UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

PLAINTIFF, INDIVIDUALLY and ON BEHALF OF ALL OTHERS SIMILARLY SITUATED, Plaintiff, v. VERU INC., MITCHELL STEINER, and MICHELE GRECO Defendants.	Case No. _____ **CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** Jury Trial Demanded

Plaintiff, by and through his attorneys, alleges upon personal knowledge as to himself, and upon information and belief as to all other matters, based upon the investigation conducted by and through his attorneys, which included, among other things, a review of documents filed by Defendants (as defined below) with the United States Securities and Exchange Commission (the "SEC"), news reports, press releases issued by Defendants, and other publicly available documents, as follows:

NATURE AND SUMMARY OF THE ACTION

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired Defendant Veru Inc. ("Veru" or the "Company") common stock between May 11, 2022, through November 9, 2022, inclusive (the "Class Period"). This action is brought on behalf of the Class for violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (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.

2. Veru is primarily an oncology-based biopharmaceutical company that develops drugs for the management of breast and prostate cancers. Veru also develops medicines for

COVID-19 and other diseases related to viral and acute respiratory distress syndrome ("ARDS"), and has two FDA-approved products for sexual health.

3. Veru "opportunistically" developed sabizabulin (VERU-111), an orally administered "microtubule disruptor" – a drug that inhibits a virus' ability to replicate itself – for the treatment of COVID-19 in hospitalized patients at high risk for ARDS. Veru had originally developed sabizabulin with the intention of using it as a treatment for prostate cancer. In January 2022, however, the FDA granted Veru's COVID-19 program Fast Track designation. At the time, there was no authorized or approved treatment for hospitalized patients with severe COVID-19 infections.

4. Throughout the Class Period, Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the data from the sabizabulin Phase 3 trial and the Company's interactions with the FDA. Specifically, Veru misled its shareholders to believe that the data from the Phase 3 trial was sufficient to support Emergency Use Authorization ("EUA") and even the submission of a New Drug Application ("NDA") without any further studies. VERU's filings therefore concealed the true risks faced by the Company in gaining approval for its EUA request.

5. Veru conducted a randomized, double-blind Phase 3 trial of sabizabulin's effectiveness in treating hospitalized adults with moderate to severe COVID-19 at high risk for ARDS. The Phase 3 study sought to enroll 210 patients and evaluate mortality after 60 days of treatment.

6. On April 11, 2022, Veru issued a press release announcing that the company would be terminating sabizabulin's Phase 3 trial early on the basis of positive interim data, after Veru's Independent Data Safety Monitoring Committee conducted an interim analysis of the first 150

patients randomized into the study. Veru reported that sabizabulin "resulted in a clinically and statistically meaningful 55% relative reduction in deaths" relative to the placebo group (45% mortality at 60 days for the placebo group vs. 20% mortality for the sabizabulin-treated group).

7. On an investor call held that same day, Veru's Chairman, President, and Chief Executive Officer Mitchell Steiner, M.D. ("Steiner") told investors that Veru had been in "constant dialogue with FDA" since receiving the Fast Track designation and that the Company "plan[ned] to meet with FDA to discuss the next steps" including submitting an application for Emergency Use Authorization ("EUA") on the strength of the positive Phase 3 interim results. Steiner also addressed the placebo group's 45% mortality rate, stating that this death rate "underscores how sick these patients really are."

8. During the call, an analyst from Cantor Fitzgerald asked Steiner to "elaborate" on any differences in the standard of care between the placebo group and the sabizabulin-treated group in the Phase 3 trial. Steiner responded: "So, there are no imbalances with males and females and with standard of care is exactly – I mean, the system works, so the randomization works. So, there are no imbalances."

9. Veru's share price more than doubled on April 11, 2022, from an opening price of $5.99 per share to a closing price of $12.28.

10. On May 2, 2022, Veru announced that the FDA had granted the Company a pre-EUA meeting to discuss sabizabulin's Phase 3 results, to be held on May 10, 2022.

