Investor Relations - SWK Holdings

Veru Reports Strong Fiscal 2019 Second-Quarter Financial Results

— Prostate Cancer Clinical Trials Advancing; Early Clinical Observations Look Promising – — Strong Financial Results for Q2 and YTD FY 2019 — — Company to Host Investor Conference Call on Wednesday, May 15, 2019, 8 a.m. ET –

MIAMI, May 15, 2019 (GLOBE NEWSWIRE) — Veru Inc. (NASDAQ: VERU) an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer treatment and prostate cancer supportive care, today announced its financial results for its fiscal 2019 second quarter ended March 31, 2019.

Business and Operational Highlights

- VERU-111: Our oral, next-generation, first-in-class, alpha and beta antitubulin is being evaluated in men who have metastatic prostate cancer and whose disease is resistant to both castration and novel androgen blocking agents (abiraterone or enzalutamide). The open label Phase 1b clinical trial being conducted to determine the maximally tolerated dose is progressing. The open label Phase 2 clinical study is expected to commence in the Fall of 2019. Oral drugs for advanced prostate cancer, abiraterone and enzalutamide, had over $3 billion in U.S. annual sales in 2018 and $6 billion in 2018 global revenue. Men with metastatic castration resistant prostate cancer who have failed these novel androgen blocking agents is the population that VERU-111 is targeting which represents an estimated $4.5 billion annual global market.
- Zuclomiphene Citrate: Enrollment of approximately 100 men in the Phase 2 clinical trial is progressing in approximately 17 clinical sites in the US. Top line results of the study are expected Summer 2019. Zuclomiphene Citrate is 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. Based on an independent market analysis sponsored by the Company, the expected U.S. sales potential for zuclomiphene citrate is estimated to exceed $600 million annually.
- TADFIN™ (Tadalafil and Finasteride Combination Tablet): As previously announced, the Company completed a successful bioavailability and bioequivalence clinical trial for TADFIN for benign prostatic hyperplasia. The Company filed patent applications that, if issued, would have an expiry of 2040. NDA submission expected late 2019 to early 2020 with anticipated approval in 2020. BPH is an established multi-billion-dollar market.

“The clinical development of our proprietary drug pipeline is advancing,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “In clinical observations, VERU-111 appears to be well tolerated, with no documented complaints or evidence of neurotoxicity or neutropenia. Moreover, in a number of men whose PSA was rising prior to enrollment into the Phase 1b clinical trial, we are seeing some evidence of PSA stabilizations and reductions even at the lowest doses of VERU-111 being tested, which is a promising early indication of efficacy. As for our zuclomiphene citrate product, based on the blinded aggregate preliminary clinical data from our placebo-controlled trial, we can make the following general clinical observations: men are experiencing reductions in hot flashes; and as for safety, zuclomiphene citrate appears to be well tolerated.”

Fiscal 2019 Second Quarter vs Fiscal 2018 Second Quarter Financial Results

- Net revenues up 171% to $7.0 million from $2.6 million. Company reported FC2 sales growth in both its public sector and its US prescription channels;
- Gross profit up 285% to $4.6 million, or 66% of net revenues, from $1.2 million, or 47% of net revenues;
- FC2 US prescription channel net revenues up 753% to $2.6 million from $0.3 million;
- FC2 public sector channel net revenues up 88% to $4.2 million from $2.3 million;
- Financial results do not reflect the new tender orders that will be coming from South Africa. We expect new orders from South Africa to commence shipping during the third quarter of this fiscal year;
- Commercial segment, which includes FC2, PREBOOST® and drug commercialization costs, generated operating income of $3.2 million versus an operating loss of $163,000;
- Operating loss significantly narrowed to $2.1 million from $4.7 million; and
- Net loss was $4.0 million, or $0.06 per share, compared with $3.8 million, or $0.07 per share.

Fiscal 2019 Year-to-Date vs Fiscal 2018 Year-to-Date Financial Results

- Net revenues up 159% to $13.3 million from $5.2 million;
- Gross profit up 268% to $9.3 million, or 69% of net revenues, from $2.5 million, or 49% of net revenues;
- Net revenue from the US prescription channel was up 1,000% to $5.0 million from $458,000 in the prior-year period;
- Net revenue for the public sector channel was up 73% to $8.1 million from $4.7 million in the prior-year period;

- Net revenue for PREBOOST/ Roman Swipes was $180,000 compared to $4,600 in the prior-year period; an increase of 3800%;
- Operating loss down 74% to $3.1 million from $12.1 million (fiscal 2018 year to date included a $3.8 million loss for the settlement of Brazilian receivables); and
- Net loss was $6.2 million, or $0.10 per share, compared with $8.1 million, or $0.15 per share.

“We have achieved strong operating results through the first two quarters of fiscal 2019,” said Dr. Steiner. “Positive financial growth continued into our second quarter, with sequential quarterly increases to net revenues from both our FC2 US prescription and public sector channels. Growth of our US FC2 prescription channel is particularly noteworthy as it appears to be less reliant on traditional intermittent ordering patterns present in our FC2 public sector channel.”

