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): August 8, 2019

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))

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 2.02 Results of Operations and Financial Condition

On August 8, 2019, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and nine months ended June 30, 2019 and reiterating fiscal 2019 financial guidance. 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 August 8, 2019.

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: August 8, 2019

VERU INC.

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

Contact:
Sam Fisch 800-972-0538

Veru Reports Higher Net Revenues and Gross Profit for its Fiscal 2019 Third Quarter

Promising Clinical Observations for Both Advancing VERU-111 and Zuclomiphene Prostate Cancer Clinical Trials —

— Added VERU-100, Novel First GnRH Antagonist 3 Month Depot Formulation for Androgen Deprivation —

— Had Successful PreNDA meeting with FDA for TADFIN for BPH and NDA Submission Expected in Summer 2020 —

— Company to Host Investor Conference Call on Thursday, August 8, 2019, 8 a.m. ET –

MIAMI – August 8, 2019 – Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer treatment and prostate cancer supportive care, today announced its financial results for its fiscal 2019 third quarter ended June 30, 2019.

Business and Operational Highlights

- **VERU-111**. VERU-111 is an oral, first-in-class, alpha and beta antitubulin being evaluated in a Phase 1b/2 clinical trial in men who have metastatic prostate cancer and whose disease is resistant to both castration and novel androgen blocking agents (abiraterone or enzalutamide). The objective of this clinical trial is to determine the dose limiting toxicity of VERU-111. At this point we have dosed 6 cohorts (18 men total) with escalating doses of VERU-111. In clinical observations, VERU-111 is well-tolerated with a favorable safety profile and no dose limiting toxicity has been observed. In some of the men whose PSA blood level was rapidly rising at enrollment, a marker of cancer progression, we have observed that VERU-111 treatment resulted in PSA stabilizations and reductions consistent with early promising signals of anticancer efficacy. Once we have reached a dose level that has dose limiting toxicity, we will be able to select the dose that will be evaluated in the Phase 2 clinical study. There are no drugs that are FDA approved to treat men who have both castration and novel androgen blocking agent resistant prostate cancer and which are also prechemotherapy (chemotherapy naïve), representing an estimated $4.5 billion annual global market.
- **Zuclomiphene Citrate**. Zuclomiphene Citrate is a novel, proprietary, oral, nonsteroidal, estrogen receptor agonist being evaluated as a treatment for hot flashes caused by androgen deprivation therapy for men with advanced prostate cancer. Hot flashes are one of the main reasons why men want to stop androgen deprivation therapy. Approximately 100 men will be randomized in the Phase 2 clinical trial evaluating 2 doses (10mg and 50mg) of oral zuclomiphene versus placebo. Top line results expected late Summer/early Fall 2019. Based on an independent market analysis sponsored by the Company, expected U.S. sales potential for zuclomiphene citrate is estimated to exceed $600 million annually.

- **VERU-100**. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist for the treatment of hormone sensitive advanced prostate cancer. Currently, there are no GnRH antagonists commercially approved beyond 1 month, which would make VERU-100, if approved, the only commercially available GnRH antagonist3-month depot. Recently, we added this proprietary internally developed peptide drug candidate to the Company's late-stage drug development pipeline. Based on regulatory clarity obtained in the preIND meeting with FDA in May 2019, we plan to initiate a Phase 2 clinical study in early 2020 after GMP manufacturing of VERU-100. Androgen deprivation therapy for advanced prostate cancer is an established multi-billion-dollar global market.
- **TADFIN® (Tadalafil and Finasteride Combination Capsule)**. TADFIN is being developed for BPH and would be the first combination of a PDE5 inhibitor and 5 alpha reductase inhibitor. The Company had a successful preNDA meeting with FDA in May 2019. After the Company has 12-month stability data on manufacturing batches, the Company will submit an NDA for TADFIN which is expected in Summer of 2020. BPH is an established multi-billion-dollar market.

"We are delivering on our strategy of providing multiple prostate cancer and prostate cancer supportive care medicines for the continuum of prostate cancer care," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. "We are pleased with the clinical progress we are making in advancing our product development program and in adding a high value, late stage drug candidate that complements our existing portfolio."

