surrounding a waiver of such condition. As a result of the number and extent of such potential facts and circumstances,

it is impracticable to predict and address the material consequences of such hypothetical waivers.

<u>Information Statement Summary</u> <u>Product Candidates, page 28</u>

2. We note the inclusion of the product candidate "UC1MT" for the indications of inflammatory and autoimmune diseases and certain other preclinical product candidates in your pipeline table labeled "BHV-TBD." In addition, we note your disclosure on page 112 that you "currently operate in a single business segment developing a portfolio of innovative, late-stage product candidates targeting neurological diseases." Given the limited disclosure related to UC1MT, please explain why it is sufficiently material to your business to warrant inclusion in your pipeline table. If it is material, please expand your disclosure in the Business section to provide a more fulsome discussion of this candidate, including a description of preclinical studies, development activities conducted, or ongoing clinical trials. Alternatively, remove UC1MT and any other preclinical product candidates that are not currently material to your business from your pipeline table on pages 7 and 75.

<u>Company Response</u>: In response to the Staff's comment, the Company has removed UC1MT, TRPM3, MATE3, MoDE and TDP-43 from the pipeline table, as these preclinical product candidates are not currently material to the Company's business.

The Separation and Distribution The Distribution Agreement, page 57

3. We note disclosure here stating Biohaven Research Ltd will be assigned liabilities resulting from "certain specified legal proceedings." We further note disclosure in your Legal Proceedings section stating you are currently not party to any material legal proceedings. Please reconcile your disclosure or advise.

<u>Company Response</u>: In response to the Staff's comment, the Company has revised the disclosure on pages 59 and 116 of the Information Statement.

Business

Product Candidates, page 75

4. Please remove the references throughout your information statement to "first-in-class" or "best-in-class" product candidates as these descriptions imply an expectation of regulatory approval and are inappropriate given the length of time and uncertainty with respect to securing marketing approval.

<u>Company Response</u>: In response to the Staff's comment, the Company has removed references to "first-in-class" or "best-in-class" from the Information Statement.

5. Please revise any statements concluding your product candidates are safe or effective to instead refer to objective trial results. For example only, we note disclosure on page 75 where you state that your Kv7 platform is a "potent"

activator, on page 82 where you state that troriluzole demonstrated "acceptable safety" consistent with past clinical trial experiences and on page 87 where you state "BHV-2100 shows promising efficacy." Please remove these statements, and any similar statements, as conclusions of safety and efficacy are within the sole authority of the FDA and comparable foreign regulators.

<u>Company Response</u>: In response to the Staff's comment, the Company has revised or removed these statements and similar statements in the Information Statement.

6. At first use, please define abbreviations. For example only, we note that "SCA," "ALS" and "SMA" are not defined at first use.

<u>Company Response</u>: In response to the Staff's comment, the Company has defined all abbreviations at first use in the Information Statement.

- 7. In your discussion of the preclinical and clinical development of your material programs, please revise your disclosure to specify the following information with respect to the trials that you have conducted, are currently conducting or plan to conduct:
 - the trial design;
 - the number of participants in the trial;
 - the primary and secondary endpoints as well as the results as they relate to those endpoints; and
 - the occurrence of any serious adverse events.

As example only, we refer to your disclosure on page 125 that "Troriluzole was well tolerated with a safety profile consistent with past clinical trial experience." Please revise to expand your disclosure to discuss the observance of any serious adverse events for each of you material product candidates under development or otherwise advise. In addition, we note your disclosure here that, [t]wo Phase 3 studies are currently ongoing with enrollment expected to be completed in the second half of 2022." Please revise to discuss the trial design and primary and secondary endpoints of the ongoing studies or otherwise advise.

<u>Company Response</u>: In response to the Staff's comment, the Company has revised the disclosure of the preclinical and clinical development of material programs to include the requested information, to the extent available, on pages 74-95 with information available as of August 10, 2022. With respect to secondary endpoints, the Company has disclosed all secondary endpoints that it believes are material to investors. However, given that a large number of secondary endpoints exist that are generally not material to FDA approval and that are otherwise publicly available, the Company has not disclosed the secondary endpoints that it believes are immaterial (and potentially confusing) to investors. As noted in the Information Statement, the Company is evaluating and has not yet finalized potential clinical trial designs, including trial size, and primary and secondary endpoints, for BHV-7000, BHV-2100, TDP-43, MoDE platform, BHV-1200, UC1MT and the Artizan Biosciences Inc. License Option.

TDP-43 Mechanisms of Action, page 88

8. Please revise to provide narrative disclosure explaining the graphic depicted in this section.

<u>Company Response</u>: In response to the Staff's comment, the Company has provided narrative disclosure on page 88-89 explaining the graphic depicted in this section.

Intellectual Property Patents and Patent Applications, page 95

9. Please revise your discussion of each material patent or patent application to disclose the jurisdictions where each patent or patent application is protected.

<u>Company Response</u>: In response to the Staff's comment, the Company has revised its discussion of material patent or patent application to disclose the jurisdictions where each patent or patent application is protected on page 96–100 of the Information Statement.

