UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

RONDOLPH HO, Individually and on Behalf of All Others Similarly Situated,

Case No.

Plaintiff,

CLASS ACTION COMPLAINT

v.

JURY TRIAL DEMANDED

SAVARA INC., MATTHEW PAULS, and DAVID LOWRANCE,

Defendants.

Plaintiff Rondolph Ho ("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 Savara Inc. ("Savara" 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 Savara securities between March 7, 2024 and May 23, 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. Savara is a clinical-stage biopharmaceutical company focused on rare respiratory diseases. The Company's lead product candidate is MOLBREEVI (also referred to as "molgramostim"), an inhaled granulocyte-macrophage colony-stimulating ("GM-CSF") factor. MOLBREEVI is in a Phase 3 IMPALA-2 pivotal clinical trial for the treatment of autoimmune pulmonary alveolar proteinosis ("aPAP"), a chronic and debilitating rare lung disease characterized by the abnormal build-up of surfactant in the alveoli of the lungs. Savara has consistently represented that, based on investments in MOLBREEVI and its purported "track record of strong fiscal discipline," the Company is "sufficiently capitalized" as early as through 2026 and as late as into the second half of 2027.
- 3. In December 2024, Savara began a rolling submission of a Biologics License Application ("BLA")—*i.e.*, a submission requesting approval to distribute a biologic product across state lines—to the U.S. Food and Drug Administration ("FDA") for MOLBREEVI for the potential treatment of aPAP (the "MOLBREEVI BLA"). In a press release announcing the submission, the Company touted that, "[g]iven the positive results of the pivotal, Phase 3 IMPALA-2 trial, we believe MOLBREEVI demonstrates a favorable benefit-risk profile and could fundamentally change the way aPAP is treated," and that "[i]nitiation of the [MOLBREEVI] BLA is an important milestone in potentially addressing the unmet need in aPAP, for which there are no approved medicines in the U.S. and Europe." Moreover, Savara represented that it "expect[ed] to complete the submission of the rolling [MOLBREEVI] BLA by the end of [the first quarter of] 2025."

- 4. To obtain FDA approval of the MOLBREEVI BLA, Savara must submit, among other things, information regarding MOLBREEVI's chemistry, manufacturing, and controls ("CMC"). Specifically, the CMC section of a BLA must provide a detailed account of a product's manufacturing process—including process validation runs, stability testing, and analytical method validation—and detailed descriptions of facilities, equipment, and quality control procedures.
- 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) the MOLBREEVI BLA lacked sufficient information regarding MOLBREEVI's chemistry, manufacturing, and/or controls; (ii) accordingly, the FDA was unlikely to approve the MOLBREEVI BLA in its current form; (iii) the foregoing made it unlikely that Savara would complete its submission of the MOLBREEVI BLA within the timeframe it had represented to investors; (iv) the delay in MOLBREEVI's regulatory approval increased the likelihood that the Company would need to raise additional capital; and (v) as a result, Defendants' public statements were materially false and misleading at all relevant times.
- 6. On May 27, 2025, Savara issued a press release "announc[ing] that the Company received [a refusal to file ("RTF")] letter from the FDA for the [MOLBREEVI BLA] as a therapy to treat patients with [aPap]." Specifically, Savara revealed that "[u]pon preliminary review, the FDA determined that the [MOLBREEVI BLA] was not sufficiently complete to permit substantive review and requested additional data related to Chemistry, Manufacturing, and Controls (CMC)."
- 7. Market analysts were quick to comment on the Company's announcement. For example, on May 27, 2025, Guggenheim published a report (the "Guggenheim Report") revising its price target for Savara to \$8.00, down from the previous \$9.00. Guggenheim stated that it

"do[es] not expect Savara to be profitable on a continuing basis until 2028 and expect[s] the company may raise additional capital, potentially through a secondary stock offering that could dilute the holdings of current investors." In addition, the Guggenheim Report noted that the "CMC Delay Could Lead to Change in Molbreevi Manufacturing Strategy," predicting a delayed market launch sometime in early 2027, a year later than initially expected.

