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): December 13, 2018

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.)

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 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 2.02 Results of Operations and Financial Condition

On December 13, 2018, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and fiscal year ended September 30, 2018. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit No.	Document
99.1	Press Release of Veru Inc., issued December 13, 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: December 13, 2018

VERU INC.

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

Exhibit 99.1

Contact:
Kevin Gilbert 786-322-2213

Veru Reports Strong Net Revenues and Gross Profit for Fiscal 2018 Fourth-Quarter

— Advancing Multiple Drug Candidates, Two Drugs Currently in Clinical Trials, Company Transforming into Biopharmaceutical with Focus on Prostate Cancer, Successfully Completes Stock Offering, Awarded Large FC2 Tender —

Company to Host Investor Conference Call on Thursday, December 13, 2018, 8 a.m. ET

MIAMI – December 13, 2018 – Veru Inc. (NASDAQ: VERU) today announced its financial results for the fiscal (FY) 2018 fourth-quarter and full-year ended September 30, 2018.

"Our fiscal 2018 fourth-quarter and full-year financial results improved significantly driven by increased US demand for the FC2 Female Condom / FC2 Internal Condom® (FC2) and improving gross profit," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. For the fiscal 2018 fourth quarter, net revenues increased 41% to $5.2 million and gross profit grew by 78% to $3.2 million over the prior-year period."

"We continue to see increasing US Rx demand and related improving gross profit for our FC2 product through the first two months of the current fiscal quarter as well. For example, US FC2 Rx net revenues were 15% of total global FC2 net revenues in all channels for FY 2018. Q4 FY 2018 US FC2 Rx net revenues were 67% of total US FC2 Rx net revenues for the full FY 2018. Already through the first two months of the current fiscal year 2019, US FC2 Rx net revenues are at 120% of Q4 FY 2018 US FC2 Rx net revenues.

The Company also was granted a significant tender award for FC2 from the Republic of South Africa, which could generate approximately $30 million of future net revenues spread over a three-year period. No orders from this new South African tender are reflected in the FY 2018 financial results.

"Importantly, Veru is rapidly transforming into a biopharmaceutical company with a strong focus on prostate cancer with several drugs under development to provide a continuum of care for these cancer patients. To that end, earlier this quarter we announced that we have begun enrolling patients for our zuclomiphene citrate Phase 2 clinical trial for the treatment of hot flashes caused by androgen deprivation therapy for men with advanced prostate cancer with "top line" results, or general summary data, expected in the first half of FY 2019.

"In addition, in November, we submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for VERU-111 (bisindole), a first-in-class, next generation, proprietary, oral tubulin inhibitor for the treatment of metastatic prostate cancer. We expect this drug to advance into an open label Phase 1b/2 clinical trial by no later than early January 2019. We also announced earlier this month that the first patient was dosed in our bioequivalence study of Tadalafil (Cialis®) and Finasteride (PROSCAR®) combination tablet for benign prostatic hyperplasia (BPH). This combination tablet is designed to improve patient compliance and convenience with bioequivalency results expected in January 2019.

"Regarding our existing portfolio of commercial products, we have expanded our FC2 presence in the US market by partnering with a leading telemedicine marketing and sales channel, as well as utilizing a contracted independent sales force. For PREBOOST® we recently entered into a US distributor agreement with a premier and fast-growing men's health and telemedicine company that discreetly sells men's health products via the internet."

"In early October, just after the close of our fiscal year, we strengthened our balance sheet, completing an underwritten public stock offering that generated $9.2 million of net proceeds. We intend to use the proceeds for working capital and general corporate purposes, including research and development, clinical trials and marketing expenditures."

"In summary, our accomplishments over the past year further solidify our foundation and position Veru for future success. In the coming year, we look to build on these achievements with the planned submission to the FDA of New Drug Applications for Tadalafil and Finasteride combination tablets and Tamsulosin XR capsules and sprinkles. We look to continue our transformation into a biopharmaceutical company with a strong focus on prostate cancer treatment and prostate cancer supportive care with several drugs to provide a continuum of care for these patients."

