

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

_____, Individually and on Behalf of All
Others Similarly Situated,

Plaintiff,

v.

NEUROGENE INC., RACHEL L. MCMINN,
and CHRISTINE MIKAIL CVIJIC,

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff _____ (“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 Neurogene Inc. (“Neurogene” 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 Neurogene securities between March 18, 2024 and November 15, 2024, 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. Neurogene, a biotechnology company, develops genetic medicines for rare neurological diseases.

3. 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) Neurogene's Phase 1/2 open-label trial designed to evaluate NGN-401 gene therapy for the treatment of female pediatric patients with Rett syndrome was not as safe as the Company had led investors to believe; (ii) accordingly, the Company's clinical and/or commercial prospects were overstated; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

4. On November 11, 2024, Neurogene issued a press release reporting "interim clinical data in the first four participants in the low-dose cohort of its ongoing Phase 1/2 open-label trial designed to evaluate NGN-401 gene therapy for the treatment of female pediatric patients with Rett syndrome." Although Neurogene characterized the data as "positive", one of two patients given a high dose reported an emerging treatment-related serious adverse event that the Company described as "consistent with known risks of [adeno-associated virus] gene therapy[.]"

5. On this news, Neurogene's stock price fell \$31.53 per share, or 44.08%, to close at \$40.00 per share on November 12, 2024.

6. Then, on November 18, 2024, Neurogene issued a press release providing an updating, stating that the patient in question “is in critical condition” and that “Neurogene no longer anticipates completing enrollment in the 1E15 vg cohort (low-dose cohort) of NGN-401 in the fourth quarter of 2024”.

7. On this news, Neurogene’s stock price fell \$2.59 per share, or 13.06%, to close at \$17.23 per share on November 18, 2024.

8. 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

9. 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).

10. 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.

11. 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). Neurogene is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants’ actions took place within this Judicial District.

12. 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

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

14. Defendant Neurogene is a Delaware corporation with principal executive offices located at 535 W 24th St., 5th Floor, New York, NY 10011. The Company's common stock trades in an efficient market on the Nasdaq Global Market ("NASDAQ") under the ticker symbol "NGNE".

15. Defendant Rachel L. McMinn ("McMinn") has served as Neurogene's Chief Executive Officer at all relevant times.

16. Defendant Christine Mikail Cvijic ("Cvijic") has served as Neurogene's Chief Financial Officer at all relevant times.

17. Defendants McMinn and Cvijic are collectively referred to herein as the "Individual Defendants."

18. The Individual Defendants possessed the power and authority to control the contents of Neurogene's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Neurogene'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 Neurogene, 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.

19. Neurogene and the Individual Defendants are collectively referred to herein as “Defendants.”

SUBSTANTIVE ALLEGATIONS

Background

20. Neurogene, a biotechnology company, develops genetic medicines for rare neurological diseases.

Materially False and Misleading Statements Issued During the Class Period

21. The Class Period begins on March 18, 2024, when Neurogene issued a press release announcing the Company’s Q4 and full year 2023 financial results. The press release stated, in relevant part:

“We started the year with strong execution in our Phase 1/2 NGN-401 gene therapy trial for female pediatric patients with Rett syndrome, meeting our goal to expand the trial and add a high-dose cohort. We believe this expanded dataset will support future regulatory discussions to align on the design of a potential registrational study,” said Rachel McMinn, Ph.D., Chief Executive Officer and Founder of Neurogene. “NGN-401 has the potential to be a best-in-class treatment option with a targeted route of administration to deliver full-length, functional copies of the MECP2 gene. We are pleased that NGN-401 has been well-tolerated in all three patients dosed, with no signs of overexpression-related toxicity, demonstrating the potential of our EXACT transgene regulation technology to constrain MECP2 levels within a narrow and therapeutically relevant range. As we look ahead, we remain on track for interim clinical data from the NGN-401 trial in the fourth quarter of this year.”

22. On May 10, 2024, Neurogene issued a press release announcing the Company’s Q1 2024 financial results. The press release stated, in relevant part:

“We have made substantial progress in our NGN-401 Rett syndrome gene therapy program since the beginning of the year, including dosing the third patient, expanding the trial to include additional patients and a high-dose cohort, and the recent clearance to conduct the trial in Australia,” said Rachel McMinn, Ph.D.,

Founder and Chief Executive Officer of Neurogene. “We were pleased to present data at the ASGCT Annual Meeting earlier this week, which continued to show that NGN-401 has been generally well-tolerated. We remain on track to release interim efficacy data from the low-dose cohort in the fourth quarter of 2024.”

