

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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, 2017

VERU INC.

(Exact name of registrant as specified in its charter)

Wisconsin

(State or other jurisdiction of incorporation)

1-13602

(Commission File Number)

39-1144397

(I.R.S. Employer I.D. Number)

4400 Biscayne Boulevard
Suite 888
Miami, Florida

(Address of Principal Executive Offices)

33137

(Zip Code)

312-595-9123

(Registrant's telephone number, including area code)

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 August 8, 2017, Veru Inc. (formerly The Female Health Company) issued a press release (the "Press Release") announcing results for the quarter and nine months ended June 30, 2017. 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 August 8, 2017.

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, 2017

VERU INC.

BY: /s/ Daniel Haines
Daniel Haines, Chief Financial Officer



Veru Inc. Reports Fiscal Third Quarter Financial Results

MIAMI – August 8, 2017 – Veru Inc. (Nasdaq:VERU, formerly, Nasdaq:FHCO) (“Veru” or the “company”), formerly known as Veru Healthcare/The Female Health Company, a biopharmaceutical company focused on urology and oncology, today announces financial results from its fiscal third quarter 2017, which ended June 30, 2017. Management will host a teleconference and live webcast to review these results and corporate performance today at 8:00AM ET.

Summary of Accomplishments During FY Q3 and to Date

- The Company completed a positive Stage 1 of its bioequivalence (BE) study of Tamsulosin DRS, proprietary slow release granule formulation for benign prostatic hyperplasia (BPH), and in July, initiated the screening process for Stage 2 of the BE study for BPH, and started the NDA-required registration batch of the compound, which will be used for FDA submission.
- In June 2017, the Company met with FDA and, after receiving positive feedback, will advance VERU-944 (zuclopitene), its proprietary 505(b)(2) pathway drug candidate, into a Phase 2 clinical study for the treatment of hot flashes in men with advanced prostate cancer who are receiving hormone therapy.
- In June 2017, the Company released positive results from its Phase 4 trial of PREBOOST (topical 4% benzocaine wipes) for the management of premature ejaculation (PE). These results followed interim and final results that were featured in both a daily press conference and podium presentation at the 2017 American Urological Association Annual Meeting in Boston in May.
- The Company launched FC2 via prescription in the US and has established a 12-person sales force to market the product as a source of immediate new revenue.
- Unit sales of FC2 were 8.5 million in the third fiscal quarter 2017 compared to 10.7 million in the third fiscal quarter 2016.
- At a Special Meeting held on July 28, 2017, stockholders approved an increase in authorized common stock and the conversion of the outstanding Series 4 Preferred Stock to common stock, which simplifies the company’s capital structure.
- The Special Meeting also ratified the company changing its name to Veru Inc. from The Female Health Company d/b/a Veru Healthcare, reflecting a focus in biopharmaceutical products for urology and oncology.

“Veru has achieved key development milestones for both the company and our products. Our approach toward developing drug products via the 505(b)(2) development pathway means more expedited market access. We are enthusiastic about the progress for our drugs for BPH, PE and hot flashes associated with hormone therapy in men with advanced prostate cancer,” said Mitchell Steiner, MD, president and CEO of Veru. “Since the end of the third quarter, we have also made important corporate strides by launching FC2 US prescription business and by ensuring that we have flexibility to finance future opportunities, improving our ability to attract and retain top talent and clarifying our corporate identity with the consolidation under the Veru Inc. name and new ticker symbol. We are also encouraged by the unit sales of FC2 in the global public sector, which show a positive upward trend, and are confident in our ability to compete for historically large tenders in South Africa and Brazil expected later this year.”

Summary of FQ3 Financial Results

For the three months ended June 30, 2017, unit sales totaled 8.5 million, which is 21 percent lower than the 10.7 million from the same prior-year quarter. Net revenues totaled \$4.3 million, a decrease of 22 percent from the prior-year quarter of \$5.6 million. Gross profit decreased 29 percent to \$2.3 million for a margin of 53 percent compared with \$3.2 million for a margin of 58 percent in the prior-year quarter. Operating expenses increased by 49 percent from \$2.4 million for the prior-year quarter to \$3.6 million. Net loss for this fiscal quarter was approximately \$789,000, or 3 cents per diluted common share, compared to a gain of approximately \$570,000, or 2 cents per diluted common share, for the three months ended June 30, 2016.

