UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

SECURITIES AND EXCHANGE COMMISSION,
100 F St. NE
Washington, DC 20549

Plaintiff,

v.

CHERYL R. KRAMER,
28880 Jasper Lane
Easton, Talbot County, MD 21601

Defendant.

Civil Action No. 26-cv-3786

COMPLAINT

JURY TRIAL DEMANDED

Plaintiff, Securities and Exchange Commission (the "Commission"), alleges the following against defendant Cheryl R. Kramer ("Kramer" or "Defendant"):

SUMMARY

1. This case involves insider trading by Kramer in the stock of Sage Therapeutics Inc. ("Sage" or the "Company") ahead of a Company announcement that its primary drug candidate had been denied approval by the Food and Drug Administration ("FDA") for the treatment of major depressive disorder ("MDD") (the "Announcement").

2. Between on or about June 2, 2023, and on or about June 4, 2023, a senior Sage employee, to whom Kramer owed a duty of trust and confidence (the "Insider"), learned material non-public information ("MNPI") regarding the FDA's position on Sage's application for Zuranolone for the treatment of MDD. On June 5, 2023, based on the MNPI she had received, Kramer liquidated all of her shares of Sage stock, some of which she had held for more than one year. In doing so, Kramer breached her duty of trust and confidence to the Insider.

3. On August 4, 2023, Sage announced for the first time that the FDA had denied approval of Zuranolone for the treatment of MDD—approximately 93% of the target market for Zuranolone. On this negative news, Sage's stock price fell approximately 53% from the previous day's closing price. By illegally selling her Sage shares in advance of the Announcement, Kramer avoided losses of approximately $11,140.

NATURE OF THE PROCEEDING AND RELIEF SOUGHT

4. The Commission brings this action pursuant to Sections 21(d), 21(e), and 21A of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. § 78u(d), (e), and 78u-1].

5. The Commission seeks a final judgment (a) permanently enjoining Kramer from violating the federal securities laws and rules this Complaint alleges she has violated; (b) ordering Kramer to disgorge ill-gotten gains, including losses avoided, she received as a result of the violations alleged herein and to pay prejudgment interest thereon, pursuant to Sections 21(d)(5) and 21(d)(7) of the Exchange Act [15 U.S.C. §§ 78u(d)(5) and 78u(d)(7)]; (c) ordering Kramer to pay a civil penalty pursuant to Section 21A of the Exchange Act [15 U.S.C. §78u-1]; and such other relief as the Court may deem appropriate.

JURISDICTION AND VENUE

6. The Court has jurisdiction over this action pursuant to Sections 21(d), 21(e), 21A, and 27 of the Exchange Act [15 U.S.C. §§ 78u(d), 78u(e), 78u-1, and 78aa], and 28 U.S.C. § 1331.

7. Venue is proper in this Court pursuant to Sections 21(d), 21A, and 27 of the Exchange Act [15 U.S.C § 78u(d), 78u-1, and 78aa]. Kramer resides in Maryland, and certain of the acts, practices, transactions, and courses of business alleged in this Complaint occurred within the District of Maryland.

8. Kramer, directly or indirectly, made use of the means or instrumentalities of transportation or communication in interstate commerce, or the mails, including the internet and the telephone, in connection with the acts and transactions alleged herein.

DEFENDANT

9. **Cheryl R. Kramer**, age 77, resides in Easton, Maryland. Kramer owed a duty of trust and confidence to the Insider, who, during the relevant period, was a senior Sage employee.

RELEVANT ENTITY

10. **Sage Therapeutics Inc.** was a Delaware corporation based in Cambridge, Massachusetts and focused on the development of treatments for brain health disorders. During the relevant period, Sage's common stock was registered with the Commission and traded on the Nasdaq Global Market under the ticker symbol SAGE. In 2022, a year before the conduct at issue, Sage reported approximately $7.69 million in revenue from product sales for an injectable postpartum depression treatment. In December 2022, Sage and its business partner, Company A, submitted a New Drug Application ("NDA") for Zuranolone as a potential oral treatment for postpartum depression and MDD.

STATEMENT OF FACTS

A. The Insider Was Under a Duty to Keep Information Concerning Zuranolone's Approval Prospects Confidential.

11. The Insider worked at Sage during the relevant period.

12. Throughout the Insider's Sage employment, the Insider was subject to several internal policies regarding insider trading and the use of confidential information, including those set forth in a document titled "Policy on Insider Trading," which applied to all Sage employees.

13. Sage's Policy on Insider Trading expressly identified "types of information that

should be considered very carefully to determine whether they are material," including "information related to decisions by regulatory authorities regarding the Company's product candidates."

B. The Likelihood of FDA Approval of Zuranolone for the Treatment of MDD Was Critical to Sage's Business Prospects.

14. On December 6, 2022, Sage and its business partner, Company A, announced that they had submitted the Zuranolone NDA to the FDA, requesting authorization to market and sell Zuranolone as a potential oral treatment for postpartum depression and MDD.

15. On February 6, 2023, Sage publicly announced that the FDA's target date to decide whether to approve Zuranolone for postpartum depression and/or MDD was August 5, 2023.

