UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF CONNECTICUT

KAYLA TAYLOR, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. BIOHAVEN LTD., VLAD CORIC, and MATTHEW BUTEN, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Kayla Taylor ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Biohaven Ltd. ("Biohaven" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Biohaven securities between March 24, 2023 and May 14, 2025, both dates inclusive (the "Class Period"), seeking to

recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Biohaven is a biopharmaceutical company that discovers, develops, and commercializes therapies for immunology, neuroscience, and oncology. The Company is developing, among other product candidates, troriluzole for the treatment of spinocerebellar ataxia ("SCA"), among other indications, as well as BHV-7000 for the treatment of bipolar disorder, among other indications.

3. In May 2022, a Phase 3 trial evaluating troriluzole's efficacy as a treatment for SCA (the "Phase 3 SCA Trial") failed to meet its primary endpoint. Nonetheless, at all relevant times, Defendants continued to consistently tout troriluzole's purported viability and regulatory prospects as a treatment for SCA based on certain post-hac analyses and additional data.

4. In May 2023, Biohaven announced that it had submitted a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") for troriluzole as a treatment for SCA (the "troriluzole NDA"). Likewise, in October 2023, Biohaven announced that the European Medicines Agency ("EMA") had accepted the Company's Marketing Authorization Application ("MAA") for troriluzole as a treatment for SCA (the "troriluzole MAA").

5. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) troriluzole's regulatory prospects as a treatment for SCA, and/or the sufficiency of data that Biohaven submitted in support of troriluzole's regulatory approval for this indication, were overstated; (ii) BHV-7000's efficacy and clinical prospects as a treatment for bipolar disorder were likewise overstated; (iii) all the

foregoing, once revealed, was likely to have a significant negative impact on Biohaven's business and financial condition; and (iv) as a result, Defendants' public statements were materially false and misleading at all relevant times.

6. On July 27, 2023, Biohaven issued a press release disclosing that the FDA had rejected the troriluzole NDA, refusing even to review the application because the Phase 3 SCA Trial had failed to meet its primary endpoint.

7. On this news, Biohaven's stock price fell $5.38 per share, or 22.61%, to close at $18.42 per share on July 27, 2023.

8. On December 16, 2024, Biohaven issued a press release announcing, *inter alia*, that it had resubmitted the troriluzole NDA to the FDA following additional purportedly positive efficacy data and "completion of a pre-NDA meeting in" the fourth quarter ("Q4") of 2024.

9. On March 3, 2025, Biohaven issued a press release reporting its Q4 and full year ("FY") 2024 financial results and recent business developments. Therein, Biohaven disclosed that recent data from a late-stage study of BHV-7000 in bipolar mania "did not statistically separate from the comparator on the Young Mania Rating Scale primary outcome measure[.]"

10. On this news, Biohaven's stock price fell $5.12 per share, or 13.77%, to close at $32.06 per share on March 3, 2025.

11. On April 25, 2025, multiple news reports emerged that, according to the EMA, Biohaven had withdrawn its troriluzole MAA in late March 2025.

12. On this news, Biohaven's stock price fell $3.56 per share, or 15.21%, to close at $19.84 per share on April 25, 2025.

13. Then, on May 14, 2025, Biohaven issued a press release "announc[ing] that the Division of Neurology 1 within FDA's Office of Neuroscience informed the Company that

they are extending the [Prescription Drug User Fee Act ('PDUFA')[1]] date for the troriluzole [NDA] for the treatment of [SCA] by three months to provide time for a full review of Biohaven's recent submissions related to information requests from the FDA." The press release further stated that "[t]he Division also informed Biohaven that it is currently planning to hold an advisory committee meeting to discuss the application, but no date has been scheduled."

14. On this news, Biohaven's stock price fell $3.84 per share, or 19.53%, to close at $15.82 per share on May 15, 2025.

15. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Biohaven's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

16. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

18. Venue is proper in this District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Biohaven's principal executive offices are located in this District, Defendants conduct business in this District, and a significant portion of Defendants' actions took place within this District.

[1] Once the FDA accepts a filing for the approval of a drug, the agency must complete its review process within 10 months in most cases. The date at the end of the review period is referred to as the PDUFA date.

19. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

20. Plaintiff, as set forth in the attached Certification, acquired Biohaven securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

21. Defendant Biohaven is organized under the laws of the British Virgin Islands with principal executive offices located at its wholly owned subsidiary Biohaven Pharmaceuticals, Inc., 215 Church Street, New Haven, Connecticut 06510. Biohaven's common stock trades in an efficient market on the New York Stock Exchange ("NYSE") under the ticker symbol "BHVN."

22. Defendant Vlad Coric ("Coric") has served as Biohaven's Chief Executive Officer at all relevant times.

23. Defendant Matthew Buten ("Buten") has served as Biohaven's Chief Financial Officer at all relevant times.

24. Defendants Coric and Buten are collectively referred to herein as the "Individual Defendants."

25. The Individual Defendants possessed the power and authority to control the contents of Biohaven's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Biohaven's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions

with Biohaven, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

26. Biohaven and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

27. Biohaven is a biopharmaceutical company that discovers, develops, and commercializes therapies for immunology, neuroscience, and oncology. Biohaven was formed in May 2022 in anticipation of Pfizer Inc.'s acquisition of the Company's former parent company, Biohaven Pharmaceutical Holding Company Ltd. (the "Biohaven Parent"). In October 2022, Biohaven was spun-off from the Biohaven Parent as part of this acquisition (the "Spin-Off").

28. Prior to the Spin-Off, in May 2022, Biohaven had announced top-line results from the Phase 3 SCA Trial evaluating the efficacy and safety of its product candidate troriluzole in treating patients with SCA, which had failed to meet its primary endpoint—namely, change from baseline to Week 48 on the modified functional Scale for the Assessment and Rating of Ataxia ("f-SARA"). According to the Company, the Phase 3 SCA Trial's primary endpoint had failed to reach statistical significance in the overall SCA population because there was purportedly less than expected disease progression over the course of the study.

29. Notwithstanding the Phase 3 SCA Trial's failure to meet its primary endpoint, at all relevant times, Defendants continued to consistently tout troriluzole's purported viability and regulatory prospects as a treatment for SCA based on certain post-hac analyses and additional data.

30. During the Class Period, Defendants likewise touted Biohaven's drug discovery platform targeting Kv7 ion channels, including, *inter alia*, BHV-7000, the Company's lead asset from the Kv7 platform for the treatment of, among other things, bipolar disorder. According to the Company, preclinical and pilot clinical data suggested a potential therapeutic role for Kv7 activation in bipolar disorder.

Materially False and Misleading Statements Issued During the Class Period

31. The Class Period begins on March 24, 2023. On March 23, 2023, during after-market hours, Biohaven issued a press release reporting its Q4 and FY 2022 financial results and recent business developments. The press release stated, in relevant part[2]:

> **Regulatory engagement planned for first half of 2023 in SCA** - In May 2022, the Company reported top-line results from a Phase 3 clinical trial evaluating the efficacy and safety of its investigational therapy, troriluzole, in patients with [SCA]. ***While the primary endpoint, did not reach statistical significance in the overall SCA population . . . post hoc analysis of efficacy measures by genotype suggested a treatment effect in patients with the SCA Type 3 (SCA3) genotype.*** SCA3 represents the most common form of SCA and accounted for 41 percent of the study population. ***The Company intends to interact with the FDA and/or EMA in the first half of 2023.*** We could seek advice through various formal or informal interactions with regulatory agencies ***or we could choose to submit a[n NDA] if we believe that is warranted from the results of our ongoing post-hoc analyses***.

32. Also on March 23, 2023, during after-market hours, Biohaven filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for its Q4 and FY ended December 31, 2022 (the "2022 10-K"). Notwithstanding the failure of the Phase 3 SCA Trial to meet its primary endpoint, the 2022 10-K assured investors, in relevant part:

[2] All emphasis in both bold and italics hereinafter is added unless otherwise indicated.

