

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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

Plaintiff,

v.

FORTRESS BIOTECH, INC., LINDSAY A.
ROSENWALD, and ROBYN M. HUNTER,

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 Fortress Biotech, Inc. (“Fortress” 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 Fortress securities between December 11, 2019 and October 9, 2020, 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. Fortress develops and commercializes pharmaceutical and biotechnology products. In December 2019, the Company's majority-controlled subsidiary, Avenue Therapeutics, Inc. ("Avenue"), which Fortress founded in 2015, submitted a New Drug Application ("NDA") for its intravenous ("IV") Tramadol product to the U.S. Food and Drug Administration ("FDA") for the management of moderate to moderately severe pain in adults in a medically supervised health care setting.

3. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) IV Tramadol was not safe for the intended patient population; (ii) as a result, it was foreseeable that the FDA would not approve the NDA for IV Tramadol; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

4. On October 12, 2020, Avenue disclosed receipt of a Complete Response Letter ("CRL") from the FDA regarding the NDA for its IV Tramadol product. Specifically, the FDA advised Avenue that "it cannot approve the application in its present form" because "IV tramadol, intended to treat patients in acute pain who require an opioid, is not safe for the intended patient population." Specifically, the CRL stated: "[I]f a patient requires an analgesic between the first dose of IV tramadol and the onset of analgesia, a rescue analgesic would be needed. The likely choice would be another opioid, which would result in opioid 'stacking' and increase the likelihood of opioid-related adverse effects."

5. On this news, Fortress's stock price fell \$1.00 per share, or 23.98%, to close at \$3.17 per share on October 12, 2020.

6. 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

7. 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).

8. 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.

9. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b), as the alleged misstatements entered and the subsequent damages took place in this Judicial District. Pursuant to Fortress's most recent annual report on Form 10-K, as of March 12, 2020, there were a total of 78,458,755 shares of the Company's common stock outstanding. Fortress's common stock trades on the Nasdaq Capital Market ("NASDAQ"). Accordingly, there are presumably hundreds, if not thousands, of investors in Fortress's common stock located within the U.S., some of whom undoubtedly reside in this Judicial District.

10. 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

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

12. Defendant Fortress is a Delaware corporation with principal executive offices located at 2 Gansevoort Street, 9th Floor, New York, New York 10014. Fortress securities trade in an efficient market on the NASDAQ under the ticker symbol “FBIO.”

13. Defendant Lindsay A. Rosenwald, M.D. (“Rosenwald”) has served as Fortress’s Chairman, President, and Chief Executive Officer at all relevant times.

14. Defendant Robyn M. Hunter (“Hunter”) has served as Fortress’s Chief Financial Officer at all relevant times.

15. Defendants Rosenwald and Hunter are sometimes referred to herein as the “Individual Defendants.”

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

17. Fortress and the Individual Defendants are collectively referred to herein as “Defendants.”

SUBSTANTIVE ALLEGATIONS

Background

18. Fortress develops and commercializes pharmaceutical and biotechnology products. In December 2019, the Company’s majority-controlled subsidiary, Avenue, which Fortress founded in 2015, submitted an NDA for its IV Tramadol product to the FDA for the management of moderate to moderately severe pain in adults in a medically supervised health care setting.

Materially False and Misleading Statements Issued During the Class Period

19. The Class Period begins on December 11, 2019, when, during pre-market hours, Avenue issued a press release, also published on Fortress’s website, announcing the submission of the NDA for its IV Tramadol product to the FDA for the management of moderate to moderately severe pain in adults in a medically supervised health care setting (the “December 2019 Press Release”). That press release touted, in relevant part, that the IV Tramadol NDA “is based on positive results from two pivotal Phase 3 clinical efficacy and safety trials in patients following bunionectomy and abdominoplasty surgeries, as well as an open-label safety study with a total of more than 500 patients who received the IV tramadol 50 mg dosing regimen.”

20. On March 16, 2020, Fortress filed an annual report on Form 10-K with the SEC, reporting the Company’s financial and operating results for the quarter and year ended December 31, 2019 (the “2019 10-K”). The 2019 10-K touted IV Tramadol’s suitability for its intended patient population, stating, in relevant part, that “IV Tramadol may fill a gap in the acute pain market between IV acetaminophen/NSAIDs and IV conventional narcotics”; that IV Tramadol’s “first pivotal Phase 3 study met its primary endpoint and all key secondary endpoints”; that IV

Tramadol’s “second pivotal Phase 3 study met its primary endpoint and all key secondary endpoints,” which “also included a standard-of-care IV opioid as an active comparator,” wherein “IV tramadol also demonstrated similar . . . safety to that of IV morphine”; and that, finally, “[i]n December 2019, Avenue submitted a[n] [NDA] for IV Tramadol to treat moderate to moderately severe postoperative pain.”