Financial Guidance
Management expects net revenues will grow to $29-32 million for the full year FY2019 which represents a 95% increase over the full year FY2018, and management expects gross margin will be approximately 66% in FY2019 compared to 55% in FY2018.

“Based on current cash on hand and expected cash from current sales forecasts, along with existing sources of capital, the Company does not anticipate the need for a new equity financing until at least fiscal 2021,” said Dr. Steiner.

The Company does not expect to update the guidance for the full year fiscal 2019 provided above before the release announcing results for the next fiscal quarter. The Company notes that the statements of future performance made in this release, including the guidance for the full fiscal year 2019, are based upon current expectations and are subject to factors that could cause actual results to differ materially from those suggested here, including those factors set forth in the “Safe Harbor” Statement below.

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 US callers, or 412-317-0088 from outside the U.S., passcode 10130716. 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 treatment and prostate cancer supportive care as well as 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 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.

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 is currently approved for treatment 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 anticipates submitting an NDA for its TADFIN™ tablet under the 505(b)(2) regulatory pathway between the fourth quarter of calendar year 2019 and the first quarter of calendar year 2020. 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.

The Company’s commercial products include the FC2 Female Condom / FC2 Internal Condom® (“FC2”), an FDA-approved product for the dual protection of unwanted pregnancy and sexually transmitted infections, and the

PREBOOST® 4% benzocaine medicated individual wipe for the prevention of premature ejaculation (also marketed as Roman Swipes). 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. FC2 is available by prescription and OTC in the U.S. including through the virtual doctor smartphone app "HeyDoctor" 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. For PREBOOST, the Company 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 U.S. distributor 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 website www.getroman.com. To learn more about Veru 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 under "Financial Guidance" regarding expected net revenues and gross margin for the full fiscal year 2019 and the Company's anticipation that it will not need a new equity financing until at least fiscal year 2021 and statements relating to the timing of orders and shipments from South Africa, the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies, clinical study results including potential benefits, and FDA submissions, the market potential for the Company's drug candidates, and whether clinical trial results will support the effectiveness and safety profile shown by initial clinical data. 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, including, with respect to the financial guidance, assumptions regarding the timing of orders and shipments and the impact on gross margins of the mix of sales in the public sector channel as compared to the U.S. prescription channel. 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 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.

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	March 31, 2019	September 30, 2018
Cash	$ 5,896,536	$ 3,759,509
Accounts receivable, net	4,027,235	3,972,632
Inventory, net	2,998,201	2,302,030
Prepaid expenses and other current assets	1,220,908	1,148,345
Total current assets	14,142,880	11,182,516
Plant and equipment, net	320,802	404,552
Deferred income taxes	8,570,150	8,543,758
Intangible assets, net	20,323,112	20,477,729
Goodwill	6,878,932	6,878,932
Other assets	776,178	965,152
Total assets	$ 51,012,054	$ 48,452,639
Accounts payable	$ 2,525,162	$ 3,226,036
Accrued expenses and other current liabilities	2,910,350	3,447,014
Credit agreement, short-term portion	5,836,615	6,692,718
Unearned revenue	–	187,159
Total current liabilities	11,272,127	13,552,927
Credit agreement, long-term portion	2,717,934	2,701,570
Residual royalty agreement	2,341,522	1,753,805
Deferred income taxes	895,860	844,758
Other liabilities	240,594	118,161
Total liabilities	17,468,037	18,971,221
Total stockholders' equity	33,544,017	29,481,418
Total liabilities and stockholders' equity	$ 51,012,054	$ 48,452,639

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Net revenues	$ 6,976,115	$ 2,572,872	$ 13,347,924	$ 5,159,485
Cost of sales	2,367,264	1,374,936	4,094,993	2,647,928
Gross profit	4,608,851	1,197,936	9,252,931	2,511,557
Operating expenses	6,733,441	5,894,486	12,389,248	14,644,689
Operating loss	(2,124,590)	(4,696,550)	(3,136,317)	(12,133,132)
Non-operating expenses	(1,884,278)	(437,084)	(2,928,851)	(503,707)
Loss before income taxes	(4,008,868)	(5,133,634)	(6,065,168)	(12,636,839)
Income tax expense (benefit)	25,167	(1,302,416)	117,665	(4,548,469)
Net loss	$ (4,034,035)	$ (3,831,218)	$ (6,182,833)	$ (8,088,370)
Net loss per basic and diluted common share outstanding	$ (0.06)	$ (0.07)	$ (0.10)	$ (0.15)
Basic and diluted weighted average common shares outstanding	62,767,258	53,355,944	62,659,352	53,253,901

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

	Six Months Ended March 31,	
	2019	2018

Net loss	$ (6,182,833)	$ (8,088,370)
Adjustments to reconcile net loss to net cash used in operating activities	4,291,238	325,404
Changes in operating assets and liabilities	(2,110,984)	3,579,775
Net cash used in operating activities	(4,002,579)	(4,183,191)
Net cash used in investing activities	(644)	(1,913)
Net cash provided by financing activities	6,140,250	9,880,000
Net increase in cash	2,137,027	5,694,896
Cash at beginning of period	3,759,509	3,277,602
Cash at end of period	$ 5,896,536	$ 8,972,498

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