11. On May 11, 2022, Veru issued a press release announcing that in the May 10, 2022, pre-EUA meeting, the FDA "agreed that the efficacy and safety data from the completed Phase 3 clinical study in hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome are sufficient to support the submission of a request for Emergency Use Authorization

(EUA)." The press release quoted Steiner as saying "The discussion with FDA in the Pre-EUA meeting has established a direct path forward to expedite the availability of sabizabulin to the high risk hospitalized patients with COVID-19 . . . In the Phase 3 COVID-19 clinical study, sabizabulin demonstrated a clear mortality benefit in hospitalized moderate to severe COVID-19 patients on current standard of care with no significant safety signals."

12. The May 11, 2022 press release further stated that the FDA had "agreed that the current safety data available for sabizabulin is sufficient to support the safety portion of a request for EUA submission," and that "additional safety data that would be collected during the use of sabizabulin under the EUA, if granted, will be sufficient to support an NDA submission, and furthermore, that no additional safety clinical studies are required." Veru's stock price rose from its closing price of $7.79 per share on May 10, 2022, the day of the pre-EUA meeting with the FDA to close at $13 per share on May 13, 2022 the day after Veru filed its 2022 Second Quarter 10-Q in which it reported on the results of its pre-EUA meeting with the FDA.

13. On June 7, 2022, Veru submitted an EUA request with the FDA for use of sabizabulin to treat COVID-19.

14. On September 7, 2022, the FDA scheduled an October 6, 2022 meeting of the Pulmonary-Allergy Drugs Advisory Committee ("AdCom") to vote on whether sabizabulin should be granted EUA. Although AdCom recommendations are not binding, the FDA ordinarily follows them.

15. On September 19, 2022, it was announced that the FDA had postponed the AdCom meeting to November 9, 2022.

16. On August 11, 2022, Veru filed its Quarterly Report for the second quarter of 2022 on Form 10-Q with the SEC, which stated that during the May 10, 2022 pre-EUA meeting, the

FDA had "agreed that no additional efficacy studies were required to support an EUA application or a new drug application (NDA)" for sabizabulin, that "no additional safety data was required," and that "[t]he FDA agreed that the request for the EUA is supported by efficacy and safety [data] from our positive Phase 3 COVID-19 study . . . and no additional clinical trials are required to support an NDA submission."

17. On November 9, 2022, the AdCom voted against granting Veru's EUA request by an 8-5 margin. One AdCom member who voted against approval explained that there was "no direct evidence to support [sabizabulin's] antiviral activity." Veru's stock price plummeted on the news, falling from its closing price of $15.01 per share on November 8, 2022 to close at $6.97 per share on November 10, 2022, a 54% one-day drop, wiping out over $640 million in market capitalization.

18. 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

19. The federal law claims asserted herein arise under §§ 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, as well as under the common law.

20. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331 and § 27 of the Exchange Act, 15 U.S.C. § 78aa.

21. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

22. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b), as the Company has its principal executive offices located in this District and conducts substantial business here.

23. In connection with the acts, omissions, conduct and other wrongs in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce including but not limited to the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

24. Plaintiff acquired and held shares of the Company at artificially inflated prices during the class period and has been damaged by the revelation of the Company's material misrepresentations and material omissions.

25. Defendant Veru is a Wisconsin corporation with its principal place of business in Miami, Florida. The Company trades on the NASDAQ stock exchange under the ticker symbol "VERU" and claims that it is a "biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and acute respiratory distress syndrome (ARDS)-related diseases and for the management of breast and prostate cancers."

26. Defendant Mitchell Steiner, M.D. ("Steiner") has served as the Chairman, President, and Chief Executive Officer of Veru since 2016.

27. Defendant Michele Greco ("Greco") has served as Veru's Chief Financial Officer and Chief Administrative Officer since 2012.

28. Collectively, Steiner and Greco are referred to throughout this complaint as the "Individual Defendants".

29. The Individual Defendants, because of their positions at the Company, possessed the power and authority to control the content and form of the Company's annual reports, quarterly

reports, press releases, investor presentations, and other materials provided to the SEC, securities analysts, money and portfolio managers and investors, *i.e.*, the market. The Individual Defendants authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent the issuance of these false statements or to cause them to be corrected. Because of their position with the Company and access to material non-public 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 false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

30. Veru is a biopharmaceutical company that develops medicines for the management of breast and prostate cancers and for ARDS-related diseases, including COVID-19.

