

August 14, 2018



## Veru Reports Fiscal 2018 Third Quarter Financial Results

*-- Investigational New Drug Application with the FDA Accepted for Phase 2 Study of Zuclomiphene --*

*-- VERU-111 Preclinical Efficacy Data in Four Different Cancers Presented at American Society of Clinical Oncology (ASCO) Annual Meeting --*

*-- FC2 Female Condom Business Has Strong Quarter in Net Revenues --*

*-- Company to Host Investor Conference Call on Tuesday, Aug. 14, 2018, at 8 a.m. ET--*

MIAMI, Aug. 14, 2018 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company, today announced its financial results for the fiscal 2018 third quarter ended June 30, 2018.

"We have made strong progress in this quarter advancing our pipeline of proprietary prostate cancer product candidates and suite of urology specialty pharmaceuticals," commented Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer. "We look forward to enrolling the first patient in the Phase 2 trial of zuclomiphene (aka *cis*-clomiphene) to treat hot flashes caused by prostate cancer hormone therapy during the fiscal fourth quarter of 2018. Within this calendar year, we expect to conduct the bioequivalence studies for new formulation product candidates tamsulosin DRS granules and XR capsules, as well as tadalafil-finasteride combination tablets. Our product candidates address unmet medical needs in prostate cancer, prostate cancer supportive care, and urology which are multibillion dollar markets."

"With regard to our financial results: net revenues, which are primarily derived from product sales of *FC2 Female Condoms*<sup>®</sup>, increased 28% in the third quarter of fiscal 2018 over the comparable prior year period and more than doubled from the preceding quarter. We are expecting the South African government to announce soon the results of the tender award for 40 million female condoms per year -- a total of 120 million units over the full three-year tender time period — and we are confident that we will receive a substantial portion of the award."

### Summary of Accomplishments During FY Q3

In June 2018, the Company submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration for a Phase 2 clinical study of zuclomiphene for the treatment of hot flashes in men with advanced prostate cancer who are receiving hormone

therapy, which has been accepted. Also in June, the U.S. Patent and Trademark Office issued Patent No. 9,913,815, which provides protection until 2035 for the use of zuclomiphene in men with prostate cancer as a method of treating and preventing side effects caused by androgen deprivation therapy (ADT), including hot flashes, loss of bone mineral density and bone fractures.

In May 2018, preclinical results for VERU-111, a novel oral alpha and beta tubulin inhibitor with potential for development in the treatment of prostate and other cancer types, were featured in a moderated poster session at the 2018 American Urological Association Annual Meeting. In June 2018, preclinical results showing the efficacy of VERU-111 in four different cancer models (novel androgen blocking agent resistant human prostate cancer, a paclitaxel sensitive and resistant triple negative breast cancer, as well as ovarian cancer and pancreatic cancer) were presented as part of the American Society of Clinical Oncology (ASCO) Annual Meeting.

### **Fiscal Third Quarter Results: 2018 vs. 2017**

For the third quarter of fiscal 2018, net revenues increased to \$5.5 million from \$4.3 million for the third quarter of fiscal 2017. Gross profit rose to \$3.1 million, or 56% of net revenues, from \$2.3 million, or 53% of net revenues, for the third quarter of fiscal 2017. Operating expenses were \$8.0 million compared with \$3.6 million. Net loss was \$7.9 million, or \$0.15 per share, compared with \$0.8 million, or \$0.03 per share, for the third quarter of fiscal 2017.

Significant quarter-to-quarter variations in the Company's results have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for female condoms.

### **Conference Call Event Details**

Veru Inc. will host a conference call on Tuesday, Aug. 14, 2018, at 8 a.m. Eastern Time 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 ET by dialing 877-344-7529 for U.S. callers, or 412-317-0088 from outside the U.S., passcode 10122133. 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 and prostate cancer supportive care as well as near term specialty pharmaceuticals to address significant unmet needs in urology.

The Veru prostate cancer pipeline includes zuclomiphene citrate (aka VERU-944, *cis*-clomiphene) and VERU-111 (bisindole). Zuclomiphene citrate is an estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men who have advanced prostate cancer. VERU-111 is an oral, next-generation, first-in-class, antitubulin agent targeting alpha and beta tubulin of microtubules to treat castration and novel androgen blocking agent (abiraterone or enzalutamide) resistant metastatic prostate cancer that Veru expects to enter Phase 1/2

development in late 2018.

Veru is advancing four new drug formulations in our specialty pharmaceutical pipeline addressing unmet medical needs in urology. Tamsulosin DRS granules and XR capsules are formulations of a super selective alpha-1 adrenergic receptor antagonist for the treatment of benign prostatic hyperplasia (BPH) without a food effect, allowing for potentially safer administration and improved drug compliance (NDA filing expected in 2018). Tadalafil/finasteride combination tablets are for inhibition of both phosphodiesterase type 5 (PDE5) and 5-alpha-reductase to shrink an enlarged prostate, treat symptoms of BPH and treat erectile dysfunction (NDA filing expected in 2019). Solifenacin DRG slow release granules are a formulation of a selective M3 muscarinic receptor antagonist for the treatment of overactive bladder in patients who have difficulty with swallowing tablets (NDA filing expected in 2019).

