

Veru Announces Notification from Nasdaq Related to Delayed Quarterly Report on Form 10-Q

MIAMI, FL, Feb. 27, 2024 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for preserving muscle for higher quality weight loss, oncology, and viral induced acute respiratory distress syndrome (ARDS), today announced that it received a delinquency notification letter ("Notice") from the Listing Qualifications staff of the Nasdaq Stock Market LLC ("Nasdaq") on February 21, 2024 due to the Company's non-compliance with Nasdaq Listing Rule 5250(c)(1) as a result of the Company's failure to timely file its Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2023 (the "Form 10-Q"). Nasdaq Listing Rule 5250(c)(1) requires listed companies to timely file all required periodic financial reports with the Securities and Exchange Commission (the "SEC").

The Notice states that the Company has 60 calendar days to submit to Nasdaq a plan to regain compliance with the Nasdaq Listing Rules. If Nasdaq accepts the Company's plan, then Nasdaq may grant the Company up to 180 calendar days from the prescribed due date for filing the Form 10-Q or until August 19, 2024, to regain compliance. If Nasdaq does not accept the Company's plan, then the Company will have the opportunity to appeal that decision to a Nasdaq Hearings Panel.

As previously disclosed, the Company's estimated research and development expenses recorded were higher than the actual expenses that were incurred, leading to the Company's failure to file the Form 10-Q on a timely basis. The net result of these research and development estimated expenses being recorded at too high of an amount is that the Company's cash on hand is expected to last longer than initially stated. The Company continues to work diligently to complete the Form 10-Q and plans to file the Form 10-Q as promptly as possible to regain compliance with the Listing Rule.

This announcement is made in compliance with Nasdaq Listing Rule 5810(b).

About Veru Inc.

Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of metabolic diseases, oncology, and ARDS. The Company's drug development program includes two late-stage novel small molecules, enobosarm and sabizabulin.

Enobosarm, a selective androgen receptor modulator (SARM), is being developed for two

indications: (i) Phase 2b clinical study of enobosarm as a treatment to augment fat loss and to prevent muscle loss in sarcopenic obese or overweight elderly patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness and (ii) subject to the availability of sufficient funding, Phase 3 ENABLAR-2 clinical trial of enobosarm for the treatment of androgen receptor positive (AR+), estrogen receptor positive (ER+) and human epidermal growth factor receptor 2 negative (HER2-) metastatic breast cancer in the 2nd line setting.

Sabizabulin, a microtubule disruptor, is being developed as a Phase 3 clinical trial for the treatment of hospitalized patients with viral-induced ARDS. The Company does not intend to undertake further development of sabizabulin for the treatment of viral-induced ARDS until we obtain funding from government grants, pharmaceutical company partnerships, or other similar third-party external sources.

The Company also has an FDA-approved commercial product, the FC2 Female Condom® (Internal Condom), for the dual protection against unplanned pregnancy and sexually transmitted infections.

Forward-Looking Statements

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995, including, without limitation, express or implied statements related to whether and when the planned phase 2b trial of enobosarm discussed above will commence or produce topline data or patients will progress into the extension study, the planned design, timing, endpoints, patient population and patient size of such trial and whether such trial will successfully meet any of its endpoints, expectations for the rest of the Company's development pipeline, the timing of the Company's delinquent Form 10-Q filing and other future filings, whether Nasdag will accept the Company's plan to regain compliance with Nasdag listing standards and the timing of regaining compliance with Nasdag listing standards, the potential magnitude of the actual expenses to be recorded and the length of time that the Company's cash is expected to last. The words "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" and similar expressions are intended to identify forwardlooking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based upon current plans and strategies of Veru Inc. (the Company) 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 press release. The Company assumes no obligation to update any forward-looking statements contained in this press 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 risks detailed in the Company's periodic reports filed with the SEC, including the Company's Form 10-K for the year ended September 30, 2023.

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Source: Veru Inc.