UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	
v.	:	Civ. A. No. 1:23-cv-11470
JUAN ROMAN,	:	JURY TRIAL DEMANDED
Defendant.	:	

COMPLAINT

Plaintiff Securities and Exchange Commission (the "Commission") alleges the following against defendant Juan Roman ("Roman"):

PRELIMINARY STATEMENT

1. This case involves illegal insider trading by Roman in the securities of Acceleron Pharma Inc. ("Acceleron"), a formerly publicly-traded Massachusetts-based biopharmaceutical company. At the end of 2019 and beginning of 2020, Acceleron issued two important public announcements concerning milestones for its drug product candidates. Defendant Roman was an employee of Acceleron, responsible for planning the eventual marketing and sale of the company's products once they achieved approval from the U.S. Food and Drug Administration ("FDA").

2. As an Acceleron employee, Roman owed Acceleron a duty to abstain from trading on the company's material, nonpublic information, including during the time before issuance of the two public announcements.

3. Moreover, in advance of these particular announcements, Acceleron issued company-wide securities trading blackouts, forbidding employees, including Roman, from trading Acceleron's securities.

4. As will be explained in further detail below, despite Acceleron's internal policies and its prophylactic efforts, Roman breached his duty to the company and reaped an unfair advantage by trading Acceleron securities in advance of the announcements based upon material, nonpublic information that he had learned about milestones of the company's drug product candidates.

5. After the company publicly announced its material information, Roman received unjust profits from his illicit trading.

6. By knowingly or recklessly engaging in the conduct described in this Complaint, defendant Roman violated Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5] thereunder.

7. The Commission seeks an injunction against future violations, an order barring Roman from serving as an officer or director of any issuer required to register securities or to file reports with the Commission, disgorgement of illicit profits, prejudgment interest thereon, and a civil penalty.

JURISDICTION AND VENUE

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

9. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331, and Sections 21(d), 21(e), 21A, and 27 of the Exchange Act [15 U.S.C. §§ 78u(d), 78u(e), 78u-1, and 78aa]. The Defendant has directly or indirectly made use of the means or instrumentalities of

interstate commerce, or of the mails, or the facilities of a national securities exchange in connection with the acts, practices, transactions, and courses of business alleged in this Complaint.

10. Venue in this district is proper under 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act [15 U.S.C. § 78aa] because the acts, practices, transactions and courses of business constituting the alleged securities law violation(s) occurred in substantial part within this district and because Roman resides in this district.

DEFENDANTS AND RELEVANT ENTITIES

11. Juan Roman, age 44, is a resident of Wayland, Massachusetts. From March 2019 through March 16, 2020, he was an employee of Acceleron and served as Senior Director of Market Access.

12. Acceleron Pharma Inc., is a biopharmaceutical development company with a principal place of business in Cambridge, Massachusetts. It is currently a subsidiary of Merck & Co., Inc. ("Merck"), a New Jersey-based global health care company. Prior to November 2021, Acceleron was a publicly traded corporation. Its common stock was registered with the Commission and traded on the Nasdaq exchange under the symbol XLRN. In October and November 2021, Merck acquired Acceleron by tender offer in a cash transaction valued at $11.5 billion. After completion of the acquisition, Acceleron's stock was delisted, and the company terminated its stock registration.

FACTUAL ALLEGATIONS

13. Acceleron develops certain protein-based biological products ("biologics") to treat serious and rare diseases. Biologics are, like other drugs, used for the treatment, prevention or cure of disease in humans. Acceleron has focused and prioritized its biologics research and

development activities within three therapeutic areas – hematologic, neuromuscular and pulmonary.

14. In order for a biologic to be marketed or sold in the United States, it must be evaluated by the FDA. Generally speaking, a biologic cannot be marketed or sold in the United State without full approval from the FDA. In order to be approved, biopharmaceutical companies, like Acceleron, must submit a Biologic License Application ("BLA") to the FDA that includes scientific evidence demonstrating the proposed biologic's efficacy and safety for use in humans.

15. Biopharmaceutical companies support their BLAs with clinical trials to show the proposed biologic's efficacy and safety. Human clinical trials are conducted in three phases. Phase 1 trials focus on dosing and side effects; Phase 2 trials determine whether there is adequate evidence of efficacy and safety to justify further development; and Phase 3 trials are supposed to provide evidence of efficacy and safety to enable the FDA to evaluate the overall risk-benefit relationship of the biologic under consideration for approval.

