

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

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SECURITIES AND EXCHANGE COMMISSION,)	
)	
	Plaintiff,)	
v.)	Civil Action No. _____
)	
EDWARD J. KOSINSKI,)	JURY TRIAL DEMANDED
)	
	Defendant.)	
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COMPLAINT

Plaintiff Securities and Exchange Commission (the “Commission”) alleges the following against defendant Edward J. Kosinski (“Kosinski”).

SUMMARY

1. This case involves insider trading by Kosinski in the shares of Regado Biosciences, Inc. (“Regado” or “the company”), a New Jersey-based biotech company, ahead of two announcements by the company concerning its phase III¹ trial of REG-1, a two-drug system intended to enable physicians to better regulate clotting in patients undergoing percutaneous coronary intervention (“the Regulate-PCI Trial” or “the trial”).

2. Kosinski, a principal investigator at a clinical site involved in the Regulate-PCI Trial, received an e-mail from the manager of the trial on Sunday, June 29, 2014, notifying him that enrollment in the trial was being suspended because there had been several allergic reactions and the Data Safety and Monitoring Board (“DSMB”) needed time to review the events.

¹ Before a pharmaceutical company can release a new drug, it must conduct clinical trials to determine whether the drug is safe and effective. Clinical trials generally proceed in three phases (designated I through III). Phase III is the last stage of clinical review before submission of a New Drug Application (“NDA”) to the Food and Drug Administration (“FDA”).

3. Based on this material nonpublic information, the next morning, June 30, 2014, Kosinski placed an order to sell all of his Regado stock (40,000 shares). After the markets closed on July 2, 2014, Regado announced the trial suspension and DSMB review, and the following day, Regado's price fell to \$2.81 per share from its previous close of \$6.76 per share, a drop of approximately 58%. Because of his timely sales, Kosinski avoided a loss of approximately \$160,000.

4. A month later, on July 29, 2014, Kosinski received another email from the trial manager informing him that an allergic reaction that had led to the suspension of the trial had caused the death of one of the subjects. Based on this material non-public information, on July 31, 2014, Kosinski purchased put option contracts (betting that the price of Regado stock would decrease) with an expiration date in October 2014. When Regado later announced that the company was permanently terminating enrollment in the Regulate-PCI Trial due to the frequency and severity of the allergic reactions reported, Kosinski exercised his put options for a gain of approximately \$3,291.

NATURE OF THE PROCEEDING AND RELIEF SOUGHT

5. The Commission brings this action pursuant to Section 20(b) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. 77t(b)] and Section 21(d) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. § 78u(d)]. The Commission seeks a permanent injunction against the defendant, enjoining him from engaging in the transactions, acts, practices, and courses of business alleged in this Complaint; disgorgement of ill-gotten gains, including losses avoided, from the unlawful insider trading activity set forth in this Complaint, together with prejudgment interest; and a civil penalty pursuant to Section 21A of the Exchange Act [15 U.S.C. § 78u-1] and the Insider Trading and Securities Fraud Enforcement Act of 1988. In addition, the Commission

seeks any other relief the Court may deem appropriate pursuant to Section 21(d)(5) of the Exchange Act [15 U.S.C. § 78u(d)(5)].

JURISDICTION AND VENUE

6. The Court has jurisdiction over this action pursuant to Securities Act Section 22(a) [15 U.S.C. § 77v(a)] and Exchange Act Sections 21(d), 21(e), and 27 [15 U.S.C. §§ 78u(d), 78u(e), and 78aa].

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

DEFENDANT

8. **Edward Kosinski**, age 68, is a resident of Weston, Connecticut. Kosinski is a cardiologist at St. Vincent's Medical Center in Bridgeport, Connecticut and also the president of Connecticut Clinical Research, LLC ("CCR"). CCR served as a clinical site in the Regulate-PCI Trial, and Kosinski served as the principal investigator at CCR for the trial. Kosinski had served as a principal investigator for at least 70 clinical trials before the Regulate-PCI Trial. By virtue of his role in the clinical trial and in accordance with his contractual responsibilities to both Regado and its agent the Cleveland Clinic Foundation, Kosinski owed a duty to Regado and/or the Cleveland Clinic Foundation to hold in strict confidence all information learned in connection with his participation in the clinical trial and to use such information only for the benefit of Regado.

