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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

vs.

GEORGE N. DEMOS,

Defendant.

Case No. **'25CV0539 RSH JLB**

COMPLAINT

Jury Trial Demanded

Plaintiff Securities and Exchange Commission ("SEC") alleges:

SUMMARY

1. This case involves insider trading by Defendant George N. Demos ("Demos") in the securities of biopharmaceutical company Acadia Pharmaceuticals Inc. ("Acadia"). Demos, at the time of his trading, was Acadia's Vice President of Drug Safety and Pharmacovigilance, where he had access to material nonpublic information.

2. Acadia developed the antipsychotic drug pimavanserin, sold under the brand name NUPLAZID. In 2016, the U.S. Food and Drug Administration ("FDA")

approved NUPLAZID for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis. In June 2020, Acadia submitted to the FDA a supplemental new drug application for NUPLAZID ("NUPLAZID application") for the treatment of hallucinations and delusions associated with dementia-related psychosis. Approval of the NUPLAZID application had the potential to significantly expand the market for NUPLAZID.

3. On July 20, 2020, Acadia publicly announced that the FDA had accepted the NUPLAZID application for filing and would respond to the application by April 3, 2021. Acadia did not publicly announce that the FDA further notified Acadia that the FDA planned to communicate its own proposed labeling for NUPLAZID for dementia-related psychosis by March 3, 2021, if no major deficiencies were identified during the review.

4. As a core member of the NUPLAZID labeling team, Demos knew of the March 3, 2021 date by which the FDA planned to communicate its proposed labeling, and knew that the labeling team was scheduled to meet on March 4 to discuss any FDA labeling requests. But March 3 came and went, and Demos learned that the March 4 meeting was rescheduled to March 5 because, Demos was told, Acadia management was "not quite ready yet to discuss FDA feedback." The meeting was again rescheduled to Monday, March 8, 2021, and finally to Tuesday, March 9, 2021. As a result of his access to this non-public information, Demos concluded that the FDA had made an adverse decision about the proposed labeling.

5. Demos knew, or was reckless in not knowing, that this information was material and non-public and that he was prohibited from trading on the basis of it.

6. On the morning of March 8, 2021, Demos, based on this material nonpublic information exercised nearly all his vested Acadia stock options and immediately sold his shares.

7. Later that same day, just a few hours after Demos sold his shares, Acadia issued an aftermarket press release announcing that the FDA had notified Acadia on

March 3, 2021, that the FDA had identified deficiencies in the NUPLAZID application that precluded discussion of labeling and other issues. The next day, on March 9, 2021, Acadia's shares closed about 45% lower than they had closed on March 8, before the press release.

8. By trading on the basis of material nonpublic information, Demos avoided about $1.3 million in losses.

9. By knowingly or recklessly engaging in the conduct alleged in this complaint, Demos violated Section 17(a) of the Securities Act of 1933 ("Securities Act"), 15 U.S.C. § 77q(a), and Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated under the Exchange Act, 17 C.F.R. § 240.10b-5. The SEC seeks permanent injunctions, disgorgement of all ill-gotten gains with prejudgment interest, civil penalties, and an officer and director bar.

JURISDICTION AND VENUE

10. The Court has jurisdiction over this action under Section 22(a) of the Securities Act, 15 U.S.C. § 77v(a), and Sections 21(d)(1), 21(d)(3)(A), 21A, and 27(a) of the Exchange Act, 15 U.S.C. §§ 78u(d)(1), 78u(d)(3)(A), 78u-1, 78aa.

11. The SEC brings this action under Sections 20(b) and 22(a) of the Securities Act, 15 U.S.C. §§ 77t(d), 77v(a), and Sections 21(d) and 21A of the Exchange Act, 15 U.S.C. §§ 78u(d), 78u-1. Demos, directly or indirectly, made use of the means or instrumentalities of interstate commerce, of the mails, or of the facilities of a national securities exchange in connection with the transactions, acts, practices, and courses of business alleged in this complaint.

12. Venue is proper in this district under Section 22(a) of the Securities Act and Section 27(a) of the Exchange Act, 15 U.S.C. § 78aa(a), because certain of the transactions, acts, practices, and courses of conduct constituting violations of the federal securities laws occurred within this district and because Demos resides in this district.

THE DEFENDANT

13. **George N. Demos**, age 64, is a resident of Rancho Santa Fe, California. Demos is a medical doctor, though his medical license is expired. Demos worked at Acadia from October 15, 2014, to August 13, 2021, and in 2020, was promoted to Vice President of Drug Safety and Pharmacovigilance. He currently is a Vice President at a publicly traded clinical-stage biotechnology company.