> Post hoc analysis of efficacy measures by genotype suggests a treatment effect in patients with the [SCA3] genotype, which represents the most common form of SCA and accounted for 41% of the study population.
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> Across all SCA genotypes, and SCA3 specifically, patient reported falls, as measured by adverse events, reveal reductions of fall risk in the troriluzole group compared to the placebo.
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> The risk reduction of falls in the troriluzole group combined with the progression of f-SARA scores in the untreated SCA3 group compared to SCA3 patients on troriluzole demonstrates that SCA3 patients experienced a clinically meaningful improvement in ataxia symptoms on troriluzole treatment. ***Given these findings and the debilitating nature of SCA, we intend to interact with the FDA and/or [EMA] in the first half of 2023.*** We have not yet decided on the format of such a regulatory interaction but we could seek advice through various formal or informal interactions with regulatory agencies ***or we could choose to submit an NDA if we believe that is warranted from the results of our ongoing post-hoc analyses***.

33. Appended as exhibits to the 2022 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein the Individual Defendants certified, in relevant part, that the 2022 10-K "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report[.]"

34. On May 31, 2023, Biohaven issued a press release providing an overview of its clinical progress, regulatory updates, and pipeline developments, including, *inter alia*, its submission of the troriluzole NDA with the FDA. The press release stated, in relevant part:

- NDA supported by consistent treatment benefits observed in patients with genotype SCA3 in Study BHV4157-206 across multiple outcome measures including the change from baseline f-SARA at Week 48, CGI-I total score at Week 48, and a robust reduction in fall risk over the study period. A rigorous analysis by genotype was possible as patients were randomized by genotype strata at baseline prior to randomization in the pivotal Phase 3 48-week, double-blind, placebo-controlled phase of Study BHV4157-206.
- SCA3 represented 41% of study participants, consistent with being the most common subtype. SCA3 affects approximately 10,600 people in North America and in the EU and Japan.

- NDA further supported by a composite scale development (SCACOMS) and analysis of Study BHV4157-206, and confirmatory evidence of efficacy provided by data from the 3-year, long-term open-label (OLE) extension phase of two studies (BHV4157-206 and BHV4157-201) using a Matching Adjusted Indirect Comparison (MAIC) to an external control group.

35. The same press release also quoted Defendant Coric as stating, in relevant part:

> The NDA we submitted for troriluzole for SCA3 represents approximately seven years of effort by the Biohaven team to bring forward a potentially new treatment for this ultra-rare disease . . . . The Biohaven clinical trials in SCA were a first of its kind in this area and utilized a newly developed rating scale (the functional SARA or f-SARA) that was developed in close consultation with the FDA using standard regulatory pathways to elucidate this new scale. We look forward to interactions with the US FDA, EMA and other regulatory agencies across the globe as our submissions advance in the review process[.]

36. The statements referenced in ¶¶ 31-35 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) troriluzole's regulatory prospects as a treatment for SCA, and/or the sufficiency of data that Biohaven submitted in support of troriluzole's regulatory approval for this indication, were overstated; (ii) the foregoing, once revealed, was likely to have a significant negative impact on Biohaven's business and financial condition; and (iii) as a result, Defendants' public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

37. On July 27, 2023, during pre-market hours, Biohaven issued a press release providing a preliminary electroencephalogram ("EEG") data update for its Kv7 platform, including BHV-7000 as a treatment for bipolar disorder, as well as a regulatory update on the troriluzole NDA (the "July 2023 Press Release"). That press release disclosed, *inter alia*, that the

FDA had rejected the troriluzole NDA, refusing even to review the application because the Phase 3 SCA Trial had failed to meet its primary endpoint:

> **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.

38. On this news, Biohaven's stock price fell $5.38 per share, or 22.61%, to close at $18.42 per share on July 27, 2023. Despite this decline in the Company's stock price, Biohaven securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions—namely, with respect to troriluzole's regulatory prospects and/or the data submitted in support thereof as a treatment for SCA, as well as BHV-7000's efficacy and clinical prospects as a treatment for bipolar disorder.

39. For example, despite the FDA's rejection of the troriluzole NDA, Defendant Coric, as quoted in the July 2023 Press Release, stated in relevant part:

> [W]e believe [all available data for troriluzole] show disease modifying effects for [SCA] . . . . 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 . . . . 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 . . . . 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.

40. Additionally, with respect to BHV-7000 as a treatment for bipolar disorder, the July 2023 Press Release stated, in relevant part:

> **Biohaven reported positive, interim data from an [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 . . . . 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 [*inter alia*] . . . bipolar disorder . . . . The preliminary data highlight BHV-7000's differentiation and potentially favorable clinical profile[.]