23. On August 9, 2024, Neurogene issued a press release announcing the Company’s Q2 2024 financial results. The press release stated, in relevant part:

“We are pleased that NGN-401 gene therapy for Rett syndrome received RMAT designation, in addition to the recent selection by the U.S. FDA for its START Pilot Program, two programs that provide distinct opportunities for enhanced collaboration and communication with the FDA to accelerate NGN-401’s development,” said Rachel McMinn, Ph.D., Founder and Chief Executive Officer of Neurogene. “We continued to advance the NGN-401 program with the first patient dosed in Cohort 2 in May, marking an important program milestone and demonstrating an early favorable safety profile with high-dose NGN-401, and reporting in mid-June that low-dose NGN-401 remained well-tolerated by the first three patients dosed in Cohort 1. As we look ahead, we continue to expect to release interim efficacy data from the low-dose cohort in the fourth quarter of this year, with plans to share additional low-dose as well as high-dose data in the second half of next year.”

24. The statements referenced in ¶¶ 21-23 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) Neurogene’s Phase 1/2 open-label trial designed to evaluate NGN-401 gene therapy for the treatment of female pediatric patients with Rett syndrome was not as safe as the Company had led investors to believe; (ii) accordingly, the Company’s clinical and/or commercial prospects were overstated; and (iii) as a result, the Company’s public statements were materially false and misleading at all relevant times.

The Truth Emerges

25. On November 11, 2024, Neurogene issued a press release reporting “interim clinical data in the first four participants in the low-dose cohort of its ongoing Phase 1/2 open-label trial designed to evaluate NGN-401 gene therapy for the treatment of female pediatric

patients with Rett syndrome.” Although Neurogene characterized the data as “positive”, one of two patients given a high dose reported an emerging treatment-related serious adverse event that the Company described as “consistent with known risks of [adeno-associated virus] gene therapy[.]”

26. On this news, Neurogene’s stock price fell \$31.53 per share, or 44.08%, to close at \$40.00 per share on November 12, 2024.

27. Then, on November 18, 2024, Neurogene issued a press release providing an updating, stating that the patient in question “is in critical condition” and that “Neurogene no longer anticipates completing enrollment in the 1E15 vg cohort (low-dose cohort) of NGN-401 in the fourth quarter of 2024”.

28. On this news, Neurogene’s stock price fell \$2.59 per share, or 13.06%, to close at \$17.23 per share on November 18, 2024.

29. 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.

SCIENTER ALLEGATIONS

30. 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

31. 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 Neurogene 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.

32. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Neurogene 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 Neurogene 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.

33. 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.

34. 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.

35. 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 Neurogene;
- whether the Individual Defendants caused Neurogene 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 Neurogene 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.

36. 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.

37. 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;
- Neurogene 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 Neurogene 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.

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

39. 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)

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

41. 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.

42. 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 Neurogene securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Neurogene 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.

43. 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 Neurogene 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 Neurogene's finances and business prospects.

44. By virtue of their positions at Neurogene, 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.

45. 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 Neurogene, the Individual Defendants had knowledge of the details of Neurogene's internal affairs.

46. 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 Neurogene. 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 Neurogene'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 Neurogene securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Neurogene's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Neurogene 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.

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

48. 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.

49. 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)

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

51. During the Class Period, the Individual Defendants participated in the operation and management of Neurogene, and conducted and participated, directly and indirectly, in the conduct of Neurogene's business affairs. Because of their senior positions, they knew the adverse

non-public information about Neurogene's misstatement of income and expenses and false financial statements.

52. 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 Neurogene's financial condition and results of operations, and to correct promptly any public statements issued by Neurogene which had become materially false or misleading.

53. 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 Neurogene disseminated in the marketplace during the Class Period concerning Neurogene's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Neurogene to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Neurogene 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 Neurogene securities.

54. Each of the Individual Defendants, therefore, acted as a controlling person of Neurogene. By reason of their senior management positions and/or being directors of Neurogene, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Neurogene to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Neurogene 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.

55. 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 Neurogene.

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: _____, 2024