RELEVANT ENTITY

14. **Acadia Pharmaceuticals Inc.** is a Delaware corporation with its principal place of business in San Diego, California. Acadia is a biopharmaceutical company focused on medications treating psychoses and neurological diseases. Acadia's common stock is registered under Section 12(b) of the Exchange Act and is quoted on NASDAQ Stock Market under the ticker symbol "ACAD."

THE ALLEGATIONS

A. Acadia seeks FDA approval of NUPLAZID for dementia-related psychosis.

15. In 2016, NUPLAZID became Acadia's first FDA-approved drug, which Acadia began marketing and promoting for use in the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

16. NUPLAZID sales grew rapidly, from about $17 million in 2016 to almost $442 million in 2020.

17. NUPLAZID's FDA-approved label described the treatment of Parkinson's disease psychosis as NUPLAZID's only indicated use.

18. Acadia, like other pharmaceutical companies, was prohibited from promoting or marketing NUPLAZID's use for any indication not described in the product's FDA-approved label.

19. Beginning in 2017, Acadia began evaluating NUPLAZID for use in the treatment of hallucinations and delusions associated with dementia-related psychosis.

20. In October 2017, the FDA granted Acadia's request for a Breakthrough

Therapy Designation to pimavanserin, the active ingredient in NUPLAZID, for dementia-related psychosis, indicating its potential as a substantial improvement over other available drugs on the market.

21. In June 2020, after promising results in a clinical study, Acadia submitted the NUPLAZID application requesting the FDA approve NUPLAZID for an additional indicated use in the treatment of hallucinations and delusions associated with dementia-related psychosis.

22. Because many more people suffer from dementia-related psychosis than Parkinson's disease psychosis, approval of the NUPLAZID application could have significantly expanded the market for NUPLAZID.

23. On July 10, 2020, the FDA notified Acadia by letter that it had accepted the NUPLAZID application for filing, and that the date by which the FDA expected to complete its review of the application and notify Acadia if the application was approved, was April 3, 2021.

24. The FDA's July 2020 letter also informed Acadia that, if "major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing requirement/commitment requests by March 3, 2021."

25. On or about July 20, 2020, Acadia publicly announced that the FDA had accepted Acadia's NUPLAZID for dementia-related psychosis application for filing, with an "action date" of April 3, 2021. Acadia did not publicly disclose the March 3, 2021 labeling information date.

B. Demos receives material nonpublic information indicating that the FDA will not provide a label for NUPLAZID for dementia-related psychosis.

26. As part of the NUPLAZID application, Acadia submitted proposed labeling that expanded NUPLAZID's label to include treatment of hallucinations and delusions associated with dementia-related psychosis as an additional indicated use.

27. Demos was one of eight core members of the team Acadia had

assembled to draft the proposed new labeling as part of the NUPLAZID application.

28. The March 3, 2021 proposed labeling response date was not public knowledge, but Demos, as a core member of the labeling team, knew that the FDA planned to communicate its proposed labeling information to Acadia on that date.

29. In the weeks before March 3, Demos and the labeling team began planning and holding regular meetings to develop Acadia's responses to potential labeling proposals the FDA might make.

30. For example, on February 12, 2021, Acadia's Executive Director of Regulatory Affairs overseeing the NUPLAZID application ("Executive Director") emailed Demos: "Just wanting to touch base on the label and make sure we are ready to duke it out with labeling negotiations."

31. On February 24, the Executive Director emailed Demos and other labeling team members to advise them that the FDA reported it was still on track to provide its labeling communication around March 3.

32. In fact, even though Demos was scheduled to be on vacation from March 1 through March 5, he planned to be available on March 3 in anticipation of the FDA's labeling communication expected that day.

33. A placeholder meeting of the labeling team was scheduled for March 4, 2021, which Demos planned to attend, to discuss the FDA's potential labeling feedback.

34. Instead of receiving proposed labeling on March 3, the Executive Director received a letter from the FDA stating that deficiencies in the NUPLAZID application precluded discussion of labeling at that time.

35. March 3 arrived, and Demos began to worry when he heard nothing about the expected communication from the FDA.

36. At about 12:10 p.m. Pacific Time on March 3, Demos texted the Executive Director, whom he would have expected to message him when the FDA feedback arrived: "So anything? I'm in [a] 'bad feeling' state of mind[.]"

37. A few minutes later, Demos' manager also texted the Executive Director: "What's the word from [the] FDA?"

38. Before he received a response from the Executive Director, Demos texted his manager: "Bad news I guess? [The Executive Director has] gone dark on me…."