31. The Class Period begins on May 11, 2022. On that day, Veru issued a press release regarding the May 10, 2022 pre-EUA meeting with the FDA, in which the Company announced that the "FDA has agreed that the efficacy and safety data from the completed Phase 3 clinical study in hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome are sufficient to support the submission of a request for Emergency Use Authorization (EUA)." The press release also stated:

> FDA agreed that the Phase 3 COVID-19 study that was stopped by the Independent Data Monitoring Committee for overwhelming efficacy is sufficient to support the efficacy portion of a request for EUA submission and for an NDA submission.
>
> FDA agreed that the current safety data available for sabizabulin is sufficient to support the safety portion of a request for EUA submission. FDA informed the Company that additional safety data that would be collected during the use of sabizabulin under the EUA, if granted, will be sufficient to support an NDA submission, and furthermore, that no additional safety clinical studies are required.

32. These statements, including stating that "no additional safety clinical studies" would be required to support an NDA submission and stating that the FDA "agreed" that the safety and efficacy data from the Phase 3 trial were "sufficient" were materially false and misleading when made, as the FDA did not agree that the size of the Phase 3 trial was insufficient and that the safety data was adequate to support an NDA.

33. The May 11, 2022 press release also quoted Defendant Steiner as stating: "The discussion with FDA in the Pre-EUA meeting has established a direct path forward to expedite the availability of sabizabulin to the high risk hospitalized patients with COVID-19 . . . In the Phase 3 COVID-19 clinical study, sabizabulin demonstrated a clear mortality benefit in hospitalized moderate to severe COVID-19 patients on current standard of care with no significant safety signals."

34. The above statement was materially false and misleading when made, as it failed to disclose that the FDA disagreed with Veru."

35. On May 12, 2022, Veru filed its Quarterly Report for the first quarter of 2022 with the SEC on Form 10-Q. The May 12, 2022 10-Q stated:

> On May 10, 2022, the Company had a pre-Emergency Use Authorization (EUA) meeting with the FDA to discuss next steps including the submission of an EUA application regarding sabizabulin for COVID-19. The outcome of this meeting was: (i) the FDA agreed that no additional efficacy studies were required to support an EUA application or a new drug application (NDA); and (ii) the FDA agreed that no additional safety data was required to support an EUA application and that collection of safety data under the EUA will satisfy the safety requirement for an NDA. The FDA agreed that the request for the EUA is supported by efficacy and safety [data] from our positive Phase 3 COVID-19 study in hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS and death and no additional clinical trials are required to support an NDA submission. We plan to submit the EUA application in the second quarter of calendar year 2022.
>
> (emphasis added)

36. These statements, including that the "FDA agreed that no additional efficacy studies were required to support an EUA application or a new drug application (NDA)," that the FDA "agreed that no additional safety data was required," and that the EUA request was "supported by efficacy and safety [data] from our positive Phase 3 COVID-19 study," were materially false and misleading when made, as they failed to disclose that the FDA disagreed with Veru.

37. The Company's May 12, 2022 Form 10-Q was signed by Defendants Steiner and Greco and contained certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), signed by Defendants Steiner and Greco, who each certified:

> 1. I have reviewed this quarterly report on Form 10-Q of Veru Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
>
> 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
>
> 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
>
> > (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

38. On August 11, 2022, Veru filed its Quarterly Report for the second quarter of 2022 on Form 10-Q with the SEC. The August 11, 2022 10-Q stated:

On May 10, 2022, the Company had a pre-Emergency Use Authorization (EUA) meeting with the FDA to discuss next steps including the submission of an EUA application regarding sabizabulin for COVID-19. The outcome of this meeting was: (i) the FDA agreed that no additional efficacy studies were required to

> support an EUA application or a new drug application (NDA); and (ii) the FDA agreed that no additional safety data was required to support an EUA application and that collection of safety data under the EUA may satisfy the safety requirement for an NDA. The FDA agreed that the request for the EUA is supported by efficacy and safety [data] from our positive Phase 3 COVID-19 study in hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS and death and no additional clinical trials are required to support an NDA submission.