- 8. On this news, Savara's stock price fell \$0.90 per share, or 31.69%, to close at \$1.94 per share on May 27, 2025.
- 9. Then, after the end of the Class Period, on August 13, 2025, Savara issued a press release announcing the Company's financial results for the second quarter of 2025. Among other things, the press release revealed that, contrary to the Company's prior representations that it would complete its rolling submission of the MOLBREEVI BLA in the first quarter of 2025, Savara now "plan[s] to resubmit the [MOLBREEVI] BLA in December [2025]."
- 10. 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.

JURISDICTION AND VENUE

- 11. 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).
- 12. This Court has jurisdiction over the subject matter of this action pursuant to 28U.S.C. § 1331 and Section 27 of the Exchange Act.
- 13. 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). Savara is headquartered in this District, Defendants

conduct business in this District, and a significant portion of Defendants' actions took place within this District.

14. 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

- 15. Plaintiff, as set forth in the attached Certification, acquired Savara securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.
- 16. Defendant Savara is a Delaware corporation with principal executive offices located at 1717 Langhorne Newtown Road, Suite 300, Langhorne, Pennsylvania 19047. The Company's common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "SVRA."
- 17. Defendant Matthew Pauls ("Pauls") has served as Savara's Chairman and Chief Executive Officer at all relevant times.
- 18. Defendant David Lowrance ("Lowrance") has served as Savara's Chief Financial Officer, Chief Administrative Officer, and Secretary at all relevant times.
- 19. Defendants Pauls and Lowrance are collectively referred to herein as the "Individual Defendants."
- 20. The Individual Defendants possessed the power and authority to control the contents of Savara's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Savara'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 Savara, 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.

21. Savara and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

22. Savara is a clinical-stage biopharmaceutical company focused on rare respiratory diseases. The Company's lead product candidate is MOLBREEVI (molgramostim), an inhaled GM-CSF factor. MOLBREEVI is in a Phase 3 IMPALA-2 pivotal clinical trial for the treatment of aPAP, a chronic and debilitating rare lung disease characterized by the abnormal build-up of surfactant in the alveoli of the lungs.

Materially False and Misleading Statements Issued During the Class Period

23. The Class Period begins on March 7, 2024, when Savara filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2023 (the "2023 10-K"). In providing an overview of the Company, the 2023 10-K stated, in relevant part, "[o]ur management team has significant experience in

orphan drug development and pulmonary medicine, identifying unmet needs, and *effectively* advancing product candidates to approval and commercialization."

24. Further, in discussing the Company's corporate strategy, the 2023 10-K stated, in relevant part:

Our goal is to become a leader in rare respiratory therapeutics through the development and commercialization of novel, best-in-class medicines that address unmet medical needs in this field. Key elements of our strategy include:

- Continued advancement of the molgramostim aPAP program and the Phase 3 IMPALA-2 pivotal clinical trial. The IMPALA-2 trial design has been endorsed by regulatory authorities in the U.S. (FDA), Europe [], United Kingdom Medicines and Healthcare Products Regulatory Agency [], and Japan [], and regulatory and ethics committees in various countries and sites where the trial is being conducted. The dosing of the first patient was initiated in June 2021. During the second quarter of 2023, patient enrollment in the trial was completed (target enrollment was 160, the trial enrolled 164 patients) with top line results expected to be reported at the end of the second quarter of 2024.
- 25. Finally, in discussing the "key advantages" of molgramostim, the 2023 10-K stated, in relevant part:

Based on data from the completed Phase 2/3 IMPALA trial and building upon the published investigator-sponsored treatment experience with inhaled GM-CSF, we believe molgramostim has the potential to become the treatment of choice for aPAP. The following characteristics of molgramostim may contribute to the clinical profile of the investigational product candidate, as well as facilitate potential regulatory approval and successful commercialization.