Licensing Agreements, page 97

10. Please revise your discussion of your Licensing Agreements to disclose the aggregate potential milestone payments and quantify the amount paid to date under such agreements. Please also file these material agreements as exhibits to your registration statement or provide your analysis as to why you do not believe filing is required. Refer to Item 601 of Regulation S-K for guidance.

<u>Company Response</u>: In response to the Staff's comment, the Company has revised its discussion of Licensing Agreements to disclose the aggregate potential milestone payments and to quantify the amount paid to date under such agreements on page 100 of the Information Statement. As noted in the response to comment 2 above, the Company removed from the pipeline table all preclinical product candidates that are not currently material to the Company's business. The licensing agreements associated with the material product candidates included in the pipeline table have been filed as Exhibits 10.1–10.5 to the registration statement.

Financial Statements

10. Subsequent Events

Kv7 Platform Acquisition, page F-26

- 11. You state that in April 2022 you acquired Channel Biosciences, LLC which you expect to account for as an asset acquisition since substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset. Please address the following:
 - Tell us why you believe that substantially all of the gross assets acquired was concentrated in a single identifiable asset.
 - Tell us your consideration of including financial statements and pro forma information in accordance with Rule 3-05 and Article 11 of Regulation S-X. In this regard, if you continue to believe the criteria in ASC 805-10-55-5A has

been met, please address if the acquisition met the definition of a business in Rule 11-01(d) of Regulation S-X.

Company Response:

The Company acknowledges the Staff's comment and respectfully advises the Staff that it has considered ASC 805-10-55-5A through 5C and Rule 11 01(d) of Regulation S-X in its evaluation of whether or not the acquisition (the "Acquisition") of Channel Biosciences, LLC ("Channel") from Knopp Biosciences LLC ("Knopp") constitutes the acquisition of a business.

In consideration of the guidance under ASC 805-10-55-5A, the Company concluded that substantially all the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets and accordingly that the set of assets and activities acquired in the Acquisition is not a business as defined in US generally accepted accounting principles (GAAP).

At the acquisition date, Channel consisted of:

- a single in-process research and development asset ("IPR&D"), specifically intellectual property ("IP") related to the Kv7 platform lead asset, now referred to as BHV-7000 by the Company;
- insignificant laboratory equipment;
- an insignificant right of use ("ROU") asset and lease liability relating to laboratory facilities; and
- 2 full-time employees.

While not required by the guidance under ASC 805-10-55-5A through 5C, the Company performed a quantitative analysis of the fair values of the assets, which demonstrated that substantially all the fair value (approximately 99%) of the gross assets acquired is concentrated in the IPR&D. The estimated fair value of each of the laboratory equipment, the assumed ROU asset and lease liability and the acquired workforce of 2 employees (included only in the total assets) is insignificant (approximately 1% of the fair value). As such, the set of assets acquired does not meet the definition of a business pursuant to the "screen test" guidance in ASC 805-10-55-5A through 5C.

The Company also respectfully advises the Staff that the acquisition of Channel did not meet the definition of a "business" under Rule 11-01(d) of Regulation S-X. Thus, the Company concluded the requirement to provide financial statements and related pro forma financial information for Channel pursuant to Rule 3-05 and Article 11 of Regulation S-X does not apply.

Rule 11-01(d) of Regulation S-X states, in relevant part, that for purposes of the rule, "the term 'business' should be evaluated in light of the facts and circumstances involved and whether there is sufficient continuity of the acquired entity's operations prior to and after the transactions so that disclosure of prior financial information is material to an understanding of future operations". The guidance further states that, among the facts and circumstances which should be considered, the registrant may consider whether the "nature of the revenue-producing activity" will "remain generally the same as before the transaction" (11-01(d)(1) of Regulation S-X) and

the extent to which the physical facilities, employees, distribution systems, sales force, customer base, operating rights, production techniques or trade names will remain after the transaction (11-01(d)(2) of Regulation S-X).

Prior to the Acquisition, the IPR&D acquired from Channel was in the discovery and development stage and thus never generated revenue. Accordingly, there is no continuity of "revenue-producing activity" post-Acquisition. Given the lack of revenue, the Company also assessed whether the nature of the expense activities previously associated with Channel would generally remain the same after the Acquisition, as well as the additional factors identified in Rule 11-01(d)(2) of Regulation S-X.

Prior to the Acquisition, Knopp was developing the preclinical Kv7 platform directed to small-molecule treatments for developmental and epileptic encephalopathies, other epilepsies, neuropathic pain, and tinnitus, and its primary expenses, related specifically to the Kv7 platform, were for personnel and contract research and collaborations associated with discovery research and development activities. Further, prior to the Acquisition, Knopp brought the Kv7 platform lead asset, now BHV-7000, to the point of being ready for clinical development. Knopp did not have the infrastructure to take BHV-7000 into clinical development. Following the Acquisition, the Company's Clinical Trial Application for BHV-7000 was approved by Health Canada and the Company subsequently began clinical development. The nature of the expenses following the acquisition will be inherently different due to new activities that will be applied to the IP in clinical development, such as expenses related to manufacturing scale-up expenses and the cost of acquiring and manufacturing clinical trial material and commercial materials; patient enrollment in, and the initiation and completion of, clinical trials; and the initiation of commercial sales of BHV-7000, if and when approved. There will be a significant increase in costs now that the IP is in the clinical phase making the historical costs to support BHV-7000 inconsequential to an investor's understanding of future operations.