During this fiscal quarter, Veru received several payments on aged receivables due from Brazil quarter totaling \$2.2 million, bringing total payments from Brazil to \$5.0 million for the nine months ended June 30, 2017. The total unpaid balance on the Brazil receivables was \$10.9 million as of June 30, 2017. An additional \$2.0 million was received subsequent to June 30, 2017, leaving a total of \$8.9 million remaining due from Brazil, \$1.1 million of which the Company expects to collect this fiscal year.

For the nine months ended June 30, 2017, unit sales totaled 19.4 million, which is down 45 percent from prior year of 35.3 million units. Excluding Brazil sales of 11.5 million units, which are included in the prior year total, unit sales were down 18 percent. Net revenues for the quarter totaled \$10 million, a decrease of 46 percent from the prior-year total of \$18.6 million. Gross profit decreased 54 percent to \$5.2 million for a margin of 52 percent compared with \$11.5 million for a margin of 62 percent in the comparable prior-year period. Operating expenses increased 34 percent from \$8.2 million for the prior-year to \$10.9 million. The increase in operating expenses was primarily due to an increase in research and development expenses for Veru's clinical development programs, which were not present in the prior year, and additional headcount associated with the FC2 prescription launch. Net loss for the nine months ended June 30, 2017 was \$3.9 million, or 13 cents per diluted common share, compared to net income of \$2.1 million, or 7 cents per diluted common share, in the nine months ended June 30, 2016.

Net working capital, which continues to benefit from collections on the Brazil receivables, was \$7.2 million as of June 30, 2017 compared to \$8.3 million as of the March 31, 2017. During the nine months ended June 30, 2017, the Company produced approximately \$405,000 of cash from operating activities, compared with using \$900,000 in the nine-month period ended 2016. As of June 30, 2017, we had \$2.7 million of cash, short term accounts receivable of \$5.8 million, and long-term accounts receivable of \$7.8 million.

Event Details

Interested investors may access the call by dialing 1-877-883-0383 from the U.S. or 1-412-902-6506 from outside the U.S. The participant entry code for all is 3833089.

In addition, investors may access a replay of the conference call at approximately noon ET dialing 1-877-344-7529 for US callers (international callers dial 1-412-317-0088) and entering the replay access code 10110602. This replay will be available for one week, after which, the recording will be available via the company's website at <https://veruhealthcare.com/investors>.

About Veru Inc.

Veru Inc. (Veru) is a biopharmaceutical company focused on urology and oncology. Veru utilizes FDA's 505(b)(2) regulatory approval pathway to develop and commercialize drug candidates. FDA's 505(b)(2) regulatory approval pathway is designed to allow for potentially expedited regulatory approval based on a previously established safety and efficacy profile of the product. Veru is developing products under the 505(b)(1) pathway as well, which is the traditional new drug application (NDA) pathway. The company is currently developing drug product candidates for benign prostatic hyperplasia (BPH or enlarged prostate), hot flashes associated with cancer treatment, male infertility and novel oral chemotherapy (alpha & beta tubulin inhibitor) for a variety of malignancies, including metastatic prostate, breast and ovarian cancers. In addition, the company sells the FC2 Female Condom® (now available by prescription in the US) and PREBOOST® medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation.

The company's division, The Female Health Company, manages the Global Public Health Division, which is focused on the global public health sector FC2 business. This division markets the company's Female Condom (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.

More information about Veru and its products can be found at www.veruhealthcare.com, www.PREBOOST.com and www.fc2femalecondom.com. For corporate and investor-related information about the Company, please visit <https://veruhealthcare.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. 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 as a result of new information or future events, developments or circumstances. Such forward-looking statements are inherently subject to known and unknown risks and uncertainties. The Company's actual results and future developments could differ materially from the results or developments expressed in, or implied by, these forward-looking 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: product demand and market acceptance; competition in the Company's markets and the risk of new competitors and new competitive product introductions; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; many of the Company's products are at an early stage of development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including 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 or restructuring; 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; the Company's reliance on its international partners in the consumer sector and on the level of spending on the female condom by country governments, global donors and other public health organizations in the global public sector; 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; risks related to the costs and other effects of litigation; 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, 2016. These documents are available on the "SEC Filings" section of our website at www.veruhealthcare.com/investors.

