

May 3, 2023



## **Veru Enters into Common Stock Purchase Agreement for Up to \$100 Million with Lincoln Park Capital**

MIAMI, FL, May 03, 2023 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of breast cancer and for SARS-CoV-2 and other viral ARDS-related diseases, today announced that it has entered into a common stock purchase agreement (Agreement) for the purchase of up to \$100 million with Lincoln Park Capital Fund (LPC), a Chicago-based institutional investor.

Under the terms of the Agreement, LPC has committed to purchase up to \$100 million of Veru's common stock at Veru's sole discretion from time to time over a 36-month period. Veru controls the timing and amount of any future sales of its shares and LPC is obligated to make purchases in accordance with the terms of the Agreement, subject to various limitations contained in the Agreement, including those under the Nasdaq listing rules.

The purchase price for the Company's common stock is set forth in the Agreement and is generally based on the prevailing market prices at the time of each sale to LPC. There are no upper limits to the price per share LPC may pay and LPC has agreed not to enter into or effect any direct or indirect short selling or hedging of Veru's common stock. No warrants are being issued in this transaction and the Agreement does not contain any rights of first refusal, participation rights, penalties, or liquidated damages provisions in favor of any party.

"We are pleased to enter into this transaction with LPC and believe that this agreement allows us to access capital in a very efficient manner," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. "We believe this purchase commitment further enhances our financial flexibility and is aligned with our long-term strategy for shareholder value creation. We intend to use any net proceeds from the sale of our common stock to LPC for working capital and for general corporate purposes, and to advance our most important drug candidates, enobosarm for 2<sup>nd</sup> line AR+ ER+ HER2- metastatic breast cancer and sabizabulin for SARS-CoV-2 viral ARDS, that could yield Phase 3 clinical trial data in 2024."

Additional information regarding the purchase agreement is set forth in a Current Report on Form 8-K, which Veru will file with the Securities and Exchange Commission (SEC).

The securities described above are being offered by the Company pursuant to a shelf registration statement on Form S-3 (File No. 333-270606) filed with the SEC on March 16,

2023 and declared effective on April 14, 2023. The offering of the securities described herein will be made only by means of a prospectus, including a prospectus supplement, forming a part of the effective registration statement. A final prospectus supplement and accompanying prospectus relating to the securities being offered will be filed with the SEC. Electronic copies of the final prospectus supplement and accompanying prospectus may be obtained, when available, on the SEC's website at <http://www.sec.gov> or by request from Veru Inc. at 2916 N. Miami Ave., Suite 1000, Miami, FL 33127.

### **About Veru Inc.**

Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of breast cancer and for SARS-CoV-2 and other viral ARDS-related diseases.

### **Oncology program focuses on breast cancer**

The Company's late-stage breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist.

- Enrolling Phase 2b/3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) combination in AR+ ER+ HER2- metastatic breast cancer (second-line metastatic setting). The Company and Eli Lilly and Company have entered into a clinical study collaboration and supply agreement for the ENABLAR-2 study. Lilly will supply Verzenio® (abemaciclib).
- Planned Phase 2b/3 study of enobosarm in nonmeasurable bone only metastatic breast cancer.

### **Infectious disease program focuses on viruses that pose serious worldwide global threat**

- **COVID-19:** Sabizabulin is an oral, first-in-class, new chemical entity, microtubule disruptor that has dual anti-inflammatory and host mediated antiviral properties. Veru has conducted a positive double-blind, randomized, placebo-controlled Phase 3 COVID-19 clinical trial in 204 hospitalized moderate to severe COVID-19 patients at high risk for ARDS and death. The primary endpoint was the proportion of deaths by Day 60. Treatment with sabizabulin resulted in a clinically meaningful and statistically significant 51.6% relative reduction in deaths ( $p=0.0046$ ) and was well tolerated. FDA granted Fast Track designation to the Company's COVID-19 program in January 2022. The Company is planning to conduct a Phase 3 confirmatory clinical trial to evaluate sabizabulin in hospitalized moderate to severe COVID-19 patients at high risk for ARDS.
- **Smallpox and Ebola viruses:** The Company is planning a pre-IND meeting with FDA to discuss the development of sabizabulin for smallpox virus and Ebola virus under the Animal Rules FDA regulatory approval pathway.
- **Influenza:** The Company is planning a Phase 3 clinical trial to evaluate sabizabulin in hospitalized influenza patients at high risk for ARDS.

### **Sexual health program – Urev**

Veru has a commercial sexual health division called Urev that is comprised of:

- FC2 Female Condom<sup>®</sup> (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: the timing, pricing and size of any potential purchases by LPC under the Agreement, including the aggregate amounts eventually issued by the Company thereunder; whether the funding pursuant to the LPC Agreement will be sufficient to fund the Company’s working capital, general corporate and research and development needs, including the planned studies of sabizabulin in COVID, influenza and pox virus and the late stage enobosarm studies in certain breast cancers; whether and when the Company will expand the study of sabizabulin into other ARDS indications; whether the current and future clinical development efforts of the Company, including all studies of sabizabulin in infectious disease indications and enobosarm in oncology indications, and any of their results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of any of the Company’s drug candidates; whether the drug candidates will be approved for the targeted line of therapy; the expected use of any proceeds from sales of shares pursuant to the Agreement; and whether the Company’s current cash and capital resources, including sales of common stock pursuant to the Agreement, will be sufficient to fund its planned or expected operations. These forward-looking statements are based on the Company’s current expectations and 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 as well as other operations of the Company; the timing of any submission to the FDA or any other regulatory authority and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines, anti-virals and other treatments 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 FC2 product and, if authorized, sabizabulin, 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; 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 and securities 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 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, 2022 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](http://www.verupharma.com/investors). The Company disclaims any intent or obligation to update these forward-looking statements.

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