August 11, 2022

Veru Reports Third Quarter Fiscal 2022 Financial Results; Progresses Sabizabulin Treatment for COVID-19 Towards Regulatory Decisions in Key Territories

--Sabizabulin for COVID-19 Emergency Use Authorization Application Submitted to U.S. FDA in June 2022--

--The UK's Medicines and Healthcare Products Regulatory Agency Informed the Company that its Sabizabulin Marketing Authorization Application Will Receive Expedited Review--

--European Medicines Agency's Emergency Task Force Initiated Review of Sabizabulin Treatment for Hospitalized COVID Patients for Emergency Use in European Union Countries--

--The New England Journal of Medicine Evidence® Published Phase 3 Clinical Trial Results Demonstrating that Sabizabulin Treatment Significantly Reduced Deaths in High-Risk Hospitalized COVID-19 Patients--

--Company Prepares for U.S. and Ex-U.S. Commercial Launches if Emergency Authorizations Are Granted--

--Company to Host Investor Conference Call Today at 8 AM ET--

MIAMI, Aug. 11, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and Acute Respiratory Distress Syndrome (ARDS)-related diseases and for the management of breast and prostate cancers, today announced financial results for its fiscal 2022 third quarter ended June 30, 2022, and sabizabulin for COVID progress towards regulatory decisions in key territories.

Third Quarter Financial Summary: Fiscal 2022 vs Fiscal 2021

- Total net revenues decreased 46% to $9.6 million from $17.7 million
- US FC2 prescription net revenues decreased 50% to $6.7 million from $13.5 million
- Gross profit decreased 49% to $7.1 million from $13.9 million
- Gross margin decreased to 74% of net revenues from 79% of net revenues
- Research and development expenses increased to $18.1 million from $11.2 million

- Operating loss was $21.8 million versus $2.9 million
- Net loss was $22.2 million, or $0.28 per share, compared to $2.7 million, or $0.03 per share

Year-to-Date Financial Summary: Fiscal 2022 vs Fiscal 2021

- Total net revenues decreased 19% to $36.8 million from $45.6 million
- US FC2 prescription net revenues decreased 9% to $29.9 million from $32.9 million
- Gross profit decreased 16% to $30.1 million from $35.6 million
- Gross margin increased to 82% of net revenues from 78% of net revenues
- Research and development expenses increased to $43.8 million from $24.4 million
- Operating loss was $38.6 million compared with operating income of $14.8 million, which included an $18.4 million gain on the December 2020 sale of the PREBOOST® business
- Net loss was $42.8 million, or $0.53 per diluted share, compared with net income, which included the gain on sale of the PREBOOST business, of $11.7 million, or $0.14 per diluted share

Balance Sheet Information

- Cash and cash equivalents were $100.6 million as of June 30, 2022 versus $122.4 million as of September 30, 2021
- Net accounts receivable were $8.3 million as of June 30, 2022 versus $8.8 million as of September 30, 2021

“COVID-19 new cases and hospitalizations are on the rise again with both summer and fall-winter surges expected. Unfortunately, the death rate in hospitalized patients with moderate to severe COVID-19 who are at risk for ARDS remains unacceptably high with current standard of care,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. “By reducing deaths in hospitalized COVID-19 patients, sabizabulin has great potential to play a critical role in the battle against COVID-19.”

Dr. Steiner added: “I am proud of how expeditiously the Veru team moved to get the Emergency Use Authorization (EUA) application submitted to FDA in June. I was also very pleased to see the UK’s Medicines and Healthcare Products Regulatory Agency’s decision to expedite review of a marketing authorization application for sabizabulin as well as the European Medicines Agency’s Emergency Task Force’s decision to initiate data review, for the first time ever under their article 18, for potential emergency use of sabizabulin in European Union member countries. Veru has scaled up manufacturing of sabizabulin 9mg capsules to meet the needs of patients in the U.S. and ex-US, if authorizations are received, and we are building our U.S. and ex-U.S. infectious disease commercial franchises.”