39. At about 2:30 p.m. Pacific Time (5:30 p.m. in the FDA's time zone), the Executive Director responded separately to both, first texting Demos, "And now they've gone home for the day[,]" and then texting to Demos' manager: "No label yet…now they have gone home. Stay tuned…"

40. Demos' manager forwarded the Executive Director's response to Demos via a group text that included another coworker with whom Demos and his manager often discussed the NUPLAZID application.

41. On March 4, the labeling team meeting was postponed to March 5, and Demos notified his coworkers in the group text.

42. Demos' manager responded that "[n]o one has heard anything on our end" and there had been "[a]nother day of radio silence."

43. When Demos told the group that the March 4 labeling team meeting was postponed to March 5, ostensibly because Acadia was "not quite ready yet to discuss FDA feedback on the draft DRP [dementia-related psychosis] label," Demos and his coworkers discussed by group text that this message was inconsistent with the Executive Director's statement that there was "no label yet" from the FDA.

44. Demos responded to his coworkers' group text: "Feedback was either 'you've got to be kidding- try again with another well controlled study' or NDD [NUPLAZID for dementia-related psychosis] is not happening[.] Your label is 019/032 which is a marketing nightmare with aggression, agitation, and anxiety as ADRs [adverse drug reactions] I'll take that…."

45. On the morning of Friday, March 5, after telling the group that the labeling team meeting for that day was canceled with an explanation from Acadia

that "we haven't received FDA feedback on DRP [dementia-related psychosis] label," Demos asked his coworkers in the group text, "How long can they hide?"

46. Demos' manager responded: "Very worrisome now."

47. Their coworker responded: "Yup. Assume clock is ticking and need to say something soon."

48. A few minutes later, Demos texted his coworkers: "This isn't a bad label[.] It's no label…."

49. Later that day, the labeling team meeting was rescheduled for Monday, March 8.

50. Over the weekend, on Sunday afternoon, March 7, the March 8 labeling team meeting was rescheduled to Tuesday, March 9, again with an explanation that Acadia had not yet received labeling feedback from the FDA.

51. On the morning of Monday, March 8, Demos texted his coworkers, "So…. today's labeling meeting moved to tomorrow…."

52. At about 9 a.m. Pacific Time, Demos texted his coworkers again, noting that a different meeting on that day's calendar, also concerning the NUPLAZID application, "was just cancelled Lol[.]"

53. One of Demos' coworkers replied, "They have to announce something soon I would think[.]"

54. Demos knew, or was reckless in not knowing, that (1) the March 3, 2021 date by which Acadia expected labeling information from the FDA; (2) the days that passed with Acadia repeatedly telling its employees that it had received "no label" or "no feedback" on the proposed label from the FDA; (3) the continued postponement, cancellation, and rescheduling of the labeling team meetings; and (4) the cancellation of another NUPLAZID for dementia-related psychosis team meeting, was material nonpublic information, which indicated there would be no label coming from the FDA for NUPLAZID for dementia-related psychosis.

55. Demos also knew, or was reckless in not knowing, that he owed a duty

of trust or confidence to keep the material nonpublic information he received confidential, and to not trade on it.

56. Annually, and as recently as December 8, 2020, Demos certified that he completed training on Acadia's Code of Business Conduct and Ethics, which expressly precluded trading Acadia stock on the basis of material nonpublic information.

C. Demos sells Acadia stock on the basis of material nonpublic information.

57. As part of his compensation at Acadia, Demos was granted stock options, which gave him the right, after the options vested, to buy specified numbers of shares of Acadia stock at specified prices.

58. As of March 8, 2021, Demos held 64,599 vested option shares of Acadia.

59. On March 8, 2021, at about 10:15 a.m. Pacific Time—a little over an hour after discussing with his coworkers the NUPLAZID for dementia-related psychosis meetings that had been rescheduled or canceled for that day—Demos logged into his brokerage account, and at about 10:32 a.m. Pacific Time, Demos exercised and sold 60,800 of his 64,599 vested option shares of Acadia, for an average price of $46.62 per share.

60. Less than three hours later, after the 4:00 p.m. Eastern Time closure of the NASDAQ market, Acadia announced that "the Company received a notification from the U.S. Food and Drug Administration (FDA) on March 3, 2021, stating that, as part of its ongoing review of the Company's supplemental New Drug Application (sNDA), the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time."

61. The next day, March 9, 2021, Acadia's shares closed at $25.02 per share, a decline of around 45% from the previous day's close at $45.78 per share, on volume more than 20 times its usual daily volume in the prior month.

62. By selling his shares in advance of the March 8 press release, Demos

avoided losses of about $1,313,263.

