
**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): February 14, 2018

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.)

4400 Biscayne Boulevard, Suite 888, Miami, Florida 33137
(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in 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.

Section 2 – Financial Information**Item 2.02 Results of Operations and Financial Condition**

On February 14, 2018, Veru Inc. issued a press release (the “Press Release”) announcing results for the quarter ended December 31, 2017. A copy of the Press Release is attached as Exhibit 99.1 to this report. The attached Exhibit 99.1 is furnished pursuant to Item 2.02 of Form 8-K.

The information in this Form 8-K and the Exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in such filing.

Section 9 – Financial Statements and Exhibits**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits.**

The following exhibit is furnished herewith:

Exhibit 99.1 [Press Release of Veru Inc., issued February 14, 2018.](#)

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: February 14, 2018

VERU INC.

By: /s/ Michele Greco

Michele Greco
Executive Vice President of Finance and
Chief Administrative Officer



Contact:
Kevin Gilbert 786-322-2213

Veru Reports Fiscal 2018 First-Quarter Financial Results

— Company Advancing Multiple Drugs from Pipeline; First New Drug Application (NDA) Remains on Track for Submission in 2018; Two Additional NDAs Expected to be Filed in 2019; Promising Oncology Drug Data Presented at Major Medical Conference —

Company to Host Investor Conference Call on Wednesday, February 14, 2018, 8 a.m. ET

MIAMI – February 14, 2018 – Veru Inc. (NASDAQ: VERU) today announced its financial results for the fiscal 2018 first quarter ended December 31, 2017.

“We continue to advance our product development program, which has been expanded to include two recently acquired late-stage urology drugs,” said Mitchell Steiner, M.D., President and Chief Executive Officer of Veru. “The two products expand our portfolio of urology and oncology drug candidates and address large patient populations. Moreover, the FDA has agreed that for each of these two products a single bioequivalence study would be acceptable for New Drug Applications (NDA).”

“Last week, we announced positive preclinical data for our VERU-111 drug candidate; the data were presented at an American Society of Clinical Oncology Genitourinary Cancers (ASCO GU) medical conference on February 9, 2018 and we expect additional data for VERU-111 will be presented at other key medical conferences later in the year. While in early stage development, VERU-111 was highly effective at inhibiting tumor growth in prostate cancer, specifically paclitaxel resistant prostate cancer, and, we believe, has strong potential in other cancer types.”

“Importantly, we remain on track to file with the FDA the Company’s first NDA for Tamsulosin DRS in 2018. Moreover, we plan to submit two additional NDAs in 2019.”

“Turning to our financial results, which currently are primarily derived from sales of FC2, our fiscal 2018 first quarter performance continues to reflect the inconsistent procurement cycles for our two largest customers, Brazil and South Africa. Both countries have announced large new tenders for female condoms. We are optimistic about potential near-term orders for FC2 from these two large international public-sector customers. Furthermore, we are seeing measurable sales growth following the implementation of several initiatives to grow our US revenue for FC2. Our US FC2 revenues for the first four months of our 2018 fiscal year were approximately \$1.5 million, which is approaching the historical average annual US FC2 revenues over the last three fiscal years of approximately \$1.9 million.”

Fiscal First Quarter Results: 2018 vs. 2017

For the first quarter of fiscal 2018, net revenues were \$2.6 million, compared with net revenues for the first quarter of fiscal 2017 of \$3.2 million. Gross profit was \$1.3 million, or 51% of net revenues, compared with \$1.7 million, or 51% of net revenues, for the first quarter of fiscal 2017. Operating expenses were \$8.8 million, which includes a \$3.8 million charge related to the settlement of certain receivables owed by our distributor in Brazil. This compares with operating expenses of \$3.5 million for the prior year first quarter, which includes non-recurring acquisition-related expenses of \$826,000. Net loss was \$4.3 million, or \$0.08 per share, compared with \$1.4 million, or \$0.04 per share, for the first quarter of fiscal 2017.

Significant quarter-to-quarter variations in the Company's results have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for female condoms.

Conference Call Event Details

Veru Inc. will host a conference call on Wednesday, February 14, 2018 at 8 a.m. Eastern Time to review the company's performance. Interested investors may access the call by dialing 877-317-6789 from the U.S., or 412-317-6789 from outside the U.S., and asking to join into the call.

In addition, investors may access a replay of the conference call the same day beginning at approximately noon Eastern Time by dialing 877-344-7529 for US callers, or 412-317-0088 from outside the U.S., passcode 10116643. The replay will be available for one week, after which, the recording will be available via the company's website at <https://verupharma.com/investors>.

About Veru Inc.

Veru Inc. (Veru) is a biopharmaceutical company focused on urology and oncology. The company is currently developing drug product candidates: Tamsulosin DRS, slow release granules, and Tamsulosin XR capsules for lower urinary tract symptoms of benign prostatic hyperplasia (BPH) (NDA planned 2018), Solifenacin DRG, slow release granules, for overactive bladder (urge incontinence, urgency and frequency of urination) (NDA planned 2019), Tadalafil/finasteride combination capsule for restricted urination because of an enlarged prostate (NDA planned 2019), VERU-944 (cis-clomiphene citrate) for hot flashes in men associated with prostate cancer hormone treatment (planned Phase 2 in 2018), and VERU-111 a novel oral anti-tubulin cancer therapy targeting alpha & beta tubulin for a variety of malignancies, including metastatic prostate, breast, endometrial and ovarian cancers (planned Phase 1/2 in 2018).

