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 12, 2020

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

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 February 12, 2020, Veru Inc. issued a press release (the "Press Release") announcing results for the quarter ended December 31, 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 February 12, 2020.

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 12, 2020

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 Continues Strong Positive Sales Momentum in Fiscal 2020 First Quarter; Net Revenues Increase 66%, Gross Profit Up 57%

— Completion of VERU-111 Phase 1b Clinical Trial and Initiation of Phase 2 Prostate Cancer Clinical Trial in Q2 FY 2020 —

— Zuclomiphene Expected to Enter Pivotal Phase 3 Clinical Trial for Treating Hot Flashes in Men with Prostate Cancer on ADT Following Planned Meeting with FDA—

— Commercial Business Continues to Deliver Robust Growth —

— Company to Host Investor Conference Call Today at 8 a.m. ET to Discuss Financial Results and Business Highlights —

MIAMI — February 12, 2020 — Veru Inc. (NASDAQ: VERU), The Prostate Cancer Company, an oncology and urology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer, today announced that net revenues increased 66% and gross profit rose 57% for its fiscal 2020 first quarter ended December 31, 2019.

First-Quarter Financial Highlights: Fiscal 2020 vs Fiscal 2019

- Net revenues increased 66% to $10.6 million from $6.4 million;
- Gross profit increased 57% to $7.3 million from $4.6 million;
- FC2 US prescription net revenues increased 148% to $6.1 million from $2.4 million;
- Operating loss was $1.8 million; and
- Net loss was $3.3 million, or $0.05 per share.

“Our robust fiscal 2020 first quarter net revenues and gross profit were driven primarily by the 148% growth in prescription sales of FC2,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “Both our top line and gross profit for the period exceeded last year’s first quarter, as well as the preceding quarter. Increased public sector sales of FC2 and growing demand for our PREBOOST®/Roman® Swipes product were also key contributors to our positive momentum. We continue to generate significant cash to invest in the clinical development of our prostate and oncology drug pipeline. We are off to a great start for fiscal 2020.

“On the clinical development front, we are on target to complete before the end of our current quarter, the Phase 1b portion and to initiate the Phase 2 portion of the clinical trial for VERU-111, our proprietary prostate cancer product. VERU-111, an oral, next generation, first-in-class, selective antitubulin, has demonstrated preliminary antitumor activity in men with metastatic castration resistant prostate cancer and appears to be well tolerated with no evidence of treatment induced 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 39 patients from 4.5 mg per day up to 81

mg per day. The study protocol called for continuing to enroll patients until a maximum tolerated dose was reached, or some safety side effect that indicates that higher doses may not be well tolerated, was observed. There have been reported side effects consistent with VERU-111's and other antitubulins' cytotoxic effects, such as mostly mild to moderate diarrhea, nausea, and vomiting, which appear to be dose dependent.

"Although this study was designed for determination of safety, we do see evidence of preliminary 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 3.7 months. In our Phase 1b/2 trial, 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 11.75, 10.4, 10.4 and 7.6 months. All these men have prostate-specific antigen (PSA) reductions. We have another 6 men that progressed at 4.2 months. The patient who has reached 11.75 months had a PSA reduction of -63% and has had cancerous lymph nodes shrink as measured by CT scan and confirmed by a second CT scan. We also have another patient who at the time of enrollment had progressing prostate cancer bone metastases, show improvements of these bone metastases based on a bone scan following treatment with VERU-111. There is also evidence that these anticancer effects appear to have a dose response—meaning higher doses at 3-week cycles have more activity.

"Last month, we announced positive top line data from our Phase 2 clinical study of Zuclomiphene citrate, a nonsteroidal oral estrogen receptor agonist, for the treatment of androgen deprivation hormone therapy (ADT) induced hot flashes in men who have advanced prostate cancer. The interim results at Day 42 indicate that Zuclomiphene has clinically meaningful activity against moderate to severe hot flashes and appears to be well tolerated with no reports of estrogen related side effects like breast tenderness or enlargement or venothromboembolic events. We plan to meet with the FDA to review the development plan and based on that discussion, we anticipate initiation of the pivotal Phase 3 clinical trial to evaluate Zuclomiphene for the treatment of ADT-induced moderate to severe hot flashes in men with prostate cancer by early summer.

"Our plan is also to submit by the end of next quarter an Investigational New Drug (IND) application forVERU-100, our long-acting 3-month, small volume, subcutaneous depot gonadotropin-releasing hormone (GnRH) antagonist for the treatment of hormone sensitive advanced prostate cancer.

"TADFIN® (Tadalafil and Finasteride Combination Capsule), which is being developed for benign prostatic hyperplasia (BPH) and would be the first combination of a PDE5 inhibitor and 5 alpha reductase inhibitor, is collecting 12-month stability data on manufacturing batches. The Company will submit an NDA for TADFIN which is expected in the second half of 2020. Our plan is to launch this product in the U.S. via telemedicine.

"Finally, two of our scientific abstracts have been accepted for presentation at the prestigious American Society of Clinical Oncology's (ASCO) 2020 Genitourinary Cancers Symposium and are to be presented this weekend. The first presentation will provide proof of concept preclinical data on VERU-100 as a long acting GnRH antagonist subcutaneous depot. The second presentation is a survey of the impact of hot flashes on a contemporary cohort of men with advanced prostate cancer on ADT. This is the patient population that Zuclomiphene is being developed for to address this unmet medical need."