RELEVANT ENTITIES

9. **Regado Biosciences, Inc.** was a development-stage biotech company incorporated in Delaware, with a principal place of business in Basking Ridge, New Jersey.

Regado was quoted on Nasdaq CM during the relevant period under the ticker symbol RGDO. The company subsequently merged with Tobira Therapeutics, Inc. on May 4, 2015, and changed its name to Tobira Therapeutics, Inc. and its ticker symbol to TBRA. Regado's securities were registered pursuant to Exchange Act Section 12(b).

10. **The Cleveland Clinic Foundation** ("C5Research") is an academic research organization that was hired by Regado to coordinate the management of the Regulate-PCI Trial pursuant to a clinical research agreement with Regado. Among its other responsibilities, it served as a signatory on agreements related to the Regulate-PCI Trial.

STATEMENT OF FACTS

A. Kosinski Agrees to Become a Principal Investigator for the Regulate-PCI Trial

11. On June 12, 2013, C5Research invited CCR to consider serving as a clinical site for the Regulate-PCI Trial. Before Regado provided information about the trial to CCR, C5Research, on behalf of Regado, required CCR to sign a Confidential Disclosure Agreement ("CDA").

12. On the same day, Kosinski, as president of CCR, signed the CDA whereby he agreed to "hold in confidence" and "not use, disclose or exploit . . . Proprietary Information for [his] own benefit or the benefit of any other person or entity."

13. The CDA defined "Proprietary Information" as all trade secrets, confidential or proprietary information of Regado disclosed by Regado to the recipient relative to the Business Purpose, whether disclosed in writing, orally, visually or in any other format. The CDA defined "Business Purpose" as evaluating interest in participating in the Regulate-PCI Trial.

14. About a month later, on July 26, 2013, Kosinski received substantive information about the Regulate-PCI Trial, including an investigator protocol containing a study history, an investigational plan, and detailed reports about REG-1 and its effects. While in possession of

this information, in October 2013, Kosinski bought 7,000 shares of Regado common stock at prices between approximately \$5.60 and \$6.08 per share.

15. Although Kosinski signed an investigator protocol agreement on December 4, 2013 that required him to disclose “any significant equity interest in Regado,” he did not disclose his ownership of Regado common stock, which was valued at approximately \$34,090 at that time.

16. A separate financial disclosure form that Kosinski also signed on December 4, 2013 asked if he had any interest in Regado exceeding \$50,000, which he did not at that time. However, this financial disclosure form further required Kosinski to “notify Regado promptly” if his financial interest in the company changed. Kosinski purchased additional shares of Regado after signing this form, and by the end of February 2014, he owned about \$64,530 worth of Regado stock (an amount which later grew to over \$250,000), but Kosinski did not file an updated financial disclosure form until October 2014, after the Regulate-PCI Trial had been terminated and after he had sold all of his Regado shares and exercised his put options.

17. CCR became an official clinical site for the Regulate-PCI Trial shortly after Kosinski signed a clinical study and research agreement on January 29, 2014. Kosinski signed the agreement both as president of CCR and independently as principal investigator, a role requiring him to supervise the conduct of the study at his site. C5Research signed this agreement as an authorized agent of Regado.

18. As part of this agreement, Kosinski agreed to maintain “in strict confidence” “any and all materials . . . and other information” provided by Regado or C5Research for a period of five years after the trial ended.

19. After signing this agreement, Kosinski purchased an additional 33,000 shares of Regado common stock between February 21, 2014 and May 16, 2014.

20. By the end of February 2014, the value of Kosinski's Regado stock was approximately \$64,530, an amount which increased to about \$250,800 by the end of May 2014.

21. As before, Kosinski did not report any of these purchases to the company, despite signing a second investigator protocol agreement on April 10, 2014 requiring him to disclose "any significant equity interest in Regado."

B. Kosinski's Receipt of Material Nonpublic Information and Trading

22. At 4:00 p.m. on the evening of Sunday, June 29, 2014, Kosinski and other principal investigators and study coordinators received an e-mail from a project manager at C5Research. The e-mail was marked as High Importance and the subject was "REGULATE-PCI URGENT – Randomization on HOLD."