16. Sage projected that, of the two proposed indications, MDD would constitute at least 93% of Zuranolone's target market. For example, in its 2022 annual report filed with the SEC on February 16, 2023 (called a "Form 10-K"), Sage stated that "approximately 21 million adults in the U.S. reported at least one major depressive episode in 2021," while estimating "that approximately 500,000 women in the U.S. each year may experience symptoms of [postpartum depression.]"

17. Accordingly, Company A agreed to make milestone payments to Sage of $150 million if the FDA approved Zuranolone for the treatment of MDD, and $75 million if the FDA approved it for the treatment of postpartum depression. By way of comparison, Sage's 2022 Form 10-K reported only $7.69 million in product revenue for all of 2022.

18. On February 9, 2023, Kramer purchased Sage shares and continued to hold those shares, and other Sage shares she had purchased in May 2022, until early June 2023.

C. The Insider Learned MNPI about Zuranolone.

19. On June 2, 2023, in anticipation of its final decision on the Zuranolone NDA, the FDA emailed Sage a redlined version of the proposed labeling for the drug that struck all references to MDD. By separate email that same day, the FDA also informed Sage that, "our assessment is that substantial evidence of effectiveness has not been demonstrated for the use of Zuranolone in the treatment of MDD"; the FDA identified deficiencies in the clinical trials that Sage had submitted in support of MDD.

20. On the night of June 2, 2023, the Insider received several internal Sage emails forwarding the FDA's redline striking MDD from the proposed label and other comments. For example, the Insider received an email from another Sage employee stating: "We have just received the draft label and there are major changes to the draft we submitted that we will discuss in the am at 9. The key point is FDA has struck MDD." The Insider participated in that discussion on the morning of June 3, 2023.

21. Also on June 3, 2023, the Insider received an internal Sage email instructing the Insider and other Sage employees to "refrain from reaching out to their [Company A] counterparts," who had not received the FDA's redline version of the label.

D. Kramer Misappropriated MNPI Concerning Zuranolone.

22. Kramer spent time in person with the Insider on both June 3, 2023, and June 4, 2023, and during their time together, Kramer and the Insider discussed the pending Zuranolone NDA.

23. On the morning of June 5, 2023, Kramer placed an order to sell all the Sage shares she held.

E. Sage Announced the FDA Had Denied Approval for MDD, and Its Stock Price Plummeted.

24. After the securities markets closed on August 4, 2023, Sage and Company A

announced that the FDA had approved Zuranolone for the treatment of postpartum depression but had denied its approval for MDD, consistent with the FDA's June 2, 2023, label comments.

25. The Announcement resulted in Sage's stock price dropping more than 53%, from a closing price of $36.10 per share on Friday, August 4, 2023, to a closing price of $16.75 per share on Monday, August 7, 2023.

26. By liquidating her Sage stock two months before the Announcement, Kramer avoided losses of approximately $11,140.

F. Kramer Breached Her Duty of Trust and Confidence to the Insider by Selling Her Shares.

27. On June 5, 2023, Kramer traded her Sage stock based on information about the FDA's striking MDD from Zuranolone's proposed label. At that time, Kramer knew or recklessly disregarded that that information was confidential and non-public.

28. Kramer willfully or recklessly violated a duty of trust and confidence she owed the Insider by selling Sage stock on the basis of MNPI.

FIRST CLAIM FOR RELIEF
Violation of Section 10(b) of the Exchange Act and Rule 10b-5

29. The Commission realleges and incorporates by references the allegations in paragraphs 1 through 28 above.

30. By engaging in the conduct described above, Defendant, directly or indirectly, in connection with the purchase or sale of securities, by use of the means or instrumentalities of interstate commerce, or the mails, or the facilities of a national securities exchange:
(a) employed devices, schemes or artifices to defraud; (b) made untrue statements of material fact or 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/or (c) engaged in acts,

practices, or courses of business which operated or would operate as a fraud or deceit upon any person in connection with the purchase or sale of any security.

31. By engaging in the conduct described above, Defendant violated, and unless restrained and enjoined will continue to violate, 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.

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests that this Court:

A. Permanently restrain Defendant, her agents, servants, employees and attorneys, and those persons in active concert or participation with her who receive actual notice of the injunction by personal services or otherwise, and each of them, from violating Section 10(b) of the Exchange Act [15 U.S.C. §§78i(a), 78j(b)], and Rule 10b-5 thereunder [17 C.F.R §240.10b-5];

B. Order Defendant to disgorge, with prejudgment interest, all ill-gotten gains, including losses avoided, that were obtained by reason of the unlawful conduct alleged in this Complaint, pursuant to Sections 21(d)(5) and 21(d)(7) of the Exchange Act [15 U.S.C. §§ 78u(d)(5) and 78u(d)(7)];

C. Order Defendant to pay a civil monetary penalty pursuant to Section 21A of the Exchange Act [15 U.S.C. §78u-1];

D. Retain jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and

F. Grant such other further relief as the Court may deem just and proper.

JURY DEMAND

The Commission demands a jury in this matter for all claims so triable.

Dated: September 24, 2026

Respectfully submitted,

/s/ *Gregory Bockin*

Gregory Bockin (Md. Bar No. 17993)
SECURITIES AND EXCHANGE COMMISSION
100 F St. NE
Washington, DC 20549
Phone: (215) 597-3192
Email: bocking@sec.gov