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 12, 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.)

48 NW 25th Street, Suite 102, Miami, Florida 33127
Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (305) 509-6897

4400 Biscayne Boulevard, Suite 888, Miami, Florida 33137
(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 December 12, 2019, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter and fiscal year ended September 30, 2019. 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 12, 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: December 12, 2019

VERU INC.

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

Exhibit 99.1

Contact:
Sam Fisch 800-972-0538

Veru Reports Fiscal 2019 Full-Year Net Revenues Doubled, Gross Profit Up 147%

—Update on Ongoing Phase 1b/2 VERU-111, Oral Selective Antitubulin, Clinical Trial Demonstrates Antitumor Activity and No Dose Related Toxicity Reached in Men with Metastatic Castration Resistant Prostate Cancer—

—VERU-111 Has Promising Signs of Progression Free Survival—

— Advancing VERU-111 into Three Phase 2 Clinical Studies in Additional Cancer Types—

—Company to Host Investor Conference Call Today at 8 a.m. ET to Discuss Financial Results and Clinical Study Data—

MIAMI – December 12, 2019 – Veru Inc. (NASDAQ: VERU), The Prostate Cancer Company, an oncology and urology biopharmaceutical company developing novel medicines for the management of prostate cancer, today announced that its fiscal 2019 full-year net revenues doubled to $31.8 million and gross profit increased 147% to $21.7 million.

“For both the fiscal 2019 fourth quarter and full year, we continue to generate impressive increases to net revenues and gross profit compared with the prior year,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “The robust ramp up of prescription as well as global public sector sales of FC2® and increased consumer demand for our PREBOOST®/Roman® Swipes product drove the significantly improved financial performance.”

“I would like to highlight on the clinical development front,VERU-111 — our proprietary, oral, next generation,first-in-class, selective antitubulin – as it continues to show antitumor activity and no dose related toxicity in men with metastatic castration resistant prostate cancer. VERU-111 appears to be well tolerated with no evidence of neutropenia, neurotoxicity or allergic (hypersensitivity) reactions that typically occur with IV taxane chemotherapy. To date, our Phase 1b/2 clinical study has enrolled and dosed 33 patients from 4.5 mg per day up to 81 mg per day. The study will continue to enroll patients using increasing doses of VERU-111 until maximum tolerated dose is observed.

“Although this study was designed for determination of safety, we do see evidence of significant antitumor activity. Historical controls from the literature report that the time to imaging based tumor progression in men like those enrolled in our study averages about 2-3 months. In our Phase 1b/2, we have 20 men in the study that had the potential to be treated for 4.5 months. Even without having an optimal dose or dose schedule yet determined, there are 4 men who are still ongoing in the trial with no progression at 9.75, 8.4, 8.4 and 5.6 months. All of these men have prostate-specific antigen (PSA) reductions. We have another 6 men that progressed at 4.2 months. The patient who has reached 9.75 months had a PSA reduction of -63% and has had 2 of his cancerous lymph nodes shrink as measured by CT scan. Another patient in the study with stable disease stopped losing weight, reported that his fatigue resolved, and had a PSA reduction.”

“Based on reports in the scientific literature, it appears that just like cabazitaxel, VERU-111 is a very active compound in metastatic castration resistant prostate cancer, and it seems to perform better than adding another androgen blocking agent in a similar patient population. VERU-111 appears to be well tolerated with a wide safety margin. Wide safety margin means that we are seeing anticancer activity at doses where we are not seeing drug toxicity. We plan to present full clinical results for this ongoing Phase 1b/2 at a future major scientific meeting.

Dr. Steiner added: “Since VERU-111 has signs of antitumor activity and an acceptable safety profile, we plan to expand and initiate in early 2020 three additional Phase 2 studies where we had demonstrated significant preclinical anticancer activity: metastatic pancreatic cancer, metastatic breast cancer and postchemotherapy (taxane) metastatic castration resistant prostate cancer. This clearly positions Veru as an oncology company with a novel oral agent that selectively targets alpha and beta subunits of tubulin.”

“We also plan to submit the Investigation New Drug (IND) application for VERU-100 – our long-acting 3-month subcutaneous depot gonadotropin-releasing hormone (GnRH) antagonist for the treatment of hormone sensitive advanced prostate cancer – in early 2020. Regarding our Phase 2 clinical trial of zuclomiphene citrate, our proprietary drug to treat hot flashes caused by androgen deprivation therapy in men with advanced prostate cancer, we expect top line clinical data by no later than next month.”

