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): May 9, 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. ☐

Section 2 – Financial Information

Item 2.02 Results of Operations and Financial Condition

On May 9, 2018, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and six months ended March 31, 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.

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 May 9, 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: May 9, 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 Fiscal 2018 Second-Quarter Financial Results

— Promising Oncology Drug Data to be Presented at Upcoming American Urological Association Medical Conference; FDA Waives Drug Application Fee; BE Clinical Studies Results Anticipated for Drugs in 2018; Clinical Trials for VERU-944 and VERU-111 Planned for 2018 —

Company to Host Investor Conference Call on Wednesday, May 9, 2018, 8 a.m. ET

MIAMI – May 9, 2018 – Veru Inc. (NASDAQ: VERU), a urology and oncology biopharmaceutical company, today announced its financial results for the fiscal 2018 second quarter ended March 31, 2018.

"During the quarter, we presented promising preclinical data on our cancer drug, VERU-111," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. "The preclinical data reinforces our belief that VERU-111 has the potential to become an important therapeutic option for patients with castration resistant prostate cancer. We have been invited to present this exciting data later this month at the prestigious American Urological Association's 2018 Annual Meeting in San Francisco.

Veru was formed to advance the development of a portfolio of late stage drug products. We remain committed to a strategy that expedites product regulatory approval. Tamsulosin DRS granules final bioequivalence clinical study results and NDA filing are expected in 2018. We are also delighted to report that the US Food and Drug Administration granted a waiver of the drug application fee, approximately $2.4 million, related to our New Drug Application for Tamsulosin DRS granules and Tamsulosin XR capsules. Our other urology drugs, Tadalafil/finasteride combination tablet and Solifenacin DRG granules final bioequivalence clinical results are also anticipated in 2018 with NDA filings in 2019.

"We plan to initiate a Phase 2 clinical trial for VERU-944 for the treatment of hot flashes in men on advanced prostate cancer hormone treatment this summer. We are also planning a Phase 1/2 clinical trial later this calendar year for VERU-111, our novel oral anti-tubulin cancer therapy targeting alpha & beta tubulin focusing on men who have metastatic prostate cancer that have failed abiraterone or enzalutamide therapies.

"Turning to our fiscal 2018 second quarter financial results. Net revenues, which are primarily derived from product sales of FC2 Female Condom®, increased 7% over the comparable prior year period. During the quarter, we successfully completed a $10 million "synthetic" royalty financing on FC2 product sales. This transaction provided immediate, non-dilutive funds to support our drug development program and operations, as well as provide financial flexibility."

Fiscal Second Quarter Results: 2018 vs. 2017

For the second quarter of fiscal 2018, net revenues increased to $2.6 million from $2.4 million for the second quarter of fiscal 2017. Gross profit was $1.2 million, or 47% of net revenues, compared with $1.3 million, or 53% of net revenues, for the second quarter of fiscal 2017. Operating expenses were $5.9 million compared with $3.9 million, which includes business acquisition expenses of $108,000. Net loss was $3.8 million, or $0.07 per share, compared with $1.8 million, or $0.06 per share, for the second 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, May 9, 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 be joined into the Veru Healthcare call.

In addition, investors may access a replay of the conference call the same day beginning at approximately noon ET by dialing 877-344-7529 for US callers, or 412-317-0088 from outside the U.S., passcode 10119574. 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 urology and oncology biopharmaceutical company. 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 and the anticipated timeframe for clinical studies and FDA submissions. 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 the extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of the 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; 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
March 31, 2018 and September 30, 2017

	March 31, 2018	September 30, 2017
Cash	$ 8,972,498	$ 3,277,602
Accounts receivable, net	2,969,073	3,555,350
Inventory, net	3,589,057	2,767,924
Prepaid expenses and other current assets	629,527	697,097
Total current assets	16,160,155	10,297,973
Other trade receivables	—	7,837,500
Plant and equipment, net	469,215	555,539
Deferred income taxes	13,480,558	8,827,000
Intangible assets, net	20,615,360	20,752,991
Goodwill	6,878,932	6,878,932
Other assets	590,880	156,431
Total assets	$ 58,195,100	$ 55,306,366
Accounts payable	$ 3,539,667	$ 2,685,718
Accrued expenses and other current liabilities	1,940,348	1,441,359
Credit agreement, short-term portion	3,912,888	—
Unearned revenue	872,370	1,014,517
Accrued compensation	322,654	345,987
Total current liabilities	10,587,927	5,487,581
Credit agreement, long-term portion	5,822,693	—
Residual royalty liability	372,070	—
Other liabilities	81,192	1,365,580
Total liabilities	16,863,882	6,853,161
Total stockholders' equity	41,331,218	48,453,205
Total liabilities and stockholders' equity	$ 58,195,100	$ 55,306,366

Veru Inc.
Condensed Consolidated Statements of Operations
Three and Six Months Ended March 31, 2018 and 2017

	Three Months Ended March 31,		Six Months Ended March 31,	
	2018	2017	2018	2017
Net revenues	$ 2,572,872	$ 2,405,519	$ 5,159,485	$ 5,649,118
Cost of sales	1,373,469	1,127,864	2,645,570	2,719,179
Gross profit	1,199,403	1,277,655	2,513,915	2,929,939
Operating expenses	5,895,953	3,856,888	14,647,047	7,383,862
Operating loss	(4,696,550)	(2,579,233)	(12,133,132)	(4,453,923)
Non-operating expenses	(437,083)	(21,442)	(503,707)	(43,002)
Loss before income taxes	(5,133,633)	(2,600,675)	(12,636,839)	(4,496,925)
Income tax benefit	(1,302,416)	(824,033)	(4,548,469)	(1,354,102)
Net loss	$ (3,831,217)	$ (1,776,642)	$ (8,088,370)	$ (3,142,823)
Net loss per basic and diluted common share outstanding	$ (0.07)	$ (0.06)	$ (0.15)	$ (0.10)
Basic and diluted weighted average common shares outstanding	53,355,944	30,982,497	53,253,901	30,979,283

Veru Inc.
Condensed Consolidated Statements of Cash Flows
Six Months Ended March 31, 2018 and 2017

	Six Months Ended March 31,	
	2018	**2017**
Net loss	$ (8,088,370)	$ (3,142,823)
Adjustments to reconcile net loss to net cash used in operating activities	325,404	(250,766)
Changes in current assets and liabilities, net of effects of acquisition of a business	3,579,775	2,333,592
Net cash used in operating activities	(4,183,191)	(1,059,997)
Net cash used in investing activities	(1,913)	(83,492)
Net cash provided by financing activities	9,880,000	—
Net increase (decrease) in cash	5,694,896	(1,143,489)
Cash at beginning of period	3,277,602	2,385,082
Cash at end of period	$ 8,972,498	$ 1,241,593