
**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): April 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 April 11, 2023, Veru Inc. (“we,” “us,” “our” or “Veru”) filed an amendment to a Registration Statement on FormS-3 that included the following “Recent Developments.”

Recent Developments

The Pill Club has historically been our largest telehealth customer for FC2, accounting for 44% of our net revenues (including 58% of our U.S. prescription channel revenue) in fiscal 2022 and 43% of our net revenues (including 57% of our U.S. prescription channel revenue) in fiscal 2021. We sell FC2 to The Pill Club at a wholesale price pursuant to purchase orders received from The Pill Club from time to time. The Pill Club takes title to FC2 and then acts as a distributor of FC2. The Pill Club is solely responsible for its interactions with health care providers and patients (including, without limitation, the conduct of the telehealth physician-patient interactions), pricing of the FC2 products that it distributes, and legal and regulatory compliance. We have no oversight of The Pill Club’s operations.

On February 7, 2023, the California Attorney General announced a settlement with The Pill Club over a number of alleged improper actions by The Pill Club, including alleged overbilling for FC2. Notwithstanding the statements in the California Attorney General’s press release, California’s allegations against The Pill Club, according to the publicly available Settlement Agreement executed as of January 18, 2023, involved not only billing related to FC2 but also billing related to emergency contraceptives, improper coding of asynchronous telemedicine visits, and billing for prescriptions sent to California patients by a Texas pharmacy not then-licensed to provide pharmacy services to California patients.

While the California Attorney General’s allegations included The Pill Club’s practices with respect to sales of FC2 by The Pill Club, we were not involved in such business practices and no claims against Veru have been made by the California Attorney General. However, to the extent that the settlement adversely affects The Pill Club’s FC2 sales, our business may be adversely affected.

As a result of the settlement, The Pill Club has informed us that it expects to modify some of its business practices regarding its sales of FC2 to patients, notwithstanding that The Pill Club did not agree that it had violated any laws in the Settlement Agreement. It is not clear to Veru at this time when such new business model will be in operation in California or in any other states. In addition, the settlement may have damaged The Pill Club’s reputation and may affect The Pill Club’s financial resources to continue large purchases of FC2. Such changes may make it difficult to restore The Pill Club’s ordering patterns in future periods, and as a result net revenues from sales of FC2 may not return to past levels.

We also have a concentration of accounts receivable with The Pill Club, which totals \$3.9 million as of March 31, 2023, including \$1.3 million of accounts receivable that are past due. At this time, Veru is uncertain as to whether or when The Pill Club will pay these amounts to Veru. Veru had been making significant efforts to obtain clarity from The Pill Club on when this payment would be made. On March 29, 2023, The Pill Club refused delivery of a shipment of FC2 for which it had previously submitted a binding purchase order and which it was contractually bound to accept. On March 30, 2023, Veru provided written notice to The Pill Club that Veru believed The Pill Club was in default for the past due payment and the refused shipment. These breaches remained uncured 10 calendar days after the default notice and, accordingly, Veru’s contract with The Pill Club for the sale of FC2 has automatically terminated by its terms.

If The Pill Club’s business and legal issues impair or have impaired its financial condition, it may no longer be able or willing to pay the past due accounts receivable balance and other outstanding invoices on a timely basis or at all, or accept any deliveries of or place new orders for FC2 from Veru. Further, with the termination of our contract with The Pill Club, we expect that our revenue from The Pill Club is likely to be substantially reduced or possibly eliminated. It is possible that individual purchases of FC2 could still be made by The Pill Club from time to time but any such potential purchases would be outside of the now terminated contract.

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: the effect of the California Attorney General settlement on our sales to The Pill Club, whether The Pill Club will timely pay outstanding invoices on a timely basis or at all, and whether The Pill Club will accept any deliveries for FC2 or place any new orders for FC2. 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 relationship with The Pill Club.

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. In particular, sales to our largest telehealth customer, The Pill Club, may not return to past levels due to risks that include potential operational challenges of The Pill Club stemming from its settlement with the California Attorney General, potential issues with The Pill Club’s business and financial condition as a result of the effects of such settlement or other reasons, and the termination of our contract with The Pill Club due to recent payment and shipment acceptance breaches by The Pill Club. 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.

We are subject to risks relating to the concentration of accounts receivable with The Pill Club.

The Pill Club is one of our largest customers, accounting for 44% of our net revenues in fiscal 2022 and 43% of our net revenues in fiscal 2021. We have a concentration of accounts receivable at The Pill Club, with \$3.9 million of accounts receivable as of March 31, 2023, including \$1.3 million of accounts receivable that are past due. Veru had been making significant efforts to obtain clarity from The Pill Club on when this payment would be made. On March 29, 2023, The Pill Club refused delivery of a shipment of FC2 for which it had previously submitted a binding purchase order and which it was contractually bound to accept. On March 30, 2023, Veru provided written notice to The Pill Club that Veru believed The Pill Club was in default for the past due payment and the refused shipment. These breaches remained uncured 10 calendar days after the default notice and, accordingly, Veru's contract with The Pill Club for the sale of FC2 has automatically terminated by its terms.

An adverse change in our relationship with The Pill Club, including as a result of the termination of our contract with The Pill Club, or in The Pill Club's business or financial condition following its settlement with the California Attorney General, could result in a delay in payment of, or an inability to pay, its outstanding accounts receivable balance or an inability or unwillingness to place new orders for FC2, any of which could have a material adverse effect on our cash flows and liquidity.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Document</u>
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: April 12, 2023

VERU INC.

By: _____/s/ Michele Greco

Michele Greco
Chief Financial Officer and
Chief Administrative Officer