Finally, Dr. Steiner noted: “We expect to have significant near-term revenue from sabizabulin for the treatment of hospitalized COVID-19 patients at high risk for ARDS, if the EUA is granted by the U.S. FDA. The decrease in the third quarter FC2 net revenues in the U.S. prescription channel is primarily due to lower volume from telemedicine customers because of some business challenges experienced by our customers which resulted in a slow-down in orders during the current quarter. We expect their historical ordering patterns to resume in future quarters, although there is uncertainty as to timing of the resumption, and we also anticipate new revenues from the launch of ENTADFI™ which is now commercially

available.”

Pharmaceutical Pipeline Highlights:

Infectious Disease Franchise:

The Company has Completed a Positive Phase 3 COVID-19 Study in Hospitalized Moderate to Severe COVID-19 Patients at High Risk for ARDS.

A double-blind, randomized, placebo-controlled Phase 3 COVID-19 clinical trial was conducted in approximately 210 hospitalized COVID-19 patients with moderate to severe COVID (≥ WHO 4-supplemental oxygen) at high risk for ARDS and death. The primary endpoint was the proportion of deaths by Day 60. Based on a planned interim analysis of the first 150 patients randomized, the Independent Data Monitoring Committee unanimously halted the study for overwhelming efficacy and safety. Treatment with sabizabulin 9mg once daily, an oral, first-in-class, new chemical entity, microtubule disruptor that has dual anti-inflammatory and antiviral properties, resulted in a clinically meaningful and statistically significant 55.2% relative reduction in deaths.

On June 6, 2022, the Company submitted a request for emergency use authorization to FDA. On July 6, 2022, the Company announced the publication of the Phase 3 COVID-19 trial results evaluating the efficacy and safety of oral sabizabulin in The New England Journal of Medicine Evidence®. On July 25, 2022, the UK’s Medicines and Healthcare Products Regulatory Agency (MHRA) informed the Company that the sabizabulin marketing authorization application will receive expedited review. On July 27, 2022, the European Medicines Agency’s Emergency Task Force initiated the review of sabizabulin treatment for hospitalized COVID-19 patients for emergency use in European Union countries.

The Company has scaled up manufacturing processes and will be able to produce commercial drug supply to address anticipated drug needs following potential FDA authorization and subsequent authorizations in the U.S. as well as other countries and regions.

The Company has initiated discussions with government agencies to discuss potential government purchases of sabizabulin in the U.S. and other countries around the world.

Breast Cancer Program

Enobosarm, a Novel Oral Selective Androgen Receptor Targeting Agonist, for the 3rd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with AR ≥ 40% Expression - Phase 3 ARTEST Clinical Study- Enrolling.

Enobosarm is an oral, new chemical entity, selective androgen receptor targeting agonist that activates the androgen receptor (AR), a tumor suppressor, in AR+ER+HER2- metastatic breast cancer without causing unwanted masculinizing side effects. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in approximately 1,450 subjects dosed, including three Phase 2 clinical studies in advanced metastatic breast cancer involving more than 250 patients. In the two Phase 2 clinical studies conducted in women with AR+ER+HER2- metastatic breast cancer, enobosarm demonstrated significant antitumor efficacy in heavily pretreated cohorts that

previously failed estrogen receptor blocking agents, chemotherapy, and/or CDK 4/6 inhibitors and enobosarm was well tolerated with a favorable safety profile.

We are enrolling the Phase 3 multicenter, international, open label, and randomized (1:1) ARTEST registration clinical trial design to evaluate enobosarm monotherapy versus physician's choice of either exemestane ± everolimus or a selective estrogen receptor modulator (SERM) as the active comparator for the treatment of AR+ER+HER2- metastatic breast cancer in approximately 210 patients with AR expression ≥40% in their breast cancer tissue who had previously received a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. In January 2022, the FDA granted Fast Track designation to the ARTEST Phase 3 registration program, a distinction that underscores the urgent need for novel, targeted therapies for this important unmet medical need.