Fiscal 2018 Fourth-Quarter Results

For the fiscal 2018 fourth-quarter, net revenues, which were primarily derived from sales of FC2, rose 41% to $5.2 million from $3.7 million for the fourth-quarter of fiscal 2017. Gross profit increased by 78% to $3.2 million, or 61% of net revenues, compared with $1.8 million, or 49% of net revenues, for the fourth-quarter of fiscal 2017. Operating expenses were $7.0 million compared with $4.6 million for the fourth-quarter of fiscal 2017. Non-operating income was $63 thousand compared with non-operating expenses of $32 thousand for the fourth-quarter of fiscal 2017. Income tax expense was $4.2 million compared with an income tax benefit of $0.1 million in the fourth-quarter of fiscal 2017. Net loss was $7.9 million, or $0.14 per share, compared with net loss attributable to common stockholders of $4.7 million, or $0.10 per share, for the fourth-quarter of fiscal 2017.

Fiscal 2018 Full-Year Results

For the fiscal 2018 full-year, net revenues, which were primarily derived from sales of FC2, climbed 16% to $15.9 million from $13.7 million for fiscal 2017. Gross profit increased 23% to $8.8 million, or 55% of net revenues, compared with $7.0 million, or 51% of net revenues, for fiscal 2017. Operating expenses were $29.7 million compared with $15.5 million for fiscal 2017. Non-operating expenses were $2.2 million compared with $0.1 million for fiscal 2017. Income tax expense was $0.9 million compared with an income tax benefit of $2.0 million in fiscal 2017. Net loss was $23.9 million, or $0.44 per share, compared with net loss attributable to common stockholders of $8.6 million, or $0.25 per share, for fiscal 2017.

As of September 30, 2018, cash (including restricted cash) was $3.8 million. Subsequent to September 30, 2018, the Company completed a stock offering that generated net proceeds of approximately $9.2 million after deducting underwriting discounts and commissions and expenses payable by the Company.

Conference Call Event Details

Veru Inc. will host a conference call today at 8 a.m. ET to review the company's performance. Interested investors may access the call by dialing 800-341-1602 from the U.S. or 412-902-6706, and asking to be joined into the call.

In addition, investors may access a replay of the conference call the same day beginning at approximately 12 p.m. (noon) ET by dialing 877-344-7529 for US callers, or 412-317-0088 from outside the U.S., passcode 10126693. 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. is an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer and prostate cancer supportive care as well as near term specialty pharmaceuticals to address significant unmet needs in urology.

The Veru prostate cancer pipeline includes zuclomiphene citrate (also known as VERU-944, ***cis-***clomiphene) and VERU-111 (bisindole). Zuclomiphene citrate is an estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men with advanced prostate cancer. VERU-111 is an oral, next-generation, first-in-class small molecule that targets and binds to alpha and beta subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen blocking agent (abiraterone or enzalutamide) therapies. Veru expects VERU-111 to enter a Phase 1b/2 clinical trial in January 2019.

Veru is also advancing four new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology. Tamsulosin DRS granules and Tamsulosin XR capsules are formulations of tamsulosin, the active ingredient in FLOMAX®, which Veru has developed to avoid the "food effect" inherent in currently marketed formulations of the drug, allowing for potentially safer administration and improved patient compliance (NDA submission expected in 2019). Veru is also developing Tadalafil/Finasteride combination tablets for inhibition of both phosphodiesterase type 5 (PDE5) and 5-alpha-reductase to shrink an enlarged prostate, to treat symptoms of BPH and to treat erectile dysfunction (NDA submission expected in 2019). Finally, Veru is developing Solifenacin DRG granules, a formulation of a selective M3 muscarinic receptor antagonist for the treatment of overactive bladder in patients who have difficulty with swallowing tablets (NDA submission expected in 2019).

Veru's currently marketed products are the PREBOOST® medicated individual wipe for the prevention of premature ejaculation and the FC2 Female Condom®. The Female Health Company Division markets the FC2 Female Condom® in the global public health sector to improve the lives, health and well-being of women around the world. To learn more please visit www.verupharma.com.