Specifically, molgramostim offers:

- a strong product foundation that applies both a previously approved active drug substance class and drug delivery technology;
- GM-CSF delivered directly to the lungs, the primary site of macrophage function deficiency in aPAP, which could result in clinical efficacy with limited systemic adverse effects;

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¹ All emphases included herein are added unless otherwise indicated.

- a nebulizer system that provides a fast and convenient method of administration; this is highly desirable for long-term treatment in a chronic disease, such as aPAP;
- a low patient impact therapy that can be carried out in the home in 3 to 5 minutes each day using the portable eFlow Nebulizer System;
- eligibility for strong market protection via orphan drug status, potential eligibility for biologic exclusivity that provides twelve years of total market protection in the U.S.;
- a proprietary cell bank used in the production of the drug substance; and
- an exclusive agreement for the specific device that is optimized for administration of molgramostim.
- 26. Appended to the 2023 10-K as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that "the information contained in the [2023 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."
- 27. That same day, Savara issued a press release announcing the Company's Q4 and full year 2023 results. The press release stated, in relevant part:
 - "We look forward to reporting IMPALA-2 top line results at the end of the second quarter and, assuming positive data, anticipate filing the BLA in the first half of 2025," said [Defendant] Pauls[.] "2023 was a year of strong execution that included the on-time, over-enrollment of the Phase 3 IMPALA-2 trial and an analysis of a health claims database that identified ~3,600 currently diagnosed aPAP patients and another ~1,400 potential, currently undiagnosed, aPAP patients in the U.S. Additionally, we launched aPAP ClearPathTM, a simple, accurate, no-cost, lab-developed GM-CSF autoantibody blood test, along with a disease state awareness campaign, that is educating U.S. pulmonologists about the disease and need for earlier testing. Finally, we completed an \$80 million equity financing last July, and with \$162 million in cash and investments and a track record of strong fiscal discipline, we believe we are capitalized into 2026."
- 28. On May 9, 2024, Savara issued a press release announcing the Company's Q1 2024 financial results. The press release stated, in relevant part:

"The IMPALA-2 trial remains on-track and we look forward to reporting top line results by the end of the second quarter," said [Defendant] Pauls[.] "Following that, and assuming positive data, we expect to file a BLA in the first half of 2025. Importantly, with \$143 million in cash and investments, we believe we are capitalized into 2026 which is well beyond the data read-out and includes investments in programs such as the extension of the IMPALA-2 open-label period from 48 weeks to 96 weeks, anticipated launch of a global Expanded Access program for molgramostim, build out of the U.S. Commercial infrastructure, and pre-Commercial preparations in Europe."

- 29. On August 12, 2024, Savara issued a press release announcing the Company's Q2 2024 financial results. The press release stated, in relevant part:
 - In July 2024, further strengthened balance sheet with an ~\$100M equity financing, which added ~\$94M to the ~\$122M in cash, cash equivalents, and short-term investments reported as of June 30, 2024; *Company expects to be sufficiently capitalized through 2026*

"Following strong top line results in the IMPALA-2 trial, we plan to complete the BLA submission for MOLBREEVI, the trade name that the FDA has conditionally accepted for molgramostim, in the first half of 2025," said [Defendant] Pauls[.] "In parallel, we are now significantly ramping up global market development activities and look forward to presenting this work, as well as data from the IMPALA-2 trial, during our investor webinar in September."

[Defendant] Pauls continued, "The IMPALA-2 data support our view that MOLBREEVI could fundamentally change the way aPAP is treated. With approximately 3,600 currently diagnosed U.S. patients and literature suggesting prevalence may be underestimated, plus our increased focus on developing the aPAP market and the potential for MOLBREEVI to be the first and only approved therapy for aPAP in the U.S. and Europe, we believe the global commercial opportunity is significant."

