UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 14, 2023

VERU INC.
(Exact name of registrant as specified in its charter)

Wisconsin	**1-13602**	**39-1144397**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2916 N. Miami Avenue, Suite 1000, Miami, Florida 33127
Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (305) 509-6897

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	VERU	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events

On March 14, 2023, at the Oppenheimer 33rd Annual Healthcare Conference, Dr. Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. ("Veru" or the "Company"), presented Veru's updated strategy as part of the Company's ongoing effort to (i) refocus its drug development efforts on those drug candidates which it believes have the best opportunity to lead to long-term success and shareholder value creation and (ii) conserve cash, including a reduction in personnel and certain other measures to reduce costs. The presentation included a description of Veru's refocused research and development strategy which includes the following: (i) plans for continued development of sabizabulin in Phase 3 COVID-19 confirmatory study in hospitalized moderate to severe COVID-19 patients at high risk for acute respiratory disease syndrome ("ARDS") and planned development of sabizabulin in Phase 3 clinical study in hospitalized influenza patients at high risk for ARDS, (ii) plans for an updated ongoing Phase 3 study of enobosarm and abemaciclib combination in the second line setting for AR+ ER+ HER2- metastatic breast cancer patients, into which Veru plans to roll the current ARTEST study, if agreed by the U.S. Food and Drug Administration (the "FDA") and the Company's clinical trial partner, Eli Lilly & Company, and (iii) a planned Phase 3 study of enobosarm in bone-only non-measurable metastatic ER+ HER2- breast cancer. In addition, Dr. Steiner announced that Veru is reserving sabizabulin for clinical development only in infectious disease indications, and accordingly, terminating the Phase 3 VERACITY trial of sabizabulin in certain prostate cancer patients. Further, Phase 2 development of the Veru-100 and zuclomiphene assets will be paused. On March 2, 2023, Veru had announced that the FDA declined to grant at this time Veru's request for Emergency Use Authorization (EUA) for sabizabulin to treat hospitalized adult patients with moderate to severe COVID-19 who are at high risk for ARDS.

Forward-Looking Statements

The statements in this report that are not historical facts are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this report include statements regarding: whether and when the Company will submit a new EUA application, or receive an EUA or any approval from the FDA or from any regulatory authority outside the U.S. for sabizabulin for certain COVID-19 patients; whether the protocol for any proposed confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients will meet its proposed primary or secondary endpoints; the proposed timing, size and scope of any such Phase 3 study; whether any potential planned interim analyses of such Phase 3 study will show sufficient efficacy and safety and whether any such interim results would be sufficient to support stopping the study early and submitting a new EUA or a new drug application (NDA) on any accelerated timeline; when the Company expects to disclose the details of the design and timing of this potential Phase 3 confirmatory study; whether the FDA will accept any results of such trial as sufficient for a new EUA or an NDA submission and, if any such application is submitted, whether the FDA will ultimately authorize or approve such application; how long the FDA will be able to continue to issue EUAs under its current emergency authorization under the U.S. Department of Health and Human Services; whether the current mortality rate of COVID-19 in the U.S. will continue, increase or decrease; whether the market forCOVID-19 treatments will be sufficient to support commercialization or continued development; whether sabizabulin will be a potentially life-saving drug for COVID-19 patients in the U.S. or elsewhere in the world; the degree to which the FDA continues to work with the Company to develop sabizabulin; the results or consequences and the expected timing of the Company's efforts to avail itself of the FDA's formal dispute resolution process regarding the FDA's recent declination of an EUA for sabizabulin; the design, timing, enrollment and potential efficacy demonstrated by a new trial of sabizabulin in influenza patients at high risk of ARDS: whether the FDA or the Company's clinical trial partner, Eli Lilly & Company, will approve the plans to combine the ARTEST and ENABLAR-2 Phase 3 studies; the expected time for enrollment and data readout for the new planned ENABLAR-2 study; whether and when the Company will resume development of the Veru-100 and zuclomiphene assets; whether the current and future clinical development efforts of the Company and any of their results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of any of the Company's other drug candidates; whether the drug candidates will be approved for the targeted line of therapy; whether the Company will be able to raise money successfully and in sufficient amounts in the equity markets, and whether the Company's current cash will be sufficient to fund its planned or expected operations. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the development of the Company's product portfolio and the results of clinical studies possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical studies and the ability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development; the timing of any submission to the FDA or any other regulatory authority and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines, anti-virals and other treatments become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities possibly taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the Company's existing products, including FC2 and ENTADFI and, if authorized, sabizabulin, and any future products, if approved, possibly not being commercially successful; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical studies, supply chain and other third-party providers, commercial efforts, and business development operations; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and

operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to successfully commercialize any of its products, if approved; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, and development costs; the Company's ability to protect and enforce its intellectual property; the potential that delays in orders or shipments under government tenders or the Company's U.S. prescription business could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; the Company's reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; the concentration of accounts receivable with our largest customers and the collection of those receivables; the Company's production capacity, efficiency and supply constraints and interruptions, including potential disruption of production at the Company's and third party manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's and third party facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; costs and other effects of litigation, including product liability claims; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed from time to time in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the fiscal year ended September 30, 2022 and subsequent quarterly reports on Form 10-Q, and the additional risk factors described below. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors. The Company disclaims any intent or obligation to update these forward-looking statements.

Risk Factors

In addition to the risks and uncertainties relating to the Company's business disclosed in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2022, the following additional risk factors relate to Veru's refocused research and development strategy and other business matters.

If we fail to obtain additional capital, we may need to reduce the scope of our development programs or we could be forced to share our rights to technologies with third parties on terms that may not be favorable to us.

We will need large amounts of capital to support our development and commercialization efforts for our drug candidates, including the Phase 3 COVID-19 confirmatory study for certain COVID-19 patients. If we are unable to secure sufficient capital to fund our operations, we will not be able to continue these efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to one or more of our drug candidates with third parties in ways that we currently do not intend or on terms that may not be favorable to us. Our ability to raise capital through equity financing may be limited by the number of authorized shares of the Company's common stock, which is currently 154 million shares. In order to raise significant additional amounts from equity financing, the Company may need to seek stockholder approval to amend our Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock, and any such amendment would require the approval of the holders of at least two-thirds of the outstanding shares of the Company's common stock. Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms and not enter into strategic collaborations, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Our ability to obtain an EUA from the FDA to market sabizabulin as a potential treatment for certain COVID-19 patients will depend on the federal government continuing to issue EUAs for treatments relating to COVID-19 in the United States.

We may submit a new EUA application sabizabulin as a potential treatment for certain COVID-19 patients based on the results of the Phase 3 COVID-19 confirmatory study for certain COVID-19 patients we plan to conduct. In addition to the risks relating to the EUA process disclosed in the risk factors in our annual report on Form 10-K for the year ended September 30, 2022, we are subject to risks relating to whether COVID-19 continues to be treated as a public health emergency supporting the issuance of EUAs for COVID-19 treatments in the United States. On January 30, 2023, the White House Office of Management and Budget announced that the Biden administration plans to terminate the COVID-19 national and public health emergencies on May 11, 2023 (the "May 11 Termination"). The FDA announced on January 31, 2023, that the May 11 Termination would not impact the FDA's ability to authorize new treatments for emergency use, that existing EUAs would remain in effect and that it may continue to issue new EUAs when criteria for issuance are met. However, if the FDA were to determine to cease issuing EUAs for COVID-19 treatments, whether as a result of the May 11 Termination or otherwise, the Company may not be able to obtain an EUA for sabizabulin as a potential treatment for certain COVID-19 patients and in that case the Company would not be able to market sabizabulin as a potential treatment for certain COVID-19 patients in the United States unless it was approved by the FDA following the submission of a new drug application.

Our net revenues from sales of FC2 may not return to past levels.

Net revenues from sales of FC2 have declined significantly in recent periods, particularly in the U.S. prescription channel. Although we are working to restore ordering and utilization patterns in future periods, net revenues from sales of FC2 may not return to past levels. Ordering patterns may not rebound or may continue to decline if our distribution partners in the telehealth sector encounter issues, we or our distribution partners are not able or willing to spend sufficient amounts to market and promote FC2, or underlying demand for FC2 decreases. Any failure to attain or sustain sales growth for FC2 in the U.S. market may have a material adverse effect on our results of operations.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 14, 2023

VERU INC.

By: /s/ Michele Greco
Michele Greco
Chief Financial Officer and
Chief Administrative Officer