To help support these clinical development programs, the company markets and sells the PREBOOST® medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation which is being co-promoted with Timm Medical Technologies, Inc. and the FC2 Female Condom® (now available by prescription in the US including through the virtual doctor smartphone app "HeyDoctor" at www.fc2.us.com) in the United States and through The Female Health Company Division in the Global Public Health Sector. The Female Health Company Division markets to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. More information about Veru and its products can be found at www.verupharma.com, www.PREBOOST.com, www.fc2.us.com and www.fc2femalecondom.com. For corporate and investor-related information about the Company, please visit <https://verupharma.com/investors>.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:

The statements in this release that are not historical fact 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 relating to the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies and FDA submissions, future demand for FC2 and potential orders of FC2 by public sector customers. Any forward-looking statements in this are based upon the Company's current plans and strategies, and reflect the Company's current assessment of the risks and uncertainties related to its business, and are made as of the date of this release. The Company assumes no obligation to update any forward-looking statements contained in this release because of new information or future events, developments or circumstances. Such forward-looking statements are inherently subject to known and unknown risks and uncertainties. The Company's actual results and future developments could differ materially from the results or developments expressed in, or implied by, these forward-looking statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, the following: product demand and market acceptance; competition in the

Company's markets and the risk of new competitors and new competitive product introductions; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; many of the Company's products are at an early stage of development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including licensing risks; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay or restructuring; a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount; the Company's reliance on its international partners in the consumer sector and on the level of spending on the female condom by country governments, global donors and other public health organizations in the global public sector; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; the Company's production capacity, efficiency and supply constraints; risks related to the costs and other effects of 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 in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended September 30, 2017. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

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FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
December 31, 2017 and September 30, 2017

	December 31,	September 30,
	2017	2017
Cash	\$ 3,572,350	\$ 3,277,602
Accounts receivable, net	3,000,308	3,555,350
Inventory, net	3,067,036	2,767,924
Prepaid expenses and other current assets	625,497	697,097
Total current assets	10,265,191	10,297,973
Other trade receivables	—	7,837,500
Other assets	582,663	156,431
Plant and equipment, net	513,224	555,539
Deferred income taxes	12,124,000	8,827,000
Intangible assets, net	20,684,175	20,752,991
Goodwill	6,878,932	6,878,932
Total assets	<u>\$ 51,048,185</u>	<u>\$ 55,306,366</u>
Accounts payable	\$ 2,517,371	\$ 2,685,718
Accrued expenses and other current liabilities	2,383,628	1,441,359
Unearned revenue	990,016	1,014,517
Accrued compensation	338,136	345,987
Total current liabilities	6,229,151	5,487,581
Other liabilities	—	1,233,750
Deferred rent	68,446	131,830
Total liabilities	6,297,597	6,853,161
Total stockholders' equity	<u>44,750,588</u>	<u>48,453,205</u>
Total liabilities and stockholders' equity	<u>\$ 51,048,185</u>	<u>\$ 55,306,366</u>

Veru Inc.
Condensed Consolidated Statements of Operations
Three Months Ended December 31, 2017 and 2016

	Three Months Ended	
	December 31,	
	2017	2016
Net revenues	\$ 2,586,613	\$ 3,243,599
Cost of sales	<u>1,272,574</u>	<u>1,591,315</u>
Gross profit	1,314,039	1,652,284
Operating expenses	<u>8,750,620</u>	<u>3,526,974</u>
Operating loss	(7,436,581)	(1,874,690)
Interest and other expense, net	(13,169)	(9,621)
Foreign currency transaction loss	<u>(53,455)</u>	<u>(11,939)</u>
Loss before income taxes	(7,503,205)	(1,896,250)
Income tax benefit	<u>(3,246,053)</u>	<u>(530,069)</u>
Net loss	<u>\$ (4,257,152)</u>	<u>\$ (1,366,181)</u>
Net loss per basic and diluted common share outstanding	\$ (0.08)	\$ (0.04)
Basic and diluted weighted average common shares outstanding	53,154,076	30,976,140

Veru Inc.
Condensed Consolidated Statements of Cash Flows
Three Months Ended December 31, 2017 and 2016

	Three Months Ended December 31,	
	2017	2016
Net loss	\$ (4,257,152)	\$ (1,366,181)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	44,229	89,284
Amortization of intangible assets	68,816	26,729
Share-based compensation	207,454	317,311
Warrants issued	—	542,930
Deferred income taxes	(3,297,000)	(591,573)
Loss on settlement of accounts receivable	3,764,137	—
Other	(5,000)	4,469
Changes in current assets and liabilities, net of effects of acquisition of a business:	<u>3,771,178</u>	<u>2,142,996</u>
Net cash provided by operating activities	296,662	1,165,965
Net cash used in investing activities	<u>(1,914)</u>	<u>(65,623)</u>
Net increase in cash	294,748	1,100,342
Cash at beginning of period	<u>3,277,602</u>	<u>2,365,082</u>
Cash at end of period	<u>\$ 3,572,350</u>	<u>\$ 3,485,424</u>