30. On September 27, 2024, the Company issued a press release entitled "Savara Announces Expanded Access Program (EAP) for Molgramostim Inhalation Solution (Molgramostim) for Patients with Autoimmune Pulmonary Alveolar Proteinosis (aPAP)." The press release stated, in relevant part:

"Expanded access is granted to investigational products that address a serious condition for which there are no comparable therapies available," said [Defendant] Pauls[.] "Given the high unmet need in aPAP, and positive results demonstrated in the Phase 3 IMPALA-2 clinical trial, we felt it was critically important to establish

the Savara Early Access Program to allow eligible aPAP patients pre-approval access to molgramostim. This program reflects our ongoing commitment to the global aPAP community and the goal of potentially delivering an effective therapy for patients with this rare lung disease as quickly as possible."

Savara plans to complete submission of a Biologics License Application to the FDA for molgramostim in aPAP in the first half of 2025. Molgramostim has been granted Orphan Drug, Fast Track, and Breakthrough Therapy designations from the FDA, Orphan Drug designation from the European Medicines Agency and Innovative Passport and Promising Innovative Medicine designation from the UK's Medicines and Healthcare Products Regulatory Agency for the treatment of aPAP.

- 31. On November 12, 2024, Savara issued a press release announcing the Company's Q3 2024 financial results. The press release stated, in relevant part:
 - "After a productive pre-BLA meeting with the FDA, we are working diligently to initiate a rolling submission for MOLBREEVI by the end of this year, with plans to complete the BLA submission by the end of 1Q 2025—thus enabling a potential approval in the U.S. by the end of 2025, if priority review is granted," said [Defendant] Pauls[.] "BLA submission, coupled with the submission of the MAA to the EMA by the end of 2025, are major regulatory milestones that could bring us one step closer to providing aPAP patients in the U.S. and Europe with the first and only approved therapeutic option for this rare and debilitating lung disease. In parallel, we are accelerating the build-out of our commercial capabilities, complimented by ongoing market development initiatives, to ensure the approximately 3,600 diagnosed aPAP patients in the U.S. get access to MOLBREEVI post-approval. Lastly, after strengthening our balance sheet, we believe our cash runway now extends from the end of 2026 through the second quarter of 2027."
- 32. On December 18, 2024, the Company issued a press release entitled "Savara Initiates Rolling Submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for MOLBREEVI* for the Potential Treatment of Autoimmune Pulmonary Alveolar Proteinosis (aPAP)." The press release stated, in relevant part:

"Given the positive results of the pivotal, Phase 3 IMPALA-2 trial, we believe MOLBREEVI demonstrates a favorable benefit-risk profile and could fundamentally change the way aPAP is treated," said [Defendant] Pauls[.] "Initiation of the BLA is an important milestone in potentially addressing the unmet need in aPAP, for which there are no approved medicines in the U.S. and Europe. We look forward to working closely with the FDA throughout the review

process and expect to complete the submission of the rolling BLA by the end of 1Q 2025."

- 33. On March 6, 2025, the Company issued a press release entitled "Savara Announces U.S. Launch of the aPAP ClearPathTM Dried Blood Spot Test to Detect Autoimmune Pulmonary Alveolar Proteinosis (aPAP)." The press release quoted Defendant Pauls as stating, in relevant part, "[a]s we near the completion of our rolling BLA submission for MOLBREEVITM in aPAP, which is on track for the end of 1Q 2025, we are steadfastly committed to our goal of providing the aPAP community with the first and only approved treatment option in the U.S."
- 34. On March 26, 2025, the Company issued a press release entitled "Savara Completes Submission of the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for MOLBREEVI* as a Treatment for Autoimmune Pulmonary Alveolar Proteinosis (aPAP)." The press release stated, in relevant part:
 - "Submission of the BLA marks an important milestone for the Company and the aPAP community," said [Defendant] Pauls[.] "We believe this unprecedented body of data demonstrates MOLBREEVI improves pulmonary gas exchange and the clinical symptoms associated with this rare lung disease. As part of the submission, Priority Review was requested and, if granted, would shorten the FDA's review to six months (from the standard ten months) following the Agency's acceptance of the application. We look forward to continuing our dialogue with the FDA and extend our gratitude to the patients and physicians who participated in our clinical trials. Our commercial preparations are on-track to support a potential launch in early 2026."
- 35. On March 27, 2025, Savara issued a press release announcing the Company's Q4 and full year 2024 financial results. The press release stated, in relevant part:
 - "Completing submission of the BLA is an important milestone in potentially addressing the significant unmet need of people living with aPAP, a rare and debilitating lung disease," said [Defendant] Pauls[.] "MOLBREEVI has the potential to be the first and only approved therapy for aPAP in the U.S. and Europe and could redefine the standard of care for the disease. If granted Priority Review, we could have a PDUFA date by the end of the year and are preparing for a commercial launch in early 2026. Lastly, with approximately \$196 million in cash, we are in a strong financial position and believe our cash runway extends