The company markets and sells the PREBOOST<sup>®</sup> medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation being co-promoted with Timm Medical Technologies, Inc. The company also markets and sells the FC2 Female Condom<sup>®</sup> (now available by prescription in the U.S. including through the virtual doctor smartphone app "HeyDoctor" at [www.fc2.us.com](http://www.fc2.us.com)) in the United States and through The Female Health Company Division in the global public health sector. The Female Health Company Division markets to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. More information about Veru and its products can be found at [www.verupharma.com](http://www.verupharma.com), [www.PREBOOST.com](http://www.PREBOOST.com), [www.fc2.us.com](http://www.fc2.us.com) and [www.fc2femalecondom.com](http://www.fc2femalecondom.com). For corporate and investor-related information about the Company, please visit <https://verupharma.com/investors>.

**"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:**

*The statements in this release that are not historical fact are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements relating to the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies and FDA submissions, and the amount and timing of the South African tender award. Any forward-looking statements in this release are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this release. The Company assumes no obligation to update any forward-looking statements contained in this release because of new information or future events, developments or circumstances. Such forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, and if any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, the following: risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; potential delays in the timing of and results from clinical trials and studies and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development; risks*

relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; product demand and market acceptance; competition in the Company's markets and the risk of new or existing competitors with greater resources and capabilities and new competitive product introductions; price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters, including costs and delays resulting from 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; 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 due to labor unrest or strikes; risks related to the costs and other effects of litigation, including product liability claims; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended September 30, 2017. These documents are available on the "SEC Filings" section of our website at [www.verupharma.com/investors](http://www.verupharma.com/investors).

**Veru Inc.**  
**Condensed Consolidated Balance Sheets**  
**June 30, 2018 and September 30, 2017**

	<b>June 30, 2018</b>	<b>September 30, 2017</b>
Cash	\$ 5,577,440	\$ 3,277,602
Accounts receivable, net	3,668,673	3,555,350
Inventory, net	2,653,887	2,767,924

Prepaid expenses and other current assets	958,481	697,097
Total current assets	12,858,481	10,297,973
Other trade receivables	—	7,837,500
Plant and equipment, net	465,789	555,539
Deferred income taxes	12,194,000	8,827,000
Intangible assets, net	20,546,544	20,752,991
Goodwill	6,878,932	6,878,932
Other assets	527,249	156,431
Total assets	<u>\$ 53,470,995</u>	<u>\$ 55,306,366</u>
Accounts payable	\$ 3,461,641	\$ 2,685,718
Accrued expenses and other current liabilities	1,713,143	1,441,359
Credit agreement, short-term portion	6,428,567	—
Unearned revenue	760,981	1,014,517
Accrued compensation	355,800	345,987
Total current liabilities	12,720,132	5,487,581
Credit agreement, long-term portion	4,274,428	—
Residual royalty agreement	517,314	—
Other liabilities	89,093	1,365,580
Total liabilities	17,600,967	6,853,161
Total stockholders' equity	35,870,028	48,453,205
Total liabilities and stockholders' equity	<u>\$ 53,470,995</u>	<u>\$ 55,306,366</u>

**Veru Inc.**  
**Condensed Consolidated Statements of Operations**  
**Three and Nine Months Ended June 30, 2018 and 2017**

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2018	2017	2018	2017
Net revenues	\$ 5,501,730	\$ 4,314,068	\$ 10,661,215	\$ 9,963,186
Cost of sales	2,424,235	2,019,154	5,069,804	4,738,333
Gross profit	3,077,495	2,294,914	5,591,411	5,224,853
Operating expenses	8,042,223	3,561,050	22,689,271	10,944,912

Operating loss	(4,964,728 )	(1,266,136 )	(17,097,860 )	(5,720,059 )
Non-operating expenses	(1,759,649 )	(33,466 )	(2,263,357 )	(76,468 )
Loss before income taxes	(6,724,377 )	(1,299,602 )	(19,361,217 )	(5,796,527 )
Income tax expense (benefit)	1,206,131	(509,713 )	(3,342,339 )	(1,863,815 )
Net loss	<u>\$ (7,930,508 )</u>	<u>\$ (789,889 )</u>	<u>\$ (16,018,878 )</u>	<u>\$ (3,932,712 )</u>
Net loss per basic and diluted common share outstanding	\$ (0.15 )	\$ (0.03 )	\$ (0.30 )	\$ (0.13 )
Basic and diluted weighted average common shares outstanding	53,789,409	30,991,247	53,432,404	30,983,271

**Veru Inc.**  
**Condensed Consolidated Statements of Cash Flows**  
**Nine Months Ended June 30, 2018 and 2017**

	<b>Nine Months Ended June 30,</b>	
	<b>2018</b>	<b>2017</b>
Net loss	\$ (16,018,878 )	\$ (3,932,712 )
Adjustments to reconcile net loss to net cash (used in) provided by operating activities	4,132,551	(534,602 )
Changes in current assets and liabilities, net of effects of acquisition of a business	3,155,109	4,872,786
Net cash (used in) provided by operating activities	(8,731,218 )	405,472
Net cash used in investing activities	(47,696 )	(119,422 )
Net cash provided by financing activities	11,078,752	—

Net increase in cash	2,299,838	286,050
Cash at beginning of period	<u>3,277,602</u>	<u>2,385,082</u>
Cash at end of period	<u>\$ 5,577,440</u>	<u>\$ 2,671,132</u>

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Source: Veru Inc.