16. In certain circumstances where the FDA staff wants additional technical advice, or an opportunity to discuss controversial issues, before the agency's official decision on a particular biologic, it convenes an advisory panel of outside experts to opine on the biologic's efficacy and safety. The FDA poses one or more questions to the panel, which responds in the form of a non-binding vote. For biologics related to cancer, the panel is called the Oncologic Drugs Advisory Committee ("ODAC").

17. For biopharmaceutical companies, like Acceleron, the outcome of clinical trials and FDA actions on BLAs are significant milestones. A biologic's success or failure in clinical trials or in the FDA approval process impacts when, if ever, the biologic will be able to be marketed and sold in the United States.

A. Acceleron's Protection of Material, Nonpublic Information

18. In 2019 and 2020, Acceleron had an Insider Trading Policy.

19. Pursuant to this policy, employees, including Roman, were prohibited from trading in the securities of Acceleron, including derivative securities such as options, if they were "aware of any material nonpublic information" about the company.

20. According to the policy, "[i]nformation is material if there is a substantial likelihood that a reasonable investor would consider it important in deciding whether to buy, hold or sell a security."

21. The policy also listed "[c]ommon examples of material information," which included "[a]nalyses of clinical trial data."

22. The policy explained that information is nonpublic if it is "not generally known or available to the public."

23. The Acceleron Insider Trading policy further provided for the imposition of certain trading blackout periods. According to the policy, "from time to time, the Company may be involved in activities . . . that are material and known only by a few people at the Company. For those individuals whose duties at the Company cause them to be aware of such activity, the General Counsel or his designee will notify them of an event-specific trading restriction and they will not be permitted to trade in Company securities."

B. Defendant Roman's Trading on December 6, 2019

24. In December 2019, Acceleron was developing a biologic called Reblozyl in a joint development partnership with another global pharmaceutical company.

25. Eight months earlier, in April 2019, Acceleron and its development partner submitted a BLA for Reblozyl to seek the FDA's approval to market and sell it for the treatment of anemia in certain adult patients with beta-thalassemia, a blood disorder that causes anemia.

26. At the same time, Acceleron and its partner submitted a supplemental BLA for Reblozyl to seek the FDA's approval to market and sell Reblozyl for a different use, as a therapy for the treatment of anemia in certain adult patients with myelodysplastic syndromes, a rare form of blood cancer.

27. In November 2019, FDA approved Acceleron's initial BLA to market and sell Reblozyl for the treatment of anemia in adult patients with beta-thalassemia.

28. Approximately a month later, on December 2, 2019, after the close of regular market trading, however, the FDA notified Acceleron that the agency decided to refer the supplemental BLA, concerning use of Reblozyl by patients with myelodysplastic syndromes, for ODAC review, which would be conducted at an ODAC meeting on December 18, 2019.

29. In the evening of December 2, 2019, Acceleron's General Counsel sent a company-wide email entitled, "Blackout Window Effective Immediately." The email told recipients that, "[e]ffective immediately and until further notice we are instituting a company-wide blackout for all employees and directors regardless of preclearance status, and for all consultants that are currently on the preclearance list. Restrictions on trading during this window apply to all forms of trading including purchases, sales, cashless/net exercising of stock options, entering into a 10b-5 trading plan and enrolling in the Employee Stock Purchase Plan."

30. Defendant Roman received this email.

31. Further, as part of his employment, Roman was involved in assessing Reblozyl's market potential in the patient populations for whom Acceleron had sought, or had already obtained, FDA approval.

32. The next day, on December 3, 2019, Acceleron issued a press release announcing the FDA's decision to refer the supplemental BLA for ODAC review. On that date, the price of Acceleron's stock fell from $49.60 at the market close on December 2, 2019 to close at $48.84 on December 3, 2019.

33. A day later, on December 4, 2019, the FDA suddenly reversed course, notifying Acceleron that the agency would not refer the supplemental BLA for ODAC review and that the application would continue in the approval process without requiring ODAC review.

34. By the morning of December 6, 2019, Roman had become aware of the material, nonpublic information that the FDA had changed course and would not be referring the supplemental BLA for ODAC review.

35. On the basis of this material, nonpublic information, on December 6, 2019 beginning at approximately 9:30 a.m., Roman purchased shares of Acceleron common stock, purchased Acceleron call options, and sold Acceleron put options.

36. An option is, in substance, a contract that gives the option's owner the right to buy or sell shares of the underlying stock at a future point in time. Options to buy shares are known as "call" options. Options to sell shares are known as "put" options.