through 2Q 2027, excluding our recent debt financing which adds additional low-cost capital options to further finance the Company."

- 36. That same day, Savara filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2024 (the "2024 10-K"). The 2024 10-K contained a substantively similar description of the Company, its corporate strategy, and the key advantages of MOLBREEVI as discussed, *supra*, in ¶¶ 23-25.
- 37. Appended to the 2024 10-K as an exhibit was a signed certification pursuant to SOX by the Individual Defendants attesting that "the information contained in the [2024 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."
- 38. On May 13, 2025, Savara issued a press release announcing the Company's Q1 2025 financial results. The press release stated, in relevant part:
 - "At the end of 1Q 2025, we announced the on-time submission of the MOLBREEVI BLA to the FDA for the treatment of autoimmune PAP and requested priority review," said [Defendant] Pauls[.] "If Priority Review is granted, we anticipate a PDUFA date by the end of the year and are preparing for a U.S. commercial launch in early 2026. We are also on track to submit the MAA in both Europe and the U.K. by the end of the year. Lastly, with approximately \$172.5 million in cash, and the optionality to further finance the company through access to low-cost capital from our recent debt financing, we are in a strong financial position and believe our current cash runway extends into 2H 2027, well beyond a U.S. launch."
- 39. The statements referenced in ¶¶ 23-38 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 MOLBREEVI BLA lacked sufficient information regarding MOLBREEVI's chemistry, manufacturing, and/or controls; (ii)

accordingly, the FDA was unlikely to approve the MOLBREEVI BLA in its current form; (iii) the foregoing made it unlikely that Savara would complete its submission of the MOLBREEVI BLA within the timeframe it had represented to investors; (iv) the delay in MOLBREEVI's regulatory approval increased the likelihood that the Company would need to raise additional capital; and (v) as a result, Defendants' public statements were materially false and misleading at all relevant times.

The Truth Emerges

- 40. On May 27, 2025, the Company issued a press release entitled "Savara Receives Refusal to File (RTF) Letter From the U.S. Food and Drug Administration (FDA) for the Biologics License Application (BLA) for MOLBREEVI* to Treat Patients With Autoimmune Pulmonary Alveolar Proteinosis (autoimmune PAP)." The press release stated, in relevant part:
 - Savara [. . .] today announced that the Company received an RTF letter from the FDA for the BLA of MOLBREEVI as a therapy to treat patients with autoimmune PAP.

Upon preliminary review, the FDA determined that the BLA submitted in March 2025 was not sufficiently complete to permit substantive review and requested additional data related to Chemistry, Manufacturing, and Controls (CMC). The RTF was not the result of safety concerns, and the FDA did not request or recommend additional efficacy studies. Within the next 30 days, the Company intends to request a Type A meeting with the Agency. Typically, Type A meetings are granted by the FDA within 30 days of the request.