Highlights Third-Quarter Financial Results: Fiscal 2019 vs Fiscal 2018

- Net revenues increased 77% to $9.7 million from $5.5 million;
- Gross profit more than doubled to $6.6 million, or 68% of net revenues, from $3.1 million, or 56% of net revenues;
- FC2 US prescription net revenues increased more than tenfold to $4.4 million from $0.4 million;
- Operating loss significantly narrowed to $1.8 million from $5.0 million; and
- Net loss was $2.8 million, or $0.04 per share, compared with $7.9 million, or $0.15 per share.

Highlights Year-to-Date Financial Results: Fiscal 2019 vs Fiscal 2018

- Net revenues rose 116% to $23.1 million from $10.7 million;
- Gross profit climbed 183% to $15.8 million, or 69% of net revenues, from $5.6 million, or 52% of net revenues;
- FC2 US prescription net revenues increased over tenfold to $9.4 million from $0.83 million;
- FC2 public sector net revenues were $13.0 million, a 33% increase from $9.8 million;
- Operating loss significantly narrowed to $5.0 million from $17.1 million (fiscal 2018 year to date included a $4.0 million loss for the settlement of Brazilian receivables); and
- Net loss was $9.0 million, or $0.14 per share, compared with $16.0 million, or $0.30 per share.

"For the fiscal 2019 third quarter, we had impressive increases to net revenues and to gross profit which combined to substantially improve our bottom line," said Dr. Steiner. "Key contributors to the quarter's performance included the continued significant ramp up of prescription sales of FC2 and the increased consumer demand for our PREBOOST®/Roman Swipes. As our revenue base has grown to include increased FC2 prescription sales, our gross profit has risen substantially. The robust growth of the US FC2 prescription business remains noteworthy as it allows us to be less reliant on traditional intermittent ordering patterns typically seen in our FC2 public sector business. All of these factors combined to significantly narrow our operating loss for the quarter compared with the prior year period, which allows us to continue to invest in our multiple prostate cancer drug candidate clinical development efforts."

Financial Outlook

The Company reiterated its fiscal 2019 full year guidance of net revenues between $29 and 32 million, which represents a 95% increase over full year fiscal 2018, and gross margin of approximately 66%.

The Company does not expect to update the guidance for the full year fiscal 2019 provided above before the release announcing results for its fiscal 2019 year end. The Company notes that the statements of future performance made in this release, including the guidance for the full year fiscal 2019, are based upon current expectations and are subject to factors that could cause actual results to differ materially from those suggested here, including those factors set forth in the "Safe Harbor" Statement below.

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 from outside the U.S. and asking to be joined into the Veru Inc. 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 U.S. callers, or 412-317-0088 from outside the U.S., passcode 10133960. 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 treatment and prostate cancer supportive care as well as urology specialty pharmaceuticals. The Veru prostate cancer pipeline includes VERU-111, zuclomiphene citrate and VERU-100. VERU-111 is an oral, next-generation, first-in-class selective small molecule that targets and disrupts alpha and beta tubulin subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen blocking agents (abiraterone or enzalutamide). VERU-111 is being evaluated in men with metastatic castration and androgen-blocking agent resistant prostate cancer in an open label Phase 1b/2 clinical trial. Zuclomiphene citrate is an oral 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-100 is a novel, proprietary peptide formulation for androgen deprivation therapy (ADT) with multiple beneficial clinical attributes addressing the shortfalls of current FDA approved ADT formulations for advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist designed to be administered as a small volume subcutaneous 3-month depot injection without a loading dose. VERU-100 will immediately suppress testosterone with no testosterone surge upon initial or repeated administration — a problem which occurs with currently approved LHRH agonists. Currently, there are no GnRH antagonists commercially approved beyond 1 month. VERU-100 is anticipated to enter Phase 2 dose finding study in early 2020.

Veru is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as the Tadalafil and Finasteride Combination (TADFIN®) for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company had a successful preNDA meeting with FDA and the expected submission of the NDA for TADFIN is summer of 2020. Veru is also developing Tamsulosin DRS granules and Tamsulosin XR capsules which are formulations of tamsulosin, the active ingredient in FLOMAX®, which Veru has designed to avoid the "food effect" inherent in currently marketed formulations of the drug, allowing for potentially safer administration and improved patient compliance.