39. These statements, including that the "FDA agreed that no additional efficacy studies were required to support an EUA application or a new drug application (NDA)," that the FDA "agreed that no additional safety data was required," and that the EUA request was "supported by efficacy and safety [data] from our positive Phase 3 COVID-19 study," were materially false and misleading when made, as they failed to disclose that the FDA disagreed with Veru.

40. The Company's August 11, 2022 Form 10-Q was signed by Defendants Steiner and Greco and contained certifications pursuant to SOX, signed by Defendants Steiner and Greco, substantially similar to the certifications described in ¶37 *supra*.

The Truth is Revealed

41. On November 9, 2022, the FDA AdCom convened. After the markets closed, it was announced that the AdCom had voted against granting Veru's EUA request by an 8-5 margin. One AdCom member who voted against approval explained that there was "no direct evidence to support [sabizabulin's] antiviral activity."

42. An article entitled "FDA panel votes against Veru's drug for severe Covid" published in STAT that evening explained that the AdCom had come to the decision "that a glimmer of potential life-saving benefit couldn't make up for a long list of questions around the company's main trial."

43. Veru's stock price cratered in the aftermath of the AdCom vote. After closing at $15.01 per share on November 9, 2022, the Company's stock price dropped to $6.97 on November 10, 2022, a 54% drop.

CLASS ACTION ALLEGATIONS

44. Plaintiff brings this action as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired VERU common stock between May 11, 2022, and November 9, 2022, inclusive. Excluded from the Class are Defendants, directors and officers of the Company, as well as their families and affiliates.

45. The members of the Class are so numerous that joinder of all members is impracticable. Investors purchased millions of shares of Veru during the class period. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.

46. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether the Exchange Act was violated by Defendants;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. Whether the price of the Company's stock was artificially inflated; and

f. The extent of damage sustained by Class members and the appropriate measure of damages.

47. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.

48. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

49. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

FRAUD ON THE MARKET

50. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine that, among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's common stock traded in efficient markets;

d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

e. Plaintiff and other members of the class purchased the Company's common stock between the time Defendants misrepresented or failed to disclose material facts and the time that the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

51. At all relevant times, the markets for the Company's stock were efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC; and

(ii) the Company regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures such as communications with the financial press, securities analysts, and other similar reporting services. Plaintiff and the Class relied on the price of the Company's common stock, which reflected all information in the market, including the misstatements by Defendants.

NO SAFE HARBOR

52. The statutory safe harbor provided for forward-looking statements under certain conditions does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

53. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

LOSS CAUSATION

54. After the market closed on November 9, 2022, the AdCom voted against approving sabizabulin because of the "long list of questions around the company's main trial," contrary to the Company's public statements made beginning on May 11, 2022 and described above about the positive effects and sufficiency of the Phase 3 trial. By the time the market closed on November 10, 2022, the Company's stock had declined by $8.04, or 54%, wiping out over $640 million in market cap. This decline is directly attributable to the announcement of the unfavorable November 9, 2022 AdCom vote.

CAUSES OF ACTION

Count I
Violation of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

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

56. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

57. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon those who purchased or otherwise acquired the Company's securities during the class period.

58. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiff and the Class would not have purchased the Company's common stock at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

Count II
Violation of § 20(a) of the Exchange Act (Against The Individual Defendants)

59. Plaintiff repeats and re-alleges each and every allegation contained above, except for those made under Count I, as if fully set forth herein.

60. The Individual Defendants acted as controlling persons of the Company within the meaning of § 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions at the Company, the Individual Defendants had the power and authority to cause or prevent the Company from engaging in the wrongful conduct complained of herein. The Individual Defendants were provided with or had unlimited access to the documents where false or misleading statements were made and other statements alleged by Plaintiffs to be false or misleading both prior to and immediately after their publication, and had the ability to prevent the issuance of those materials or to cause them to be corrected so as not to be misleading.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) determining that this action is a proper class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiff as class representative pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

(b) awarding compensatory and punitive damages in favor of Plaintiff and the other class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post-judgment interest thereon.

(c) awarding Plaintiff and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

(d) awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury in this action of all issues so triable.