Given the nature and breadth of new activities to be applied moving forward to the acquired IPR&D, the Company concluded the nature of the expense activities previously associated with the acquired IPR&D would generally not remain the same after the acquisition and therefore would not be material to an understanding of future operations.

In addition, the Company also noted the lack of continuity in a number of other attributes identified in Rule 11-01 (d)(2) of Regulation S-X, including:

- a. Physical facilities: The Company assumed a lease for lab facilities. The assumed lease is insignificant to the Company; thus, it would not be relevant to an investor and is not meaningful to this analysis.
- b. Employee base: As noted above, the Company acquired 2 full-time employees as part of the acquisition of Channel. These 2 employees will have limited involvement with the acquired IPR&D asset going forward and instead will focus on the Company's broader discovery programs. An additional 13.5 full-time equivalent ("FTE") employees from Knopp joined the Company on the acquisition effective date through separate

agreements, which the Company considered in its analysis. The 13.5 additional FTE hires include 10 biologists and chemists for discovery of new viable assets, as such; their time will not be spent on the clinical development of the acquired IPR&D. The remaining hires include 2.5 FTE employees who joined the Company's proven clinical operations organization and 1 employee who joined the Company's talent organization to support the addition and transition of these new hires. The Company's existing clinical development team will support the clinical development work for the acquired IPR&D. The Company's clinical operations organization prior to the Acquisition included over 50 FTEs, which does not include FTEs dedicated to statistics and regulatory activities or the Chief Medical Officer, all of whom are necessary to support a successful clinical development program.

- c. No market distribution systems were transferred.
- d. No sales forces were assumed.
- e. No customer contracts were acquired.
- f. No long-term operating rights were assumed.
- g. No production techniques were assumed.
- h. No trade names were acquired.

The Company also considered the following in its evaluation:

The Company acknowledges the presumption within Rule 11-01(d) of Regulation S-X that an entity, a subsidiary, or a division is a business. The Company notes that while Channel was legally a wholly-owned subsidiary of Knopp at the acquisition date, this subsidiary was formed immediately prior to and solely to effect the Acquisition. Historically, Channel had no assets or operations other than those that transferred as part of the Acquisition. As such, the Company concluded that Channel had no substance as a subsidiary.

Based on the factors above, the Company concluded that there is not sufficient continuity of Channel operations before and after the Acquisition. Channel generated no revenue either before or after the Acquisition, and the other factors or identifiers of a business referenced in Rule 11-01(d) were either not present at Channel before or after the Acquisition or have been, or will be, substantially diminished after Acquisition. Based on this analysis, the Company concluded that Channel did not meet the definition of a "business" pursuant to Rule 11-01(d) of Regulation S-X. Accordingly, the Company also concluded that the requirement to provide historical financial statements for Channel and related pro forma financial information pursuant to Rule 3-05 and Article 11 of Regulation S-X do not apply to the acquisition of Channel.

Exhibits

12. We note your disclosure on page 124 where you discuss your acquisition from Knopp Biosciences LLC of Channel Biosciences, LLC. Please file the acquisition agreement as an exhibit to the registration statement or tell us why you are not required to do so. Refer to Item 601(b)(10) of Regulation S-K.

<u>Company Response</u>: The Company has filed the acquisition agreement as Exhibit 2.3 to the registration statement.

13. We note your disclosure beginning on page 145 discussing your employment agreements and offer letters with your executive officers. Please file the agreements and include such agreements in the exhibit index or tell us why you are not required to do so. See Item 601(b)(10)(iii) of Regulation S-K.

<u>Company Response</u>: The Company has filed the current Biohaven Pharmaceutical Inc. employment agreements with Vlad Coric, Matthew Buten, Elyse Stock, Kimberly Gentile and John Tilton as Exhibits 10.6, 10.7, 10.8, 10.9 and 10.10, respectively, to the registration statement. These employment agreements will continue to be in effect immediately following the Spin-Off. Vlad Coric and Matthew Buten will have dual employment agreements with Biohaven Research Ltd., which are still being finalized. The Company respectfully advises the Staff that it will file such employment agreements as exhibits to a subsequent amendment to the registration statement once those agreements are available.

Should any member of the Staff have any questions or comments with respect to the enclosed materials, please do not hesitate to contact Robert W. Downes at (212) 558-4312.

Sincerely,

/s/ Vlad Coric, M.D.

Vlad Coric, M.D. Chief Executive Officer

cc: Robert W. Downes, Esq., Sullivan & Cromwell LLP