“Growing strong revenues from our base business will continue to support not only the current Phase 1b/2 VERU-111 oral selective antitubulin clinical trial and other VERU-111 Phase 2 clinical trials for different tumor types, but also the completion of the Phase 2 zuclomiphene citrate trial, and the planned Phase 2 VERU-100 3-month depot GnRH antagonist clinical trial in 2020. We are very pleased with the significant clinical progress we are making in advancing our entire product development program.”

Full-Year Financial Highlights: Fiscal 2019 vs Fiscal 2018

- Net revenues rose 100% to $31.8 million from $15.9 million;
- Gross profit climbed 147% to $21.7 million, or 68% of net revenues, from $8.8 million, or 55% of net revenues;
- FC2 US prescription revenue increased more than five-fold to $14.1 million from $2.4 million;
- FC2 public sector net revenues were $16.8 million, a 25% increase from $13.5 million;
- Operating loss significantly narrowed to $6.4 million from $20.9 million;
- Net loss was $12.0 million, or $0.19 per share, compared with $23.9 million, or $0.44 per share; and,
- At September 30, 2019, cash and accounts receivable were $11.3 million, an increase of $3.6 million from $7.7 million at the end of the prior year.

Fourth-Quarter Financial Highlights: Fiscal 2019 vs Fiscal 2018

- Net revenues increased 68% to $8.7 million from $5.2 million;
- Gross profit increased to $5.8 million, or 67% of net revenues, from $3.2 million, or 61% of net revenues;
- FC2 US prescription net revenues increased nearly three-fold to $4.7 million from $1.6 million;
- Operating loss significantly narrowed to $1.5 million from $3.8 million; and
- Net loss was $3.1 million, or $0.05 per share, compared with $7.9 million, or $0.14 per share.

Based on our resources on hand and the anticipated performance of our commercial businesses together with already existing sources of capital, the Company believes that it has sufficient resources to execute our clinical drug trial programs through year end 2021.

Pharmaceutical Products Development Program Highlights

- **VERU-111**. VERU-111 is an oral, next generation, first-in-class, selective small molecule that targets and binds to the alpha and beta antitubulin subunits of microtubules in cells. VERU-111 is 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, 33 men in total have received doses of VERU-111, with each separate cohort receiving a higher dose. In clinical observations, VERU-111 has been well-tolerated with a favorable safety profile, and no dose limiting toxicity has been observed. There has been no neutropenia, neurotoxicity, or allergic (hypersensitivity) reactions which typically occur with IV taxane chemotherapy. In some of the men whose PSA blood levels were rapidly rising, a marker of cancer progression, as well as bone scans and/or CT scans showing cancer lesions progression at enrollment, treatment with VERU-111 resulted in PSA stabilizations and reductions consistent with early promising signals of anticancer efficacy. Furthermore, some patients have also demonstrated arrested progression of CT and/or bone scan cancer lesions beyond 8 and 9 months. Once a dose limiting toxicity level has been reached, a dose will be selected for evaluation 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 global market of $4.5 billion annually. As VERU-111 has signs of antitumor activity and an acceptable safety profile, the Company plans to expand and initiate in early 2020 three additional Phase 2 studies where we had demonstrated significant preclinical anticancer activity: metastatic pancreatic cancer, metastatic breast cancer and postchemotherapy (taxane) metastatic castration resistant prostate cancer.

- **VERU-100**. VERU-100 is a long-acting 3-month subcutaneous depot 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 antagonist 3-month depot. Based on regulatory clarity obtained in the pre-IND meeting with the FDA in May 2019, the Company plans to submit the IND application for VERU-100 in early 2020. Androgen deprivation therapy for advanced prostate cancer is an established multi-billion-dollar 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, also known as vasomotor symptoms, are one of the main reasons why men want to stop androgen deprivation therapy. There have been no reports of gynecomastia, breast pain, or venothromboembolic events (blood clots in legs or lungs, or stroke) in the Intent to Treat safety database in the Phase 2 clinical study which are side effects commonly seen with off label use of steroidal estrogens and progestins for hot flashes in these patients. Top line clinical data results are expected by no later than next month. An independent market analysis sponsored by the Company estimates potential U.S. sales for zuclomiphene citrate to be between $600-800 million annually.

- **TADFIN® (Tadalafil and Finasteride Combination Capsule)**. TADFIN is being developed for benign prostatic hyperplasia (BPH) and would be the first combination of a PDE5 inhibitor and 5 alpha reductase inhibitor. The Company had a successful preNDA meeting with the 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 the second half of 2020. BPH is an established multi-billion-dollar market.