41. On November 14, 2023, Biohaven issued a press release reporting its third quarter ("Q3") 2023 financial results and recent business developments, including, in relevant part, that the "[EMA] informed the Company that its [MAA] for troriluzole (Dazluma) in the treatment of [SCA] has been validated and is now under review by EMA's Committee for Medicinal Products for Human Use (CHMP)[.]"

42. On February 29, 2024, Biohaven issued a press release reporting its Q4 and FY 2023 financial results and recent business developments, including, in relevant part, that the Company "has . . . continued to have constructive dialogue with the FDA regarding its SCA development program and potential future data analyses to address regulatory concerns in the previously issued refuse-to-file decision on its [troriluzole] NDA application for SCA3."

43. The same day, Biohaven filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for its Q4 and FY ended December 31, 2023 (the "2023 10-K"). The 2023 10-K continued to tout Biohaven's regulatory advancement of troriluzole for the treatment of SCA with the FDA and EMA, stating, *inter alia*:

> In followup to the [FDA's] regulatory decision on the NDA application, we held followup meetings with the FDA regarding the SCA data. We continue to have constructive dialogue with the FDA regarding our SCA development program and

> potential future data analyses to address regulatory concerns in the previously issued refuse-to-file decision on it's [*sic*] NDA application for SCA3 . . . . In October 2023, the [EMA] informed us that our [MAA] for troriluzole (Dazluma) in the treatment of SCA has been validated and is now under review by EMA's [CHMP].

44. Appended as exhibits to the 2023 10-K were substantively the same SOX certifications as referenced in ¶ 33, *supra*, signed by the Individual Defendants.

45. On May 29, 2024, Biohaven issued a press release providing an overview of its purported development and regulatory advancements across multiple therapeutic areas. With respect to BHV-7000 for the treatment of bipolar disorder, the press release stated, in relevant part, that the Company had "[i]nitiated [a] pivotal clinical trial" and that "BHV-7000 offers the potential of a highly differentiated profile, having potent efficacy without burdensome central nervous system side effects."

46. On August 8, 2024, Biohaven issued a press release reporting its second quarter 2024 financial results and recent business developments. The press release stated, in relevant part, that "SCA interactions [regarding the] troriluzole filing in Europe [are] ongoing[,]" and touted purported "constructive interactions in the US with the FDA" as well as a "[n]ew real-world evidence (RWE) protocol, incorporating feedback from the FDA, assessing 3-years of treatment with troriluzole [that is] expected to deliver topline results in [the second half of] 2024[.]"

47. The same press release also quoted Defendant Coric as stating, in relevant part:

> [W]e continue to have constructive dialogue with the FDA regarding our SCA development program and our [EMA] application for SCA3 remains under review. We now expect topline data from a new RWE protocol assessing the efficacy of troriluzole in SCA patients treated for up to 3 years— this includes new patient data that has not previously been available.

48. On September 23, 2024, Biohaven issued a press release announcing purported positive results from a pivotal study of troriluzole in treating SCA, referred to as Study BHV4157-206-RWE, stating, *inter alia*:

> - 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 [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.
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> Collectively, data across multiple analyses demonstrate a robust and clinically meaningful slowing of disease progression in SCA patients.

49. Based on the foregoing purported positive results, the press release likewise touted troriluzole's continued regulatory prospects as a treatment for SCA, as well as Biohaven's planned resubmission of the troriluzole NDA with the FDA, stating, *inter alia*:

> Based upon the topline data from Study BHV4157-206-RWE, and previous safety and efficacy data from the troriluzole development program in SCA, Biohaven plans to submit a[n NDA] to the FDA in Q4 2024. The troriluzole development program has generated the largest clinical trial dataset in SCA and now has follow-up in some patients treated with troriluzole for over 5 years . . . . Biohaven will be prepared to commercialize SCA in the US in 2025[.]

50. Additionally, the same press release quoted Defendant Coric as stating, in relevant part:

> [O]ur SCA development program has provided the first evidence of a clinically meaningful treatment benefit as well as slowing disease progression in SCA patients. We were excited to receive the positive topline results from Study BHV4157-206-RWE, which was designed with FDA input and pursuant to the principles outlined in the FDA's guidance for the use of real-world evidence . . . . We look forward to interacting with regulatory agencies to bring troriluzole to patients with SCA.