23. The e-mail stated that "[r]andomization of subjects in the REGULATE-PCI Trial is being put on hold" because "[t]here have been several allergic reactions over the past few weeks and the DMSB [sic] and trial leadership need time to review the recent events thoroughly." (Emphasis added). As a result, the e-mail continued, "[s]ites will not be able to enroll from 4:00 PM (EST) today, Sunday, June 29 until 12:00 noon (EST) on Wednesday, July 2." (Emphasis in original). This information had not been released to the public, and was sent to Kosinski and the other investigators in connection with the trial.

24. After receiving the June 29, 2014 email regarding the allergic reactions and resulting suspension of the clinical trial, the very next morning, at about 9:21 a.m., Kosinski placed a market order to sell all 40,000 shares of his Regado common stock. A market order is an order that an investor makes to buy or sell shares immediately at the best available price.

Kosinski sold his shares at an average price of approximately \$6.81 for a profit (excluding transaction costs) of about \$18,826.

25. Three days later, on July 2, 2014 at about 6:13 p.m., Regado issued a press release stating that the DSMB had initiated an unplanned review of data from the Regulate-PCI Trial with a focus on serious adverse events related to allergic reactions and that patient enrollment in the trial would be paused until the DSMB completed its review.

26. Regado's stock had closed on July 2, 2014 at a price of \$6.76 per share. The next day, July 3, 2014, Regado's trading volume spiked to about 6,418,580 shares traded (compared to about 243,403 shares traded on July 2) and the company's share price fell by approximately 58% to close at \$2.81—more than a 50% drop from the average price at which Kosinski sold his shares. By selling prior to Regado's announcement, Kosinski avoided a loss of approximately \$160,000.

C. Kosinski's Second Trade on Material Nonpublic Information

27. About a month later, on July 29, 2014 at about 4:37 p.m., Kosinski and other principal investigators and study coordinators received an e-mail from C5Research attaching a Suspect Adverse Reaction Report, commonly referred to as a SUSAR.

28. The SUSAR provided detailed information about a severe allergic reaction that preceded the June 29, 2014 enrollment halt. Specifically, the SUSAR stated that, on June 23, 2014, a 56-year-old woman had been given the study drug and, within about one minute, she had an anaphylactic reaction and, later that day, she died. This information had not been released to the public, and was sent to Kosinski and the other investigators in accordance with good clinical practice and national regulatory requirements.

29. On July 30, 2014, the day after receiving the SUSAR, Kosinski placed multiple orders to buy put option contracts for Regado's stock. A put option contract is a contract that

gives an investor the right to sell a security at a predetermined price, known as the strike price, during a certain period of time. If the price of the stock drops below the strike price, the investor can make a profit by purchasing the stock at the lower price and then selling it at the strike price. Kosinski attempted to buy Regado put options with a strike price of \$2.50, which was below the range of approximately \$2.85 to \$2.99 where the stock had been trading that day. Kosinski's multiple orders to buy put options at strike price of \$2.50 represented an attempt to place a bet that the price of Regado stock would decrease.

30. However, Kosinski's orders went unfilled, leading him to increase his order prices the following day, July 1, 2014. Ultimately, despite his attempts to buy more, Kosinski was only able to buy 50 put option contracts, each of which expired on October 18, 2014 and entitled Kosinski to sell 100 shares of Regado stock at a strike price of \$2.50 per share. In total, the contracts cost Kosinski about \$3,547.

31. Before markets opened on August 25, 2014, Regado issued a press release announcing the permanent halt of the Regulate-PCI Trial due to the frequency and severity of the allergic reactions reported. After the announcement, the company's share price fell by approximately 60% to close at \$1.13, down from the previous day's close of \$2.84, on exceptionally heavy trading volume (i.e., approximately 10,002,143 shares traded compared to 176,623 shares the prior day).

32. On August 28, 2014, Kosinski purchased 5000 shares of Regado at approximately \$1.13 a share and exercised his put options by selling those shares at a price of \$2.50 a share for a profit of approximately \$3,291.

D. Kosinski Violated His Duty By Trading on Material Nonpublic Information

33. Information regarding the suspension of enrollment in the Regulate-PCI Trial, the allergic reactions experienced by participants in the trial, and the related DSMB review, which

Kosinski obtained in the course of his work on the trial, was not publicly known or disseminated prior to the July 2, 2014 public announcement; rather Regado restricted the information to select persons and required them to keep the information confidential.