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

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 relating to the regulatory pathway to secure FDA approval of the Company's drug candidates and the anticipated timeframe for clinical studies, clinical study results and FDA submissions, statements relating to the Company's intended use of the net proceeds from its public stock offering and statements relating to anticipated revenue from the South African tender award and the anticipated timeframe for filling the award. The South African tender award could be subject in the future to reallocation for potential local manufacturing initiatives, which could reduce the size of the award to the Company, and the award indicates acceptance of the price rather than an order or guarantee of the purchase of any minimum number of units. If fewer orders are placed under the tender award than expected the Company's revenue from the award would be less than currently anticipated. As with other government tenders, ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount. In addition, the timing of orders under the South African tender award is uncertain, and any delay in orders under the award could result in lower revenue than anticipated in the earlier part of the three-year period covered by the award. Any forward-looking statements in this release 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 subject to known and unknown risks, uncertainties and assumptions, and if any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied

by such 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: risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; potential delays in the timing of and results from clinical trials and studies and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; product demand and market acceptance; competition in the Company's markets and the risk of new or existing competitors with greater resources and capabilities and new competitive product introductions; price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters, including costs and delays resulting from extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of products; some of the Company's products are in development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including the uncertainty of obtaining patents, the effectiveness of the patents or other intellectual property protections and ability to enforce them against third parties, the uncertainty regarding patent coverages, the possibility of infringing a third party's patents or other intellectual property rights, and licensing risks; 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, restructuring or substantial delayed payments; 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 or award; penalties and/or debarment for failure to satisfy tender awards; 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; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; 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 and interruptions, including due to labor unrest or strikes; risks related to the 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 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
(unaudited)

	September 30,	
	2018	2017
Cash	$ 3,759,509	$ 3,277,602
Accounts receivable, net	3,972,632	3,418,738
Inventory, net	2,302,030	2,767,924
Prepaid expenses and other current assets	1,148,345	833,709
Total current assets	11,182,516	10,297,973
Other trade receivables	—	7,837,500
Other assets	965,152	186,431
Plant and equipment, net	404,552	555,539
Deferred income taxes	8,543,758	8,827,000
Intangible assets, net	20,477,729	20,752,991
Goodwill	6,878,932	6,878,932
Total assets	$48,452,639	$55,336,366
Accounts payable	$ 3,226,036	$ 2,685,718
Accrued research and development costs	981,357	200,710
Accrued compensation	584,047	406,110
Accrued expenses and other current liabilities	1,866,317	1,180,526
Credit agreement, short-term portion	6,692,718	—
Unearned revenue	202,452	1,014,517
Total current liabilities	13,552,927	5,487,581
Credit agreement, long-term portion	2,701,570	—
Residual royalty agreement	1,753,805	—
Other liabilities	30,000	1,263,750
Deferred rent	88,161	131,830
Deferred income taxes	844,758	—
Total liabilities	18,971,221	6,883,161
Total stockholders' equity	29,481,418	48,453,205
Total liabilities and stockholders' equity	$48,452,639	$55,336,366

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30,		Years Ended September 30,	
	2018	2017	2018	2017
Net revenues	$ 5,203,268	$ 3,692,406	$ 15,864,483	$13,655,592
Cost of sales	2,012,177	1,897,747	7,081,981	6,636,080
Gross profit	3,191,091	1,794,659	8,782,502	7,019,512
Operating expenses	6,965,638	4,568,712	29,654,909	15,513,624
Operating loss	(3,774,547)	(2,774,053)	(20,872,407)	(8,494,112)
Non-operating income (expenses)	63,477	(31,910)	(2,199,880)	(108,378)
Loss before income taxes	(3,711,070)	(2,805,963)	(23,072,287)	(8,602,490)
Income tax expense (benefit)	4,208,441	(126,628)	866,102	(1,990,443)
Net loss attributable to common stockholders before preferred stock dividend	(7,919,511)	(2,679,335)	(23,938,389)	(6,612,047)
Preferred stock dividend	—	(1,990,771)	—	(1,990,771)
Net loss attributable to common stockholders	$ (7,919,511)	$ (4,670,106)	$(23,938,389)	$ (8,602,818)
Net loss per basic and diluted common share outstanding	$ (0.14)	$ (0.10)	$ (0.44)	$ (0.25)
Basic and diluted weighted average common shares outstanding	55,136,704	45,492,167	53,861,981	34,640,308