51. On November 12, 2024, Biohaven issued a press release reporting its Q3 2024 financial results and recent business developments. In addition to continuing to tout Study BHV4157-206-RWE's results, the press release assured investors that the study's design, as well as the significance of the study's generated data, were in alignment with the FDA. For example, the press release stated, *inter alia*, that "[b]oth the study protocol and statistical analysis plan were submitted to, and reviewed by, the [FDA] prior to topline data analysis[,]" and that the "[s]tudy [was] designed in discussion with the FDA and utilized Phase 3 data and an external control of matched, untreated SCA subjects from the U.S. Clinical Research Consortium for the Study of Cerebellar Ataxia (CRC-SCA) in accordance with the FDA's Guidance on Real-World Evidence (RWE) of effectiveness[.]"

52. The same press release also assured investors that the troriluzole MAA "remains under review[,]" that "Biohaven completed a clarification meeting with CHMP Rapporteurs in 4Q 2024[,]" and that "MAA documents are being updated to include the new positive BHV4157-206-RWE study data with broader indication to include ***all*** SCA genotypes."

53. On December 16, 2024, Biohaven issued a press release announcing the purported "achievement of several clinical and regulatory milestones" across its product candidates. In particular, the Company announced that it had resubmitted the troriluzole NDA "to the US FDA for troriluzole in the treatment of ***all*** genotypes of [SCA], following the completion of a pre-NDA meeting in 4Q 2024[,]" while touting the sufficiency of its "recently reported positive topline pivotal results in SCA in September 2024" to support the NDA.

54. The same press release also touted the advancement and clinical prospects of the Phase 2/3 study of BHV-7000 in treating bipolar disorder, stating, *inter alia*:

> Biohaven . . . complet[ed] . . . enrollment in a pivotal BHV-7000 Phase 2/3 trial in bipolar disorder in 4Q 2024. BHV-7000 is a selective activator of Kv7 potassium channels that offers a novel and compelling mechanism of action for the treatment of bipolar disorder[.]

55. On January 13, 2025, Biohaven issued a press release highlighting the purported "broad portfolio progress" of its product candidates. With respect to BHV-7000, the press release stated, in relevant part, that "BHV-7000[, a s]elective activator of Kv7.2/7.3 potassium channels, [is] a breakthrough target in neurology and neuropsychiatry with blockbuster potential" and "a clinically validated target for treating mood disorders[,]" while simultaneously touting the "[r]egistrational stud[y of BHV-7000] ongoing in bipolar disorder[.]"

56. With respect to troriluzole, the same press release stated, *inter alia*, that Biohaven is "[p]reparing for commercial launch in SCA in 2025, while awaiting [a] filing decision from [the] FDA on the troriluzole all-genotype SCA NDA resubmission."

57. On February 11, 2025, Biohaven issued a press release announcing that the FDA had accepted the resubmitted troriluzole NDA, stating, *inter alia*:

> [T]he [FDA] has accepted for review the Company's [NDA] for troriluzole for the treatment of adult patients with [SCA] and has granted Priority Review . . . . The FDA's decision regarding the NDA is expected within 6 months of filing (during 3Q2025). Based on FDA Priority Review timelines and if ultimately approved, Biohaven is prepared to commercialize troriluzole for SCA in the US in 2025.
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> The NDA submission was based, in part, on positive topline results from Study BHV4157-206-RWE (NCT06529146), in which troriluzole 200 mg dosed orally in patients with SCA met the study's primary endpoint of change from baseline on the functional [f-SARA], in all SCA genotypes, at 3 years compared to an external control arm. Troriluzole showed statistically significant superiority across 9 consecutive, prespecified primary and secondary endpoints with highly consistent, sustained, robust and clinically meaningful treatment effects. SCA patients treated with troriluzole showed a 50-70% slower rate of decline, representing 1.5-2.2 years delay in disease progression, over the 3-year study period . . . . The NDA also includes confirmatory and supportive data from Studies BHV4157-201 and BHV4157-206, the first large, multi-center registrational trials in SCA. Notably,