Enobosarm and Abemaciclib, CDK 4/6 Inhibitor, Combination Therapy for the 2nd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with AR ≥ 40% Expression- Phase 3 ENABLAR-2 Clinical Study-Enrolling.

We are enrolling the Phase 3 multicenter, open label, randomized (1:1), active control clinical study, named ENABLAR-2 to evaluate the treatment of the enobosarm and abemaciclib combination versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ER+HER2- metastatic breast cancer who have failed first line palbociclib (a CDK 4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and who have an AR ≥ 40% expression in their breast cancer tissue in approximately 186 subjects. We have a clinical trial collaboration and supply agreement with Lilly for our Phase 3 ENABLAR-2 trial.

Sabizabulin, Novel Oral Cytoskeleton Disruptor Agent, for the 3rd Line Treatment of AR+ER+HER2- Metastatic Breast Cancer with AR< 40% Expression- Phase 2b Clinical Study.

We intend to conduct a Phase 2b clinical study which will be an open label, multicenter, and randomized (1:1) study evaluating sabizabulin 32mg monotherapy versus active comparator (exemestane ± everolimus or a SERM, physician's choice) for the treatment of AR+ER+HER2- metastatic breast cancer in approximately 200 patients with AR <40% expression in their breast cancer tissue who have previously received a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

Prostate Cancer Program

Sabizabulin for the Treatment of Metastatic Castration and Androgen Receptor Targeting Agent Resistant Prostate Cancer – Phase 3 VERACITY Clinical Study - Enrolling.

The Company is enrolling the open label, randomized (2:1), multicenter Phase 3 VERACITY clinical study evaluating sabizabulin 32mg versus an alternative androgen receptor targeting agent for the treatment of chemotherapy naïve men with metastatic castration resistant prostate cancer who have tumor progression after previously receiving at least one androgen receptor targeting agent. The primary endpoint is radiographic progression free survival in approximately 245 patients from 45 clinical centers.

VERU-100, a Novel Proprietary Long-Acting Gonadotropin-Releasing Hormone (GnRH) Antagonist Peptide 3-Month Subcutaneous Depot Formulation, for Androgen Deprivation Therapy of Advanced Prostate Cancer – Phase 2 Clinical Study - Enrolling.

VERU-100 is designed to address the current limitations of commercially available androgen deprivation therapy. Androgen deprivation therapy is currently the mainstay of advanced prostate cancer treatment and is used as a foundation of treatment throughout the course of the disease even as other endocrine, chemotherapy, or radiation treatments are added or stopped. Specifically, VERU-100 is a chronic, long-acting GnRH antagonist peptide administered as a small volume, three-month depot subcutaneous injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration, a problem that occurs with currently approved luteinizing hormone-releasing hormone agonists used for androgen deprivation therapy. There are no GnRH antagonist depot injectable formulations commercially approved beyond a one-month injection. In June 2021, the Company initiated the Phase 2 dose finding clinical study of VERU-100 androgen deprivation therapy for hormone sensitive advanced prostate cancer. The Phase 2 VERU-100 clinical study is expected to enroll approximately 45 patients. A Phase 3 registration clinical study has been agreed upon with FDA and will enroll approximately 100 men.

Urev - Sexual Health Division

ENTADFI™ (tadalafil and finasteride) capsule, a new Treatment for Benign Prostatic Hyperplasia (BPH) – commercially launched

Today the Company initiated the U.S. commercial launch and availability of ENTADFI™– a new oral treatment for benign prostatic hyperplasia. ENTADFI has been shown to be more effective to treat urinary tract symptoms caused by BPH with less potential for adverse sexual side effects compared to finasteride monotherapy. ENTADFI dosing is one capsule orally once a day, and the FDA approved indication is to initiate treatment of the signs and symptoms of BPH in men with an enlarged prostate for up to 26 weeks. ENTADFI will be featured on GoodRx®, a leading consumer-focused digital healthcare platform, to drive awareness among consumers and providers.