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. The call will also be available through a live, listen-only audio broadcast via the Internet at www.verupharma.com. Listeners are encouraged to visit the website at least 10 minutes prior to the start of the scheduled presentation to register,

download and install any necessary software. A playback of the call will be archived and accessible on the same website for at least three months. A telephonic replay of the conference call will be available, beginning the same day at approximately 12 p.m. (noon) ET by dialing 877-344-7529 for U.S. callers, or 412-317-0088 from outside the U.S., passcode 10138979, for one week.

About Veru Inc.

Veru Inc. is an oncology and urology biopharmaceutical company with a focus on 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. The clinical development program for VERU-111 is being expanded with plans to initiate additional Phase 2 studies. Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being evaluated for estrogenic activity in a Phase 2 trial (Stage 1 testing placebo, Zuclomiphene 10mg, and Zuclomiphene 50mg) to treat hot flashes, a common side effect caused by androgen deprivation therapy (ADT) in men with advanced prostate cancer. Veru plans to initiate a Phase 3 clinical trial for Zuclomiphene in the first half of 2020. 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. There are no GnRH antagonists commercially approved beyond a one-month injection. VERU-100 is anticipated to enter a 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 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 calendar year 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 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 against unwanted pregnancy and the transmission of 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 multiple third party telemedicine and internet pharmacy providers, 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 exclusively through online sales in the U.S. 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 and the absence of adverse events and the market potential for the Company's drug candidates. 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; the risk that the Company's products may not be commercially successful; 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; the risk that the Company's will be affected by regulatory developments, including a reclassification of products; 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 or the Company's U.S. prescription business 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, an outbreak of a contagious disease (such as the coronavirus), 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 fiscal year ended September 30, 2019. 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)

	December 31, 2019	September 30, 2019
Cash and cash equivalents	$ 4,174,957	$ 6,295,152
Accounts receivable, net	5,970,163	5,021,057
Inventory, net	4,595,390	3,647,406
Prepaid expenses and other current assets	2,075,414	1,843,297
Total current assets	16,815,924	16,806,912
Property and equipment, net	336,171	351,895
Operating lease right-of-use assets	1,153,779	—
Deferred income taxes	8,586,279	8,433,669
Intangible assets, net	20,089,403	20,168,495
Goodwill	6,878,932	6,878,932
Other assets	675,910	988,867
Total assets	$54,536,398	$53,628,770
Accounts payable	$ 3,827,874	$ 3,124,751
Accrued expenses and other current liabilities	6,103,412	5,509,575
Credit agreement, short-term portion	6,547,339	5,385,649
Operating lease liability, short-term portion	430,081	—
Total current liabilities	16,908,706	14,019,975
Credit agreement, long-term portion	1,913,573	2,886,382
Residual royalty agreement	4,768,696	3,845,518
Operating lease liability, long-term portion	970,378	—
Deferred income taxes	296,605	296,605
Other liabilities	35,907	247,154
Total liabilities	24,893,865	21,295,634
Total stockholders' equity	29,642,533	32,333,136
Total liabilities and stockholders' equity	$54,536,398	$53,628,770

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended December 31,	
	2019	**2018**
Net revenues	$10,578,016	$ 6,371,809
Cost of sales	3,308,921	1,727,729
Gross profit	7,269,095	4,644,080
Operating expenses	9,053,488	5,655,807
Operating loss	(1,784,393)	(1,011,727)
Non-operating expenses	(1,597,451)	(1,044,573)
Loss before income taxes	(3,381,844)	(2,056,300)
Income tax (benefit) expense	(76,743)	92,498
Net loss	$ (3,305,101)	$ (2,148,798)
Net loss per basic and diluted common share outstanding	$ (0.05)	$ (0.03)
Basic and diluted weighted average common shares outstanding	65,038,511	62,553,791

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

	Three Months Ended December 31,	
	2019	**2018**
Net loss	$(3,305,101)	$(2,148,798)
Adjustments to reconcile net loss to net cash used in operating activities	2,342,005	1,659,099
Changes in operating assets and liabilities	(1,547,406)	(1,016,782)
Net cash used in operating activities	(2,510,502)	(1,506,481)
Net cash used in investing activities	(21,807)	—
Net cash provided by financing activities	412,114	6,726,155
Net (decrease) increase in cash	(2,120,195)	5,219,674
Cash at beginning of period	6,295,152	3,759,509
Cash at end of period	$ 4,174,957	$ 8,979,183

Veru Inc.
Operating Income (Loss) by Segment
(unaudited)

	Three Months Ended December 31, 2019			
	Commercial	Research & Development	Corporate	Total
Net revenues				
FC2	$10,424,924	$ —	$ —	$10,424,924
PREBOOST	153,092	—	—	153,092
Total net revenues	10,578,016	—	—	10,578,016
Cost of sales	3,308,921	—	—	3,308,921
Gross profit	7,269,095	—	—	7,269,095
Operating expenses	1,465,502	5,246,381	2,341,605	9,053,488
Operating income (loss)	$ 5,803,593	$(5,246,381)	$(2,341,605)	$ (1,784,393)

	Three Months Ended December 31, 2018			
	Commercial	Research & Development	Corporate	Total
Net revenues				
FC2	$ 6,324,397	$ —	$ —	$ 6,324,397
PREBOOST	47,412	—	—	47,412
Total net revenues	6,371,809	—	—	6,371,809
Cost of sales	1,727,729	—	—	1,727,729
Gross profit	4,644,080	—	—	4,644,080
Operating expenses	1,284,899	2,361,823	2,009,085	5,655,807
Operating income (loss)	$ 3,359,181	$(2,361,823)	$(2,009,085)	$ (1,011,727)