FIRST CLAIM FOR RELIEF

Fraud in Connection with the Purchase or Sale of Securities

Violations of Section 10(b) of the Exchange Act and Rule 10b-5

63. The SEC realleges and incorporates by reference paragraphs 1 through 62 above.

64. Demos received material nonpublic information about the NUPLAZID application in the course of his duties as Acadia's Vice President of Drug Safety and Pharmacovigilance and a core team member of the NUPLAZID labeling team. Demos knew or was reckless in not knowing, that the information he possessed concerning the NUPLAZID application was material nonpublic information.

65. As Acadia's Vice President of Drug Safety and Pharmacovigilance and a core team member of the NUPLAZID labeling team, Demos at all relevant times owed a duty of trust or confidence to Acadia and its shareholders not to trade on the basis of material nonpublic information about the NUPLAZID application. Demos, with scienter, breached that duty by trading Acadia stock on the basis of that material nonpublic information on March 8, 2021.

66. By engaging in the conduct described above, Demos, directly or indirectly, in connection with the purchase or sale of a security, by the use of means or instrumentalities of interstate commerce, of the mails, or of the facilities of a national securities exchange: (a) employed devices, schemes, or artifices to defraud; (b) made untrue statements of a material fact or omitted to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices, or courses of business which operated or would operate as a fraud or deceit upon other persons.

67. By engaging in the conduct described above, Demos violated, and unless restrained and enjoined will continue to violate, Section 10(b) of the Exchange Act,

15 U.S.C. § 78j(b), and Rules 10b-5 thereunder, 17 C.F.R. § 240.10b-5.

SECOND CLAIM FOR RELIEF

Fraud in the Offer or Sale of Securities

Violations of Section 17(a) of the Securities Act

68. The SEC realleges and incorporates by reference paragraphs 1 through 62 above.

69. Demos learned material nonpublic information about the NUPLAZID application in the course of his duties as Acadia's Vice President of Drug Safety and Pharmacovigilance and a core team member of the NUPLAZID labeling team. Demos knew or was reckless in not knowing, that the information he possessed concerning the NUPLAZID application was material nonpublic information.

70. As Acadia's Vice President of Drug Safety and Pharmacovigilance and a core team member of the NUPLAZID labeling team, Demos at all relevant times owed a duty of trust or confidence to Acadia and its shareholders not to trade on the basis of material nonpublic information about the NUPLAZID application. Demos, with scienter, breached that duty by trading Acadia stock on the basis of that material nonpublic information on March 8, 2021.

71. By engaging in the conduct described above, Demos, directly or indirectly, in the offer or sale of securities, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails (a) employed devices, schemes, or artifices to defraud; (b) obtained money or property by means of untrue statements of a material fact or by omitting to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (c) engaged in transactions, practices, or courses of business which operated or would operate as a fraud or deceit upon the purchaser.

72. By engaging in the conduct described above, Demos violated, and unless restrained and enjoined will continue to violate, Section 17(a) of the Securities Act,

15 U.S.C. § 77q(a).

PRAYER FOR RELIEF

WHEREFORE, the SEC respectfully requests that the Court:

I.

Issue findings of fact and conclusions of law that Demos committed the alleged violations.

II.

Issue judgments, in forms consistent with Rule 65(d) of the Federal Rules of Civil Procedure permanently enjoining Demos and his officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with him, who receive actual notice of the judgment by personal service or otherwise, and each of them, from violating Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 thereunder, 17 C.F.R. § 240.10b-5, and Section 17(a) of the Securities Act, 15 U.S.C. § 77q(a).

III.

Order Demos to disgorge all funds received from his illegal conduct, together with prejudgment interest thereon, under Exchange Act Sections 21(d)(5) and 21(d)(7), 15 U.S.C. §§ 78u(d)(5), 78u(d)(7).

IV.

Order Demos to pay civil penalties under Section 21A of the Exchange Act, 15 U.S.C. § 78u-1, and Section 20(d) of the Securities Act, 15 U.S.C. § 77t(d).

V.

Enter an order against Demos, under Section 20(e) of the Securities Act, 15 U.S.C. § 77t(e), and Sections 2l(d)(2) of the Exchange Act, 15 U.S.C. § 78u(d)(2), prohibiting him from acting as an officer or director of any issuer that has a class of securities registered pursuant to Section 12 of the Exchange Act, 15 U.S.C. § 78l or that is required to file reports pursuant to Section 15(d) of the Exchange Act, 15 U.S.C. § 78o(d).

VI.

Retain jurisdiction of this action in accordance with the principles of equity and the Federal Rules of Civil Procedure to implement and carry out the terms of all orders and decrees that may be entered, or to entertain any suitable application or motion for additional relief within this Court's jurisdiction.

VII.

Grant any other relief that this Court may determine to be just and necessary.

Dated: March 7, 2025

/s/ Charles E. Canter
Charles E. Canter
Attorney for Plaintiff
Securities and Exchange Commission