> these data include disease stabilization in the SCA3 genotype . . . and a reduction in falls in all SCA genotypes . . . , both compared to placebo over 48 weeks in Study BHV4157-206.
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> Biohaven's troriluzole clinical development program in SCA collected data over 8 years, including a robust long-term safety profile, and was the first industry trial conducted in SCA. The external control arms used in Biohaven's BHV4157-206-RWE Study were provided from objective, third-party data gathered from two independent natural history cohorts: one in the United States and one in Europe (EUROSCA Natural History Study). The National Ataxia Foundation (NAF) sponsored the Clinical Research Consortium for the Study of Cerebellar Ataxia (CRC-SCA) that served as the basis for the US natural history cohort. The data from the CRC-SCA is managed by the University of South Florida Health Informatics Institute. A total of 35 clinical sites provided data in the US and European natural history cohorts that served as the external controls in BHV4157-206-RWE. As per instructions from FDA on the real-world evidence study design and statistical analysis plan, the external control arm was determined using a Propensity Score Matching (PSM) method to ensure that untreated subjects from the comparator natural history cohort were rigorously matched to treated subjects from the troriluzole arm of Study BHV4157-206. PSM was used on all prognostic, demographic, and baseline characteristics known to be associated with disease progression in SCA, including baseline f-SARA, age, sex, age at symptom onset, genotype, and trinucleotide repeat length (by genotype).

58. The statements referenced in ¶¶ 39-57 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) troriluzole's regulatory prospects as a treatment for SCA, and/or the sufficiency of data that Biohaven submitted in support of troriluzole's regulatory approval for this indication, were overstated; (ii) BHV-7000's efficacy and clinical prospects as a treatment for bipolar disorder were likewise overstated; (iii) all the foregoing, once revealed, was likely to have a significant negative impact on Biohaven's business and financial condition; and (iv) as a result, Defendants' public statements were materially false and misleading at all relevant times.

59. On March 3, 2025, during pre-market hours, Biohaven issued a press release reporting its Q4 and FY 2024 financial results and recent business developments. Therein, Biohaven disclosed disappointing results from a "topline analysis of treatment with BHV-7000 in the acute treatment of manic episodes associated with bipolar disorder in a 3-week trial[.]" Specifically, "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."

60. On this news, Biohaven's stock price fell $5.12 per share, or 13.77%, to close at $32.06 per share on March 3, 2025. Despite this decline in the Company's stock price, Biohaven securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions—namely, with respect to troriluzole's regulatory prospects and/or the data submitted in support of thereof for the treatment of SCA.

61. For example, also on March 3, 2025, Biohaven filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for its Q4 and FY ended December 31, 2024 (the "2024 10-K"). The 2024 10-K stated, *inter alia*:

> Collectively, data [for troriluzole] across multiple analyses demonstrate a robust and clinically meaningful slowing of disease progression in SCA patients.
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> * * *
>
> Based upon the topline data from Study BHV4157-206-RWE, and previous safety and efficacy data from the troriluzole development program in SCA, we submitted an NDA for the treatment of all SCA genotypes to the FDA in the fourth quarter of 2024. The troriluzole development program has generated the largest clinical trial dataset in SCA and now has follow-up in some patients treated with troriluzole for over 5 years.

62. Appended as exhibits to the 2024 10-K were substantively the same SOX certifications as referenced in ¶ 33, *supra*, signed by the Individual Defendants.

63. The statements referenced in ¶¶ 61-62 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) troriluzole's regulatory prospects as a treatment for SCA, and/or the sufficiency of data that Biohaven submitted in support of troriluzole's regulatory approval for this indication, were overstated; (ii) the foregoing, once revealed, was likely to have a significant negative impact on Biohaven's business and financial condition; and (iii) as a result, Defendants' public statements were materially false and misleading at all relevant times.

64. On April 25, 2025, shortly after markets opened, multiple news reports emerged that, according to the EMA, Biohaven had withdrawn its troriluzole MAA in late March 2025. For example, *Bloomberg* reported that "Biohaven shares tumble[d] as much as 26% — triggering a volatility halt — after the drug developer withdrew its marketing application for troriluzole in the EU for the treatment of adult patients with [SCA.]" Likewise, *Seeking Alpha* reported, *inter alia*:

> The company withdrew the [troriluzole MAA] ***on Mar. 24***, citing plans to collect additional data to support a new active substance status for the drug, the EMA said. Biohaven . . . intends to submit a new marketing application after collecting necessary data, the regulator added.