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 10136891. 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 the management of prostate cancer. The Veru prostate cancer pipeline includes VERU-111, zuclomiphene citrate and VERU-100. VERU-111 is an oral, next-generation, first-in-class 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 nonsteroidal estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by androgen deprivation therapy (ADT) in men with advanced prostate cancer. VERU-100 is a novel, proprietary peptide formulation for ADT with multiple potential beneficial clinical attributes addressing the shortfalls of current FDA-approved ADT formulations for the treatment of 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 luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. Currently there are no GnRH antagonists commercially approved beyond a one-month injection.

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 to treat urinary tract symptoms caused by benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment of 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 pre-NDA meeting with the FDA and the expected submission of the NDA for TADFIN is the second half of 2020. Veru is also developing Tamsulosin XR capsules which is a formulation of tamsulosin, the active ingredient in FLOMAX®, which Veru has designed to avoid the "food effect" inherent in currently marketed versions 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 against unwanted pregnancy and sexually transmitted infections, and the PREBOOST® 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. 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. In the U.S., FC2 is available by prescription through the Company's multiple telemedicine and internet pharmacy partners, and retail pharmacies, as well as OTC via the Company's website 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. PREBOOST® is marketed online in the U.S. through an exclusive marketing arrangement under the Roman Swipes brand name by Roman Health Ventures Inc. Roman is a leading telemedicine company that discreetly sells men's health products via the internet website www.getroman.com. To learn more about Veru products please visitwww.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 regarding the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies and FDA submissions, clinical study results including potential benefits, the market potential for the Company's drug candidates, and the Company's belief that it has sufficient resources to execute its clinical drug program through year end 2021. 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. 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; clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all; 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)

	September 30, 2019	2018
Cash and cash equivalents	$ 6,295,152	$ 3,759,509
Accounts receivable, net	5,021,057	3,972,632
Inventory, net	3,647,406	2,302,030
Prepaid expenses and other current assets	1,843,297	1,148,345
Total current assets	16,806,912	11,182,516
Property and equipment, net	351,895	404,552
Deferred income taxes	8,433,669	8,543,758
Intangible assets, net	20,168,495	20,477,729
Goodwill	6,878,932	6,878,932
Other assets	988,867	965,152
Total assets	$ 53,628,770	$ 48,452,639
Accounts payable	$ 3,124,751	$ 3,226,036
Accrued expenses and other current liabilities	5,509,575	3,447,014
Credit agreement, short-term portion	5,385,649	6,692,718
Unearned revenue	—	187,159
Total current liabilities	14,019,975	13,552,927
Credit agreement, long-term portion	2,886,382	2,701,570
Residual royalty agreement	3,845,518	1,753,805
Deferred income taxes	296,605	844,758
Other liabilities	247,154	118,161
Total liabilities	21,295,634	18,971,221
Total stockholders' equity	32,333,136	29,481,418
Total liabilities and stockholders' equity	$ 53,628,770	$ 48,452,639

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended September 30,		Year Ended September 30,	
	2019	2018	2019	2018
Net revenues	$ 8,728,403	$ 5,203,268	$ 31,803,387	$ 15,864,483
Cost of sales	2,895,670	2,016,472	10,146,565	7,091,942
Gross profit	5,832,733	3,186,796	21,656,822	8,772,541
Operating expenses	7,290,308	6,961,343	28,092,716	29,644,948
Operating loss	(1,457,575)	(3,774,547)	(6,435,894)	(20,872,407)
Non-operating (expenses) income	(2,024,022)	63,477	(5,885,405)	(2,199,880)
Loss before income taxes	(3,481,597)	(3,711,070)	(12,321,299)	(23,072,287)
Income tax (benefit) expense	(421,140)	4,208,441	(303,933)	866,102
Net loss	$ (3,060,457)	$ (7,919,511)	$(12,017,366)	$(23,938,389)
Net loss per basic and diluted common share outstanding	$ (0.05)	$ (0.14)	$ (0.19)	$ (0.44)
Basic and diluted weighted average common shares outstanding	65,037,604	55,136,704	63,323,127	53,861,981

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

	Year Ended September 30,	
	2019	**2018**
Net loss	$(12,017,366)	$(23,938,389)
Adjustments to reconcile net loss to net cash used in operating activities	8,096,208	8,852,822
Changes in operating assets and liabilities	(1,564,049)	3,539,376
Net cash used in operating activities	(5,485,207)	(11,546,191)
Net cash used in investing activities	(108,517)	(50,654)
Net cash provided by financing activities	8,129,367	12,078,752
Net increase in cash and cash equivalents	2,535,643	481,907
Cash and cash equivalents at beginning of period	3,759,509	3,277,602
Cash and cash equivalents at end of period	$ 6,295,152	$ 3,759,509