Investor Relations - SWK Holdings

Veru Reports Strong Fiscal 2019 First Quarter Financial Results

— Drug Development Advancing: Successful TADFIN Clinical Trial with NDA Filing in 2019; Two Prostate Cancer Clinical Trials Enrolling — — Company to Host Investor Conference Call on Wednesday, February 13, 2019, 8 a.m. ET —

MIAMI, Feb. 13, 2019 (GLOBE NEWSWIRE) — Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company developing novel medicines for the prostate cancer continuum of care and urology specialty pharmaceuticals, today reported financial results and business highlights for its fiscal 2019 first quarter ended December 31, 2018.

Fiscal 2019 First Quarter Financial Results

- Company net revenues up 146% to $6.4 million from $2.6 million in the prior-year first quarter. Company reported FC2 Female Condom / FC2 Internal Condom® (FC2) sales growth in both its prescription business and in its public sector business;
- Company gross profit up 254% to $4.6 million from $1.3 million in the prior-year first quarter;
- Company gross margin increased to 73% from 51% in the prior-year first quarter;
- FC2 prescription business net revenues up 1,500% to $2.4 million from $0.15 million in the prior-year first quarter. Compound Annual Growth Rate (CAGR) of 100% over last five quarters for net revenues of FC2 prescription business;
- FC2 public sector business net revenues up 60% to $3.9 million from $2.4 million in the prior-year first quarter;
- CAGR of 25% over the last five quarters for net revenues of total FC2 business;
- Commercial Segment (FC2, PREBOOST® and drug commercialization costs) operating income was $3.7 million versus $0.1 million in the prior-year first quarter;
- Operating loss significantly narrowed by 86% to $1.0 million from $7.4 million in the fiscal 2018 first quarter (the fiscal 2018 first quarter included a $3.8 million loss for the settlement of Brazilian receivables); and
- Net loss of $2.1 million, or $0.03 per share, was significantly less than $4.3 million, or $0.08 per share, in the first quarter of fiscal 2018.

“We are pleased to report strong financial results in the fiscal 2019 first quarter, including excellent topline growth, substantially higher gross profit and a significantly lower operating loss,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. “The improvement was driven by increased sales of FC2 in our prescription business as well as in our public sector business. We recently changed the sales strategy of our FC2 prescription business, which has a higher gross margin, making the growth of that part of our business particularly gratifying. Growing prescription sales of FC2 should help smooth out some of the fluctuations in total FC2 net revenues that we have historically seen due to ordering patterns related to our FC2 public sector business.”

Recent Business and Operational Highlights

- Announced the Company’s strategy to become known as “the prostate cancer company” and to provide a “continuum of care” for prostate cancer patients. Prostate cancer remains the second most frequent cause of cancer deaths in men and drugs to manage prostate cancer are large market opportunities. Our drug development and drug commercial activities will largely align with the clinical management of prostate cancer patients. Anticipated revenue from our urology specialty pharma business and existing commercial products will help to support these efforts;
- Initiated a Phase 1b/2 clinical trial and enrolled patients for VERU-111, a novel, proprietary, next generation, first-in-class oral selective antitubulin agent that targets and disrupts alpha and beta tubulin for advanced prostate cancer and potentially other cancers, with clinical data expected in 2019. Drugs for advanced prostate cancer currently have over $3 billion in U.S. annual sales;
- Initiated a Phase 2 clinical trial and enrolled patients for zuclomiphene citrate, a novel, proprietary, oral, nonsteroidal, estrogen receptor agonist to treat hot flashes caused by androgen deprivation therapy, or hormone treatment for men with advanced prostate cancer; top line results expected Summer 2019. Based on an independent market analysis sponsored by the Company, the Company estimates the U.S. market potential for zuclomiphene citrate is over $600 million annually;
- Completed a successful bioavailability and bioequivalence clinical trial for the Company’s proprietary tadalafil and finasteride combination tablet (TADFIN™) for benign prostatic hyperplasia with a New Drug Application (NDA) to be submitted in 2019 and approval expected in 2020. BPH is an established multi-billion-dollar market;
- Signed a multi-year exclusive supply and distribution agreement to supply the Company’s PREBOOST® premature ejaculation wipes to 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;
- Four abstracts accepted for presentation for VERU-111 and zuclomiphene citrate at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium in February 2019;
- Three abstracts accepted for presentation for VERU-111 at the European Association of Urology Congress in March 2019; and
- One abstract accepted for presentation for VERU-111 at the American Urological Association Annual Meeting in May 2019.

"We are focused on advancing our pipeline of drug candidates for the continuum of care for prostate cancer, which have a combined addressable market of multiple billions of dollars, noted Dr. Steiner. We continue to run a lean operation, with our existing commercial businesses helping to fund the development of our prostate cancer and our urology specialty pharmaceuticals. Even after costs associated with all of our pharmaceutical clinical development programs in the most recently completed quarter, our operating loss significantly narrowed to approximately a $1 million loss for the quarter. Anticipated strong growth in revenues from our current commercial products combined with anticipated new revenue from our TADFIN™ for BPH, which we expect to launch in 2020, should allow us to continue to significantly invest in our prostate cancer proprietary pharmaceuticals, to seek strong commercialization partnerships, and to access large, well-established urology and prostate cancer markets around the globe."

