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## **Veru Exploring Strategic Alternatives for its Legacy Female Health Business**

MIAMI, March 08, 2021 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer and breast cancer, today announced that it has engaged Morgan Stanley & Co. LLC as a financial advisor to assist the Company and its management in pursuing strategic alternatives regarding its legacy FC2 Female Condom® / FC2 Internal Condom business (FHC Business).

“With the last two consecutive quarters for our FHC Business having set all-time historical records in terms of net revenues and gross profit, and with the last three-year compound annual growth rates for the FHC Business’ net revenues and gross profit being 60% and 83%, respectively, we think this is an ideal time to consider strategic alternatives, including the possibility of monetizing this business, as we recently did with our PREBOOST business,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer. “Furthermore, with the potential for five registration clinical trials in calendar year 2021 -- four for oncology indications and one for COVID-19 — it is clear that Veru has transformed itself into a premium, late-stage, clinical biopharmaceutical company, so the strategic fit with the FHC Business is not as strong as it once was.”

Dr. Steiner added: “The FHC Business has been a great business for Veru. Fiscal year 2020 was a record year in terms of net revenues of \$41 million and gross profit of \$29 million, and Q1 fiscal year 2021 is already off on another record-setting pace. The cash flow generated by the FHC Business has allowed Veru to significantly advance its biopharmaceutical clinical programs. We are open to exploring the right kind of strategic transaction for the FHC Business with a view towards the best, long-term interests of Veru shareholders, which may include continuing to operate the FHC Business if we ultimately decide that is in our shareholders’ best interests.”

### **About the FHC Business**

The FHC Business is Veru’s legacy business. Its commercial product is the FC2 Female Condom®/ FC2 Internal Condom (“FC2”), the only FDA approved female condom that provides dual protection against unintended pregnancy and the transmission of sexually transmitted infections. FC2 is sold commercially and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple third-party telemedicine and internet pharmacy providers and retail pharmacies. 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. Over 650 million FC2 units have been sold globally in 159 countries. The FHC Business record growth has demonstrated a resiliency to the impact of the COVID-19 pandemic through a proven telemedicine prescription sales model. To learn more about the FC2 product, please visit [www.verupharma.com](http://www.verupharma.com)

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

*There can be no assurance that any FHC Business strategic transaction will occur and there is no definitive timetable for such. The Company does not intend to make future announcements concerning this matter, unless or until it enters into a definitive agreement, or its board of directors determines to conclude the process, or it otherwise deems that further disclosure is appropriate or required. 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 strategic alternatives with respect to, and the Company's ability to potentially monetize the Company's legacy FHC Business, and the anticipated timeframe for clinical studies and FDA submissions of the Company's biopharmaceutical drug candidates. 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. 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: the risk that the Company may not enter into a definitive agreement or otherwise proceed with any transaction regarding its FHC Business; costs, fees and expenses related to the process of exploring strategic alternatives with respect to the FHC Business and the risk that the process may divert management's attention from managing our business operations; 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, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies due to COVID-19, 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 and the risk that disruptions at the FDA caused by the COVID-19 pandemic may delay the review of submissions or approvals for new drugs; the risk of a delay or failure in reaching agreement with the FDA on the design of a clinical trial or in obtaining authorization to commence a clinical trial; preclinical or clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all; our pursuit of a COVID-19 treatment candidate is at an early stage and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all; risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties about the longevity and extent of COVID-19 as a global health concern and the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities*

may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the risk that the Company's products may not be commercially successful; risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations, including our ability to secure timely grant or other funding to develop VERU-111 as a potential COVID-19 treatment; 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; the risk that the Company will be affected by regulatory developments, including a reclassification of products; 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 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; 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 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; 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 fiscal year ended September 30, 2020 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).*

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EVP Corporate Development



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