65. On this news, Biohaven's stock price fell $3.56 per share, or 15.21%, to close at $19.84 per share on April 25, 2025. Despite this decline in the Company's stock price, Biohaven securities continued trading at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions regarding the resubmitted troriluzole NDA.

66. For example, on May 12, 2025, Biohaven issued a press release reporting its first quarter 2025 financial results and recent business developments. The press release stated, in

relevant part, that the Company had "[c]ompleted [an FDA] mid-cycle review meeting and regulatory inspections of Biohaven and key clinical research sites for [the] troriluzole [NDA] for the treatment of SCA (all genotypes)"; while touting "continuity of the review process and timelines maintained throughout troriluzole's review."

67. The statements referenced in ¶ 66 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the regulatory prospects of the troriluzole NDA, and/or the sufficiency of data submitted in support thereof, were overstated; (ii) the foregoing, once revealed, was likely to have a significant negative impact on Biohaven's business and financial condition; and (iii) as a result, Defendants' public statements were materially false and misleading at all relevant times.

The Truth Continues to Emerge

68. On May 14, 2025, during after-market hours, Biohaven issued a press release announcing that the FDA had extended the PDUFA date for the troriluzole NDA following the Company's responses to information requests from the FDA. The press release stated, in relevant part:

> [T]he Division of Neurology 1 within FDA's Office of Neuroscience informed the Company that they are extending the PDUFA date for the troriluzole [NDA] for the treatment of [SCA] by three months to provide time for a full review of Biohaven's recent submissions related to information requests from the FDA. The Division also informed Biohaven that it is currently planning to hold an advisory committee meeting to discuss the application, but no date has been scheduled. The FDA did not raise any new concerns in the letter. The FDA's decision regarding the NDA is now expected in 4Q 2025.

69. On this news, Biohaven's stock price fell $3.84 per share, or 19.53%, to close at $15.82 per share on May 15, 2025.

70. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

Regulation S-K Item 303

71. Defendants violated Item 303 of SEC Regulation S-K, 17 C.F.R. § 229.303(b)(2)(ii) ("Item 303"), which required Biohaven to "[d]escribe any known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." Defendants failed to disclose, *inter alia*, troriluzole's true regulatory prospects as a treatment for SCA, and/or the insufficiency of the data that Biohaven submitted in support of troriluzole's regulatory approval for this indication. Defendants also failed to disclose BHV-7000's actual efficacy and clinical prospects as a treatment for bipolar disorder. Defendants' failure to disclose these issues violated Item 303 because these issues represented known trends or uncertainties that were likely to have a material unfavorable impact on the Company's business and financial results.

SCIENTER ALLEGATIONS

72. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

73. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the Company's securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

74. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Biohaven securities were actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Biohaven or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

75. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

76. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

77. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Biohaven;
- whether the Individual Defendants caused Biohaven to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Biohaven securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

78. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

79. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Biohaven securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NYSE and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired and/or sold Biohaven securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

80. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

81. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

82. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

83. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

84. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under

which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Biohaven securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Biohaven securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

85. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Biohaven securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Biohaven's finances and business prospects.

86. By virtue of their positions at Biohaven, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

87. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Biohaven, the Individual Defendants had knowledge of the details of Biohaven's internal affairs.

88. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Biohaven. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Biohaven's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Biohaven securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Biohaven's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Biohaven securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

89. During the Class Period, Biohaven securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Biohaven securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired

said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Biohaven securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Biohaven securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

90. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

91. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

92. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

93. During the Class Period, the Individual Defendants participated in the operation and management of Biohaven, and conducted and participated, directly and indirectly, in the conduct of Biohaven's business affairs. Because of their senior positions, they knew the adverse non-public information about Biohaven's misstatement of income and expenses and false financial statements.

94. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Biohaven's financial condition and results of operations, and to correct promptly any public statements issued by Biohaven which had become materially false or misleading.

95. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Biohaven disseminated in the marketplace during the Class Period concerning Biohaven's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Biohaven to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Biohaven within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Biohaven securities.

96. Each of the Individual Defendants, therefore, acted as a controlling person of Biohaven. By reason of their senior management positions and/or being directors of Biohaven, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Biohaven to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Biohaven and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

97. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Biohaven.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: July 14, 2025