- 41. Market analysts were quick to comment on the Company's announcement. For example, on May 27, 2025, Guggenheim published a report noting the various implications of the FDA's decision, stating, in relevant part:
 - CMC Delay Could Lead to Change in Molbreevi Manufacturing Strategy: While Molbreevi is currently manufactured by GEMA (Private), as part of a strategy to ensure sufficient commercial product supply and build in manufacturing redundancy, Savara had already entered into an agreement back in Feb. 2024 with Fujifilm Diosynth Biotechnologies (Fujifilm; 4901-JP) to become their second source manufacturer. The company remains on track to complete the technology

transfer with Fujifilm in 3Q 2025, which will now be before their anticipated 4Q 2025 resubmission of the BLA. Management informed us that Fujifilm is already collecting the in-process testing data that the FDA is currently requesting, meaning that although SVRA could continue with their previous plan of filing a post-approval supplement for Fujifilm to serve as their second source manufacturer, they now potentially have additional optionality around which company will serve as the primary Molbreevi manufacturer. While a final decision cannot be made until the conclusion of their Type A meeting with the FDA, the company stated that their choice will be driven by which option provides them with the higher probability of regulatory success in the shortest time-frame. Given the RTF letter, we are lowering our POS for Molbreevi obtaining FDA approval.

- Risks: Savara finished 1Q 2025 with ~\$172.5M in cash and cash equivalents on hand, with management continuing to believe they have sufficient capital to fund operations into 2H 2027. We do not expect Savara to be profitable on a continuing basis until 2028 and expect the company may raise additional capital, potentially through a secondary stock offering that could dilute the holdings of current investors. In addition, any delays in obtaining regulatory approval, bringing their drug to the market, challenges in obtaining proper reimbursement for the products, or poor commercial execution by Savara could lead to lower sales and market share, significantly impacting the company's valuation.
- 42. On this news, Savara's stock price fell \$0.90 per share, or 31.69%, to close at \$1.94 per share on May 27, 2025.
- 43. 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.

POST-CLASS PERIOD DEVELOPMENT

44. After the end of the Class Period, on August 13, 2025, Savara issued a press release announcing the Company's financial results for the second quarter of 2025. Among other things, the press release revealed that, contrary to the Company's prior representations that it would complete its rolling submission of the MOLBREEVI BLA in the first quarter of 2025, Savara now "plan[s] to *resubmit the [MOLBREEVI] BLA in December [2025]*."

SCIENTER ALLEGATIONS

45. 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

- 46. 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 Savara 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.
- 47. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Savara securities were actively traded on the NASDAQ. 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 Savara 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.

- 48. 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.
- 49. 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.
- 50. 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 Savara;
 - whether the Individual Defendants caused Savara 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 Savara 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.
- 51. 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.

- 52. Plaintiff will rely, in part, upon the presumption of reliance established by the fraudon-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;
 - Savara 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 NASDAQ 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 Savara 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.
- 53. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.
- 54. 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)

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

- 56. 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.
- 57. 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 Savara securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Savara 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.
- 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 Savara 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 Savara's finances and business prospects.
- 59. By virtue of their positions at Savara, 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.

- 60. 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 Savara, the Individual Defendants had knowledge of the details of Savara's internal affairs.
- 61. 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 Savara. 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 Savara'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 Savara securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Savara's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Savara 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.

- 62. During the Class Period, Savara 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 Savara 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 Savara securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Savara securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.
- 63. 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.
- 64. 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)

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

- 66. During the Class Period, the Individual Defendants participated in the operation and management of Savara, and conducted and participated, directly and indirectly, in the conduct of Savara's business affairs. Because of their senior positions, they knew the adverse non-public information about Savara's misstatement of income and expenses and false financial statements.
- 67. 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 Savara's financial condition and results of operations, and to correct promptly any public statements issued by Savara which had become materially false or misleading.
- 68. 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 Savara disseminated in the marketplace during the Class Period concerning Savara's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Savara to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Savara 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 Savara securities.
- 69. Each of the Individual Defendants, therefore, acted as a controlling person of Savara. By reason of their senior management positions and/or being directors of Savara, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Savara to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Savara 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.

70. 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 Savara.

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 postjudgment 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: September 8, 2025