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 12 p.m. (noon) ET by dialing 877-344-7529 for US callers, or 412-317-0088 from outside the U.S., passcode 10128045. 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 prostate cancer continuum of care and urology specialty pharmaceuticals. The Veru prostate cancer pipeline includes zuclomiphene citrate (also known as 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 with advanced prostate cancer. VERU-111 is an oral, next-generation, first-in-class selective small molecule that targets and disrupts alpha and beta subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen blocking agent (abiraterone or enzalutamide) therapies. VERU-111 is being evaluated in men with metastatic refractory prostate cancer in an open label phase 1b/2 clinical trial.

Veru is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology. The clinical trial of the Company's proprietary Tadalafil and Finasteride Combination tablet (TADFIN™ tablet) met FDA requirements for bioavailability and bioequivalence for the co-administration of tadalafil 5mg and finasteride 5mg dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride (PROSCAR® and PROPECIA®) is currently approved for treatment BPH and male pattern hair loss. The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than either drug alone. The Company anticipates submitting an NDA for its TADFIN™ tablet under the 505(b)(2) regulatory pathway in the second half of calendar year 2019. 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.

Veru's commercial products include the FC2 Female Condom / FC2 Internal Condom® (FC2), an FDA-approved product for the dual prevention of unwanted pregnancy and sexually transmitted infections, and the PREBOOST® medicated individual wipe for the prevention of premature ejaculation. Veru's Female Health Company Division markets FC2 commercially and in the public health sector both in the U.S. and globally. FC2 is available by prescription in the U.S. including through the virtual doctor smartphone app "HeyDoctor" at www.fc2.us.com. For PREBOOST® Veru has a co-promotion and distribution agreement with Timm Medical Technologies, Inc., a specialty urology sales organization, and the Company has also entered into a multi-year exclusive supply and distribution 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. To learn more about these 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 relating to the regulatory pathway to secure FDA approval of the Company’s drug candidates, the anticipated timeframe for clinical studies, clinical study results, FDA submissions and FDA approvals, the market potential for the Company’s drug candidates, the potential for revenue growth of current commercial products, including the FC2 prescription business and public sector business, and whether clinical trial results support the effectiveness and safety profile shown by preclinical studies for VERU-111 and zuclomiphene citrate. 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 product 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, 2018. These documents are available on the “SEC Filings” section of our website at www.verupharma.com/investors.

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	December 31, 2018	September 30, 2018
Cash	$ 8,979,183	$ 3,759,509

Accounts receivable, net	2,487,096	3,972,632
Inventory, net	2,698,306	2,302,030
Prepaid expenses and other current assets	1,208,446	1,148,345
Total current assets	15,373,031	11,182,516
Plant and equipment, net	361,998	404,552
Deferred income taxes	8,546,718	8,543,758
Intangible assets, net	20,400,420	20,477,729
Goodwill	6,878,932	6,878,932
Other assets	773,861	965,152
Total assets	$ 52,334,960	$ 48,452,639
Accounts payable	$ 2,103,711	$ 3,226,036
Accrued research and development costs	569,873	981,357
Accrued expenses and other current liabilities	2,076,009	2,450,364
Credit agreement, short-term portion	4,943,543	6,692,718
Unearned revenue	49,095	202,452
Total current liabilities	9,742,231	13,552,927
Credit agreement, long-term portion	2,996,120	2,701,570
Residual royalty agreement	1,702,576	1,753,805
Other liabilities	30,000	30,000
Deferred rent	86,328	88,161
Deferred income taxes	895,862	844,758
Total liabilities	15,453,117	18,971,221
Total stockholders’ equity	36,881,843	29,481,418
Total liabilities and stockholders’ equity	$ 52,334,960	$ 48,452,639

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended December 31,	
	2018	2017
Net revenues	$ 6,371,809	$ 2,586,613
Cost of sales	1,727,729	1,272,992
Gross profit	4,644,080	1,313,621
Operating expenses	5,655,807	8,750,202
Operating loss	(1,011,727)	(7,436,581)
Non-operating expenses	(1,044,573)	(66,624)
Loss before income taxes	(2,056,300)	(7,503,205)
Income tax expense (benefit)	92,498	(3,246,053)

Net loss	$ (2,148,798)	$ (4,257,152)
Net loss per basic and diluted common share outstanding	$ (0.03)	$ (0.08)
Basic and diluted weighted average common shares outstanding	62,553,791	53,154,076

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

	Three Months Ended December 31,	
	2018	2017
Net loss	$ (2,148,798)	$ (4,257,152)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities	1,659,099	782,636
Changes in operating assets and liabilities	(1,016,782)	3,771,178
Net cash (used in) provided by operating activities	(1,506,481)	296,662
Net cash used in investing activities	—	(1,914)
Net cash provided by financing activities	6,726,155	—
Net increase in cash	5,219,674	294,748
Cash at beginning of period	3,759,509	3,277,602
Cash at end of period	$ 8,979,183	$ 3,572,350

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