34. Information that one participant died from an allergic reaction during the Regulate-PCI Trial, which Kosinski obtained in the course of his work on the trial, was not publicly known; rather Regado restricted the information to select persons and required them to keep the information confidential.

35. The information described in paragraphs 33 and 34 was material. A reasonable investor would have viewed this information as being important to his or her investment decision or a significant alteration of the total mix of information made available to the public about Regado.

36. Kosinski knew, or recklessly disregarded, that the information described in paragraphs 33 and 34, which he obtained in the course of his work on the Regulate-PCI Trial, was both material and nonpublic.

37. By trading in Regado's securities on the basis of the material nonpublic information described in paragraphs 33 and 34, Kosinski willfully or recklessly violated a duty of trust and confidence owed to Regado, its shareholders, and/or C5Research by virtue of his position as a principal investigator on the Regulate-PCI Trial and the agreements that he signed.

CLAIMS FOR RELIEF

Claim I

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

38. The Commission realleges and incorporates by reference the allegations in paragraphs 1 through 37 above.

39. The information described in paragraphs 33 and 34 was material and nonpublic and considered by Regado to be confidential. Regado had policies and procedures protecting confidential information and, in addition, protected such information through its contractual arrangements.

40. Kosinski learned of the material nonpublic information described in paragraphs 33 and 34 during the course of his participation in the Regulate-PCI Trial as a principal investigator and as president of CCR.

41. Kosinski traded in the stock of Regado based on the material nonpublic information described in paragraphs 33 and 34.

42. By virtue of the foregoing, defendant Kosinski, in connection with the purchase or sale of securities, by the use of the means or instrumentalities of interstate commerce, or of the mails, or a facility of national securities exchange, directly or indirectly: (a) employed devices, schemes or artifices to defraud; (b) made untrue statements of material fact or omitted to state material facts necessary 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 have operated as a fraud or deceit upon persons.

43. By engaging in the foregoing conduct, Kosinski, directly or indirectly, violated and, unless enjoined, will again violate, Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5] thereunder.

Claim II

Violation of Securities Act Section 17(a)

44. The Commission realleges and incorporates by reference the allegations in paragraphs 1 through 37 above.

45. By engaging in the foregoing, Kosinski directly and indirectly, acting intentionally, knowingly or recklessly, in the offer or sale of securities by the use of the means or instruments of transportation or communication in interstate commerce or by the use of the mails: (a) has employed or is employing devices, schemes or artifices to defraud; (b) has obtained or is obtaining money or property by means of untrue statements of material fact or omissions 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) has engaged or is engaging in transactions, practices or courses of business which operate as a fraud or deceit upon purchasers of the securities.

46. As a result, Kosinski has violated and, unless enjoined, will continue to violate Section 17(a) of the Securities Act [15 U.S.C. §77q(a)].

PRAYER FOR RELIEF

WHEREFORE, the Commission respectfully requests that the Court enter a Final Judgment:

A. Permanently restraining and enjoining Kosinski from violating Securities Act Section 17(a) [15 U.S.C. § 78q(a)] and Exchange Act Section 10(b) [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5] thereunder;

B. Ordering Kosinski to disgorge with pre-judgment interest, all illicit trading profits and/or losses avoided and all other ill-gotten gains received as a result of the conduct alleged in this Complaint;

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

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

E. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

The Commission hereby demands a trial by jury on all claims so triable.

Respectfully submitted,

By its attorneys,

/s/ Deena R. Bernstein

Deena R. Bernstein (Mass. Bar. No. 558721,
CT phv-02906)

Senior Trial Counsel

Andrew Palid (Mass. Bar No. 664968)

Senior Counsel

**SECURITIES AND EXCHANGE
COMMISSION**

Boston Regional Office

33 Arch Street, 24th Floor

Boston, Massachusetts 02110

Telephone: (617) 573-8813 (Bernstein direct)

Facsimile: (617) 573-4590

BernsteinD@sec.gov (Bernstein email)

Local Counsel:

/s/ John B. Hughes

John B. Hughes (Fed. Bar No. CT 05289)

Assistant United States Attorney

Chief, Civil Division

United States Attorney's Office

Connecticut Financial Center

157 Church Street, 23rd Floor

New Haven, CT 06510

(203) 821-3700

(203) 773-5373 (Facsimile)