37. Purchasers of call options, and sellers of put options, profit when the underlying security increases in price. Investors making these types of trades are said to be "bullish," anticipating an increase in the price of the underlying security.

38. At approximately 12:05 p.m. on December 6, 2019, Acceleron and its development partner issued a press release announcing the FDA's decision not to refer the supplemental BLA for ODAC review.

39. On that day, following release of this positive news, Acceleron's stock price rose from an opening price of $49.30 to a closing price of $49.88.

40. Defendant Roman's illicit trading on December 6, 2019 generated profits of $1,637.

C. Defendant Roman's Trading on January 23 and 24, 2020

41. In 2019, Acceleron was also developing a biologic called Sotatercept for the treatment of pulmonary arterial hypertension, a progressive and life-threatening blood vessel disorder.

42. By the end of 2019, Acceleron was completing a Phase 2 clinical trial for Sotatercept, called the PULSAR Phase 2 trial, with results expected to be announced in late January 2020.

43. On January 10, 2020, Acceleron's General Counsel sent a company-wide email entitled, "Blackout Window Effective Immediately." The email told recipients that, "[i]n connection with the upcoming data readout for our sotatercept Phase 2 PULSAR study in the first quarter of this year, effective immediately and until two days after the PULSAR data is announced, we are instituting a company-wide blackout for all employees and directors regardless of preclearance status, and for all consultants that are currently on the preclearance list. Restrictions on trading during this window apply to all forms of trading including purchases, sales, cashless/net exercising of stock options, entering into a 10b-5 trading plan and enrolling in the Employee Stock Purchase Plan."

44. Defendant Roman received this email.

45. On January 14, 2020, the PULSAR Phase 2 trial database was locked, indicating that all trial data was received and ready for analysis. Data analysis began the following day and certain initial results became available.

46. As part of his employment, Roman was involved with, among other things, planning for Sotatercept's eventual marketing and sale, which was contingent on the PULSAR Phase 2 trial results.

47. By at least the afternoon of January 23, 2020, Roman had become aware of material, nonpublic information concerning the results of the PULSAR Phase 2 trial.

48. Starting at approximately 1:30 p.m. on January 23, 2020, following an internal Sotatercept meeting that Roman attended, Roman began purchasing Acceleron call options on the basis of material, nonpublic information concerning the PULSAR Phase 2 trial results. Roman continued purchasing Acceleron call options, and sold Acceleron put options, the next day.

49. At approximately 4:00 p.m. on January 27, 2020, Acceleron issued a press release announcing the successful results of the PULSAR Phase 2 trial, explaining that the data demonstrated Sotatercept's efficacy and safety in treating pulmonary arterial hypertension.

50. Following release of this positive news, Acceleron's stock price soared, rising from a closing price of $52.87 on January 27, 2020 to a closing price of $79.39 on January 28, 2020.

51. Roman's illicit trading on January 23 and January 24, 2020 generated profits of $96,115.

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

52. The Commission repeats and incorporates by reference the allegations in paragraphs 1 through 51 above.

53. By engaging in the conduct described above Defendant Roman, directly or indirectly, acting knowingly or recklessly, in connection with the purchase or sale of securities, by the use of means and instrumentalities of interstate commerce, or of the mails, or of a national securities exchange: (a) employed devices, schemes or artifices to defraud; (b) made untrue statements of material facts 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; and/or (c) engaged in acts, practices or courses of business which operated or would operate as a fraud or deceit upon certain persons.

54. As a result, Defendant Roman violated and, unless 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 requests that this Court:

A. Enter a permanent injunction restraining Defendant Roman and each of his agents, servants, employees and attorneys and those persons in active concert or participation with him who receive actual notice of the injunction by personal service or otherwise, including facsimile transmission or overnight delivery service, from directly or indirectly engaging in the conduct described above, or in conduct of similar purport and effect, in violation of 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];

B. Require Defendant Roman to disgorge ill-gotten gains and losses avoided, plus pre-judgment interest;

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

D. Enter an order, pursuant to Section 21(d)(2) of the Exchange Act [15 U.S.C. §78*u*(d)(2)], barring Roman from serving as an officer or director of any issuer required to register securities with the Commission pursuant to Section 12(b) or 12(g) [15 U.S.C. §§78l(b), 78l(g)], or to file reports with the Commission pursuant to Section 15(d) [15 U.S.C. §78o(d)], of the Exchange Act.

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

F. Award 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,

SECURITIES AND EXCHANGE COMMISSION

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