FC2 Female Condom/Internal Condom®

The Company markets and sells the FC2®, an FDA-approved product for dual protection against unplanned pregnancy and the transmission of sexually transmitted infections.

Event Details
Interested parties may access the call by dialing 1-800-341-1602 from the U.S. or 1-412-902-6706 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 1-877-344-7529 for U.S. callers, or 1-412-317-0088 from outside the U.S., passcode 1902173, for one week.

About Veru Inc.
Veru is a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and ARDS-related diseases and for the management of breast and prostate cancers. Veru also has a commercial sexual health division - Urev, the proceeds of which help fund its drug development programs, comprised of 2 FDA approved products - ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia, and FC2 Female Condom® (internal condom), for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections which is sold in the U.S. and globally.

Forward-Looking Statements
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: whether and when the Company will receive an emergency use authorization or any approval from FDA, MHRA, EMA or any other regulatory authority outside the U.S. for sabizabulin for certain COVID-19 patients; whether and when sabizabulin will become an available treatment option for certain COVID-19 patients in the U.S., UK, EU or anywhere else outside the U.S.; whether the Company will have sufficient supply of sabizabulin to meet demand, if an emergency use authorization or other approval is granted in the U.S., UK, EU or in any other country; whether the Company will secure any advance purchase agreement with the U.S. government or any foreign government; whether the current and future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company’s drug candidates and companion diagnostic; whether the drug candidates will be approved for the targeted line of therapy; the anticipated design and scope of clinical studies and FDA acceptance of such design and scope; whether any regulatory pathways, including the accelerated Fast Track designations, to seek FDA approval for sabizabulin, enobosarm or any of the Company’s drug candidates are or continue to be available; whether the expected commencement and timing of the Company’s clinical studies, including the Phase 3 ENABLAR-2 study, the sabizabulin monotherapy Phase 2b clinical study for 3rd line treatment of metastatic breast cancer, the Phase 2 registration clinical study for VERU-100, and the development of the companion diagnostic will be met; when clinical results from the ongoing clinical studies will be available, whether sabizabulin, enobosarm, VERU-100, zuclomiphene, and ENTADFI will serve any unmet need or, what dosage, if any, might be approved for use in the U.S. or elsewhere, and also statements about the potential, timing and efficacy of the rest of the Company’s development pipeline, and the timing of the Company’s submissions to FDA and FDA’s review of all such submissions; whether any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm, VERU-100 or other drug candidates will be replicated in the current and planned clinical development program for such drug candidates and whether any such properties will be recognized by the FDA in any potential approvals and labeling; whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; whether FC2 U.S. Rx orders from telemedicine customers will resume historical ordering patterns; and whether ENTADFI will be commercialized successfully and whether such commercialization will lead to significant new revenues. These forward-looking statements are based on the Company’s current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the development of the Company’s product portfolio and the results of clinical studies possibly being unsuccessful or

insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical studies and the ability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development; the timing of any submission to the FDA and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities possibly taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the Company's existing products and any future products, if approved, possibly not being commercially successful; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical studies, supply chain and other third-party providers, commercial efforts, and business development operations; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to successfully commercialize any of its products, if approved; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, and development costs; the Company's ability to protect and enforce its intellectual property; the potential 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; 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; the concentration of accounts receivable with our largest customers and the collection of those receivables; the Company's production capacity, efficiency and supply constraints and interruptions, including potential disruption of production at the Company's and third party 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 and third party facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; 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 from time to time 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, 2021 and subsequent quarterly reports on Form 10-Q. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors. The Company disclaims any intent or obligation to update these forward-looking statements.