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Unaudited Condensed Consolidated Balance Sheets

	June 30, <u>2017</u>	September 30, <u>2016</u>
Cash	\$2,671,132	\$2,385,082
Accounts receivable, net	5,760,147	10,775,200
Income tax receivable	37,104	2,387
Inventory, net	2,765,369	2,492,644
Prepaid expenses and other current assets	<u>800,814</u>	<u>634,588</u>
Total current assets	12,034,566	16,289,901
Other trade receivables	7,837,500	7,837,500
Other assets	183,317	189,219
Plant and equipment, net	672,300	825,087
Deferred income taxes	9,027,096	13,482,000
Intangible assets, net	20,793,084	0
Goodwill	<u>6,878,932</u>	<u>0</u>
Total assets	<u>\$57,426,795</u>	<u>\$38,623,707</u>
Accounts payable	\$1,915,772	\$701,035
Accrued expenses and other current liabilities	1,593,830	2,380,571
Unearned revenue	964,382	0
Accrued compensation	<u>396,893</u>	<u>264,871</u>
Total current liabilities	4,870,877	3,346,477
Other liabilities	1,233,750	1,233,750
Deferred rent	61,442	0
Deferred income taxes	<u>465,766</u>	<u>110,069</u>
Total liabilities	6,631,835	4,690,296
Series 4 preferred stock	17,981,883	0
Total stockholders' equity	<u>32,813,077</u>	<u>33,933,411</u>
Total liabilities and stockholders' equity	<u>\$57,426,795</u>	<u>\$38,623,707</u>

Veru Inc.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended	
	June 30,	
	2017	2016
Net revenues	\$ 4,314,068	\$ 5,560,776
Cost of sales	2,019,154	2,327,583
Gross profit	2,294,914	3,233,193
Selling, general and administrative	3,134,239	2,361,951
Research and development	426,811	22,723
Total operating expenses	3,561,050	2,384,674
Operating (loss) income	(1,266,136)	848,519
Interest and other expense, net	(13,323)	(7,399)
Foreign currency transaction loss	(20,143)	(39,651)
(Loss) income before income taxes	(1,299,602)	801,469
Income tax (benefit) expense	(509,713)	231,211
Net (loss) income	\$ (789,889)	\$ 570,258
Net (loss) income per basic common share outstanding	\$ (0.03)	\$ 0.02
Basic weighted average common shares outstanding	30,991,247	28,655,970
Net (loss) income per diluted common share outstanding	\$ (0.03)	\$ 0.02
Diluted weighted average common shares outstanding	30,991,247	29,054,147

Veru Inc.
Unaudited Condensed Consolidated Statements of Operations

	Nine Months Ended	
	June 30,	
	2017	2016
Net revenues	\$ 9,963,186	\$ 18,564,236
Cost of sales	4,738,333	7,083,311
Gross profit	5,224,853	11,480,925
Selling, general and administrative	8,909,939	8,073,288
Research and development	2,034,973	96,138
Total operating expenses	10,944,912	8,169,426
Operating (loss) income	(5,720,059)	3,311,499
Interest and other expense, net	(35,630)	(54,551)
Foreign currency transaction loss	(40,838)	(128,442)
(Loss) income before income taxes	(5,796,527)	3,128,506
Income tax (benefit) expense	(1,863,815)	1,032,840
Net (loss) income	\$ (3,932,712)	\$ 2,095,666
Net (loss) income per basic common share outstanding	\$ (0.13)	\$ 0.07
Basic weighted average common shares outstanding	30,983,271	28,647,275
Net (loss) income per diluted common share outstanding	\$ (0.13)	\$ 0.07
Diluted weighted average common shares outstanding	30,983,271	29,058,576

Venu Inc.
Unaudited Condensed Consolidated Statements of Cash Flows

	Nine Months Ended	
	2017	June 30, 2016
Net (loss) income	\$ (5,932,712)	\$ 2,097,668
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:		
Depreciation and amortization	267,193	327,632
Amortization of intangible assets	106,916	0
Share based compensation	527,785	364,700
Warranty reserve	562,930	0
Deferred income taxes	(1,089,289)	789,197
Loss on disposition of fixed assets	9,973	496
Changes in current assets and liabilities, net of effects of acquisition of a business:		
Decrease (increase) in accounts receivable	5,022,028	(4,548,253)
Decrease (increase) in accounts payable	(34,717)	(7,249)
Decrease (increase) in inventory	(131,484)	(592,256)
Decrease (increase) in prepaid expenses and other assets	(1,595,953)	10,750
Decrease (increase) in accounts payable	127,525	(17,939)
Decrease (increase) in accrued expenses and other current liabilities	49,619	686,051
Net cash provided by (used in) operating activities	405,472	(891,705)
Net cash used in investing activities	(119,422)	(3,422)
Net increase (decrease) in cash	286,050	(895,130)
Cash at beginning of period	2,383,082	3,288,214
Cash at end of period	\$ 2,671,132	\$ 2,393,084

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