The Company's commercial products include the FC2 Female Condom / FC2 Internal Condom® ("FC2"), an FDA-approved product for the dual protection of unwanted pregnancy and sexually transmitted infections, and the PREBOOST® 4% benzocaine medicated individual wipe for the prevention of premature ejaculation (also marketed as Roman Swipes). The Company's Female Health Company Division markets and sells FC2 commercially and in the public health sector both in the U.S. and globally. FC2 is available by prescription and OTC in the U.S. at www.fc2.us.com. In the global public health sector, the Company markets FC2 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. For our premature ejaculation product, marketed as "Roman Swipes", the Company has entered into a U.S. distributor agreement with Roman Health Ventures Inc., a premier and fast-growing men's health and telemedicine company that discreetly sells men's health products via the internet website www.getroman.com. To learn more about Veru products 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 under "Financial Outlook" regarding expected net revenues and gross margin for the full fiscal year 2019 and the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies, clinical study results including potential benefits, and FDA submissions, the market potential for the Company's drug candidates, and whether clinical trial results will support the effectiveness and safety profile shown by initial clinical data. 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, including, with respect to the financial guidance, assumptions regarding the timing of orders and shipments and the impact on gross margins of the mix of sales in the public sector channel as compared to the U.S. prescription channel. 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 therapeutic areas and the risk of new or existing competitors with greater resources and capabilities and new competitive product approvals and/or 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; the risk that delays in orders or shipments under government tenders could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; 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 potential disruption of production at the Company's 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 facilities, product testing, transportation delays or regulatory actions; 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, 2018. 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)

	June 30, 2019	September 30, 2018
Cash	$ 8,039,116	$ 3,759,509
Accounts receivable, net	4,766,962	3,972,632
Inventory, net	3,130,720	2,302,030
Prepaid expenses and other current assets	1,206,003	1,148,345
Total current assets	17,142,801	11,182,516
Plant and equipment, net	314,690	404,552
Deferred income taxes	8,574,448	8,543,758
Intangible assets, net	20,245,803	20,477,729
Goodwill	6,878,932	6,878,932
Other assets	684,091	965,152
Total assets	$ 53,840,765	$ 48,452,639
Accounts payable	$ 3,134,795	$ 3,226,036
Accrued expenses and other current liabilities	3,867,918	3,447,014
Credit agreement, short-term portion	4,660,572	6,692,718
Unearned revenue	—	187,159
Total current liabilities	11,663,285	13,552,927
Credit agreement, long-term portion	4,489,540	2,701,570
Residual royalty agreement	1,824,745	1,753,805
Deferred income taxes	895,861	844,758
Other liabilities	231,167	118,161
Total liabilities	19,104,598	18,971,221
Total stockholders' equity	34,736,167	29,481,418
Total liabilities and stockholders' equity	$ 53,840,765	$ 48,452,639

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2019	2018	2019	2018
Net revenues	$ 9,727,060	$ 5,501,730	$ 23,074,984	$ 10,661,215
Cost of sales	3,155,902	2,427,542	7,250,895	5,075,470
Gross profit	6,571,158	3,074,188	15,824,089	5,585,745
Operating expenses	8,413,160	8,038,916	20,802,408	22,683,605
Operating loss	(1,842,002)	(4,964,728)	(4,978,319)	(17,097,860)
Non-operating expenses	(932,532)	(1,759,649)	(3,861,383)	(2,263,357)
Loss before income taxes	(2,774,534)	(6,724,377)	(8,839,702)	(19,361,217)
Income tax (benefit) expense	(458)	1,206,131	117,207	(3,342,339)
Net loss	$ (2,774,076)	$ (7,930,508)	$ (8,956,909)	$(16,018,878)
Net loss per basic and diluted common share outstanding	$ (0.04)	$ (0.15)	$ (0.14)	$ (0.30)
Basic and diluted weighted average common shares outstanding	62,917,362	53,789,409	62,745,355	53,432,404

Veru Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine Months Ended June 30,	
	2019	**2018**
Net loss	$(8,956,909)	$(16,018,878)
Adjustments to reconcile net loss to net cash used in operating activities	5,895,238	4,132,551
Changes in operating assets and liabilities	(1,468,534)	3,155,109
Net cash used in operating activities	(4,530,205)	(8,731,218)
Net cash used in investing activities	(74,948)	(47,696)
Net cash provided by financing activities	8,884,760	11,078,752
Net increase in cash	4,279,607	2,299,838
Cash at beginning of period	3,759,509	3,277,602
Cash at end of period	$ 8,039,116	$ 5,577,440