FINANCIAL SCHEDULES FOLLOW

Veru Inc.
Condensed Consolidated Balance Sheets
(unaudited)

	June 30, 2022	September 30, 2021
Cash and cash equivalents	$ 100,550,610	$ 122,359,535
Accounts receivable, net	8,302,745	8,794,224
Inventory, net	7,722,551	5,574,253
Prepaid expenses and other current assets	11,784,788	15,025,475
Total current assets	128,360,694	151,753,487
Plant and equipment, net	1,081,710	592,603
Operating lease right-of-use assets	4,970,311	969,839
Deferred income taxes	13,005,533	13,024,550
Intangible assets, net	3,995,238	4,048,810
Goodwill	6,878,932	6,878,932
Other assets	2,284,890	878,502
Total assets	$ 160,577,308	$ 178,146,723
Accounts payable	$ 6,936,312	$ 3,409,771
Accrued expenses and other current liabilities	17,822,991	9,120,328
Residual royalty agreement liability, short-term portion	3,050,135	3,237,211
Total current liabilities	27,809,438	15,767,310
Residual royalty agreement liability, long-term portion	11,557,190	9,397,136
Operating lease liability, long-term portion	4,264,458	609,921
Other liabilities	78,426	78,412
Total liabilities	43,709,512	25,852,779
Total stockholders' equity	116,867,796	152,293,944
Total liabilities and stockholders' equity	$ 160,577,308	$ 178,146,723

Veru Inc.
Condensed Consolidated Statements of Operations
(unaudited)

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2022	2021	2022	2021
Net revenues	$ 9,602,195	$ 17,655,592	$ 36,765,721	$ 45,613,068
Cost of sales	2,533,572	3,782,480	6,679,738	9,995,023
Gross profit	7,068,623	13,873,112	30,085,983	35,618,045
Operating expenses:				
Research and development	18,133,412	11,188,246	43,755,677	24,438,813
Selling, general and administrative	10,758,986	5,556,730	24,881,330	14,745,507
Total operating expenses	28,892,398	16,744,976	68,637,007	39,184,320
Gain on sale of PREBOOST®	—	—	—	18,410,158
Operating (loss) income	(21,823,775)	(2,871,864)	(38,551,024)	14,843,883
Non-operating expenses	(234,198)	(2,694,065)	(3,977,580)	(5,928,100)
(Loss) income before income taxes	(22,057,973)	(5,565,929)	(42,528,604)	8,915,783
Income tax expense (benefit)	137,603	(2,873,063)	224,808	(2,773,071)
Net (loss) income	$ (22,195,576)	$ (2,692,866)	$ (42,753,412)	$ 11,688,854
Net (loss) income per basic common share outstanding	$ (0.28)	$ (0.03)	$ (0.53)	$ 0.16
Basic weighted average common shares outstanding	80,088,431	79,729,370	80,054,594	75,054,871
Net (loss) income per diluted common share outstanding	$ (0.28)	$ (0.03)	$ (0.53)	$ 0.14
Diluted weighted average common shares outstanding	80,088,431	79,729,370	80,054,594	82,807,156

Condensed Consolidated Statements of Cash Flows
(unaudited)

	Nine Months Ended June 30,	
	2022	**2021**
Net (loss) income	$ (42,753,412)	$ 11,688,854
Adjustments to reconcile net (loss) income to net cash used in operating activities	9,529,631	(17,904,260)
Changes in operating assets and liabilities	6,597,275	(8,549,150)
Net cash used in operating activities	(26,626,506)	(14,764,556)
Net cash provided by investing activities	4,415,755	14,845,584
Net cash provided by financing activities	401,826	109,486,162
Net (decrease) increase in cash	(21,808,925)	109,567,190
Cash at beginning of period	122,359,535	13,588,778
Cash at end of period	$ 100,550,610	$ 123,155,968

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Source: Veru Inc.