
**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): September 11, 2023

VERU INC.

(Exact name of registrant as specified in its charter)

Wisconsin
(State or other jurisdiction
of incorporation)

1-13602
(Commission
File Number)

39-1144397
(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 September 11, 2023, the Company announced clinical data from its discontinued Phase 3 ARTEST clinical trial of enobosarm monotherapy for the 3rd line or greater in the metastatic setting of AR+ER+HER2- breast cancer. As previously announced, enrollment had been discontinued in order to prioritize and to focus the clinical development of enobosarm therapy earlier in the treatment sequence, the 2nd line metastatic setting, for androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer in the Phase 3 ENABLAR-2 (enobosarm +/- abemaciclib CDK 4/6 inhibitor) study. Data reported from the discontinued trial, which is based on an analysis of available data, may not be predictive of the results of larger, later-stage controlled clinical trials. Product candidates that have shown promising results in early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials.

Highlights of clinical data from discontinued Phase 3 ARTEST clinical study

At the time enrollment was stopped, there were 34 evaluable patients randomized to either 9mg enobosarm monotherapy (n=16) or a standard of care active control (n=18) in the Phase 3 open label, randomized (1:1) clinical trial for the treatment of AR+ER+HER2- metastatic breast cancer with sufficient AR expression in their breast cancer tissue who had previously received at least a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

The active control treatment group received an average of 2.6 (range 1-5) prior lines of treatment and the enobosarm 9mg monotherapy group received an average of 2.9 (range 1-5) prior lines of treatment. On average, enobosarm or the active control was given in the 4th line treatment for AR+ER+HER2- metastatic breast cancer.

Summary of Overall Response Rate Data*:

	<u>Enobosarm monotherapy</u>	<u>Estrogen blocking agent active control</u>
Evaluable patients	2 PR /16 (12.5%)	0 PR/18 (0%)
Evaluable patients - including an unconfirmed response	3 PR /16 (18.8%)	0 PR/18 (0%)
Patients with ≤3 lines of prior endocrine therapy	2 PR /10 (20.0%)	0 PR/15 (0%)
Patients with ≤3 lines of prior endocrine therapy with ≤1 prior treatment with CDK 4/6 inhibitor	2 PR /6 (33.3%)	0 PR/10 (0%)

*unaudited data, overall response rate = partial response (PR) + complete response (CR)

Safety: Enobosarm monotherapy was generally well tolerated without masculinizing adverse events or increases in hematocrit.

Forward-Looking Statements

The statements in this release 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 release include statements regarding: the planned design, enrollment, timing, commencement, interim and full data readout timing, scope, regulatory pathways, and results of the Company’s current and planned clinical trials, including the confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients, the Phase 3 study of enobosarm in combination with abemaciclib for the 2nd line treatment of AR+ ER+ HER2 metastatic breast cancer, the Phase 3 study of enobosarm in bone-only non-measurable hormone receptor and HER2-metastatic breast cancer, the Phase 3 study of sabizabulin in hospitalized influenza patients at high risk of ARDS, and studies of sabizabulin in smallpox virus and Ebola virus, and whether any of such studies will meet any of its primary or secondary endpoint; whether the ENABLAR-2 study will show results consistent with or greater than the ARTEST results reported above; whether the data from the ARTEST study shown above is predictive of the results of any larger, later-stage, controlled clinical trial; whether and when any of the planned interim analyses in the planned Phase 3 confirmatory study of sabizabulin for certain COVID patients will occur and what the results of any such interim analyses will be; whether the results of such interim analyses or the completed confirmatory Phase 3 study or any other interim data will be sufficient to support a new EUA application or an NDA; whether and when the Company will expand the study of sabizabulin into other ARDS indications; whether and when the Company will receive the future installment payments of the ENTADFI purchase price or sales milestone payments; and the outlook for growth in the Company’s FC2 business through telehealth customers, our direct to patient telehealth portal and the global public health sector. 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 as well as other operations of the Company; 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 or other ARDS 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 or other ARDS treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 or other ARDS treatments; the Company's existing products, including FC2 and, if authorized, sabizabulin, and any future products, if approved, possibly not being commercially successful; 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; 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, development costs, and market awareness and acceptance of any telehealth platform we develop; risks relating to our ability to increase sales of FC2 after significant declines in recent periods due to telehealth industry consolidation and the bankruptcy of a large telehealth customer; 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, product testing, transportation delays or regulatory actions; costs and other effects of litigation, including product liability claims and securities litigation; 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. The Company disclaims any intent or obligation to update these forward-looking statements.

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: September 11, 2023

VERU INC.

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