21. Appended as exhibits to the 2019 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002, wherein the Individual Defendants certified that “[t]he [2019 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934,” and that “[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company as of, and for, the periods presented in the” 2019 10-K.

22. On April 23, 2020, Avenue issued a press release, also published on Fortress’s website, announcing the online availability of, *inter alia*, an e-poster highlighting safety results from IV Tramadol’s Phase 3 program (the “April 2020 Press Release”). With respect to IV Tramadol’s safety for its intended patient population, that press release touted, in relevant part, that “[t]he Phase 3 safety study was a single-arm open label study that enrolled patients undergoing a range of surgical procedures including both orthopedic and soft tissue surgeries,” and that “IV tramadol 50 mg was well tolerated in this real-world trial, with only 4% of patients discontinuing for adverse events,” with “[t]he most commonly observed adverse events [being] nausea and vomiting, which is consistent with known tramadol pharmacology.”

23. The April 2020 Press Release also quoted an anesthesiologist at Memorial Hermann Memorial City Medical Center in Houston, Texas, who similarly touted the suitability of IV Tramadol for its intended patient population, stating that “[t]he results . . . indicate that IV tramadol

may become a useful option in patients where exposure to conventional opioids is not desired”; that “IV tramadol, with its dual mechanisms of action, may fill a gap between IV non-opioid medicine and conventional opioids”; and that “[t]he availability of IV tramadol as an alternative to conventional opioid analgesics should be a valuable option for U.S. clinicians who treat pain in the hospital setting.”

24. On September 9, 2020, Avenue issued a press release, also published on Fortress’s website, announcing the online availability of a published review of IV Tramadol (the “September 2019 Press Release”). That press release touted that the publication included IV Tramadol’s “safety record in clinical practice outside the U.S. and discusses how IV tramadol may become a useful option for patients with acute pain in the U.S.” Specifically, the September 2019 Press Release touted that the publication included “[a]n examination of the most frequently reported adverse events (‘AEs’) associated with IV tramadol use in the Vigibase, the WHO global database of Individual Case Safety Reports”; that, “[d]espite the potential limitations of this spontaneous reporting database, IV tramadol in general appears to be comparable to oral tramadol with respect to AE reports in all regions”; and that “[t]he paper concluded that the availability of IV tramadol as an alternative to pure μ opioid analgesics should be a valuable option for U.S. clinicians who treat acute pain in the hospital setting.”

25. The statements referenced in ¶¶ 19-24 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, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) IV Tramadol was not safe for the intended patient population; (ii) as a result, it was foreseeable that the FDA

would not approve the NDA for IV Tramadol; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

26. On October 12, 2020, during pre-market hours, Avenue issued a press release disclosing receipt of a CRL from the FDA regarding the NDA for its IV Tramadol product. Specifically, Avenue disclosed, in relevant part:

Avenue . . . today announced it has received a [CRL] from the [FDA] regarding the Company's [NDA] for IV tramadol.

The CRL stated that although the pivotal Phase 3 clinical trials demonstrated statistically significant outcomes for all of the primary and many secondary endpoints, the FDA has determined that it cannot approve the application in its present form. The CRL stated that IV tramadol, intended to treat patients in acute pain who require an opioid, is not safe for the intended patient population. Specifically, if a patient requires an analgesic between the first dose of IV tramadol and the onset of analgesia, a rescue analgesic would be needed. The likely choice would be another opioid, which would result in opioid "stacking" and increase the likelihood of opioid-related adverse effects.

27. On this news, Fortress's stock price fell \$1.00 per share, or 23.98%, to close at \$3.17 per share on October 12, 2020.

28. 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.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

29. 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 Fortress 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.

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

31. 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.

32. 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.

33. 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 Fortress;

- whether the Individual Defendants caused Fortress 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 Fortress 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.

34. 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.

35. 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;
- Fortress 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 Fortress 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.

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

37. 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)

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

39. 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.

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

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.

41. 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 Fortress 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 Fortress's finances and business prospects.

42. By virtue of their positions at Fortress, 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.

43. 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 Fortress, the Individual Defendants had knowledge of the details of Fortress's internal affairs.

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

45. During the Class Period, Fortress 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 Fortress 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 Fortress securities was substantially lower than the prices paid by Plaintiff and the other

members of the Class. The market price of Fortress securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

46. 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.

47. 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)

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

49. During the Class Period, the Individual Defendants participated in the operation and management of Fortress, and conducted and participated, directly and indirectly, in the conduct of Fortress's business affairs. Because of their senior positions, they knew the adverse non-public information about Fortress's misstatement of income and expenses and false financial statements.

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

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

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

53. 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 Fortress.

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: November 27, 2020