UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A
Proxy Statement Pursuant to Section 14(a) of the Securities Exchange Act of 1934
(Amendment No.)

Filed by the Registrant ☐

Filed by a Party other than the Registrant ☐

Check the appropriate box:

☐ Preliminary Proxy Statement

☐ **Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**

☐ Definitive Proxy Statement

☐ Definitive Additional Materials

☐ Soliciting Material under §240.14a-12

[Company Name]
(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

Payment of Filing Fee (Check all boxes that apply):

☐ No fee required

☐ Fee paid previously with preliminary materials

☐ Fee computed on table in exhibit required by Item 25(b) per Exchange Act Rules 14a-6(i)(1) and 0-11

On March 22, 2024, Veru Inc. issued the following press release announcing that it is postponing its Annual Meeting of Shareholders, originally scheduled to be held on March 26, 2024.

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Veru Reschedules Annual Meeting of Shareholders

—Restated historical financial statements expected to be filed no later than April 15, 2024—

—2024 Annual Meeting of Shareholders to follow financial statements filings—

MIAMI, FL – March 22, 2024 – Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing innovative medicines for preserving muscle for high quality weight loss, oncology, and viral induced acute respiratory distress syndrome, today announced that it is rescheduling its 2024 Annual Meeting of Shareholders originally scheduled to be held on March 26, 2024. As previously disclosed, the Company is in the process of restating its historical financial statements which are expected to be finalized and filed no later than April 15, 2024. The Company's estimated research and development expenses recorded were higher than the actual expenses that were incurred and the Company's cash on hand is expected to last longer than initially stated. The Annual Meeting is being rescheduled to allow shareholders ample time to review the restated financial statements.

The Company's Current Report on Form 8-K filed February 15, 2024, disclosed the need for the restatement due to overestimating certain research and development expenses associated with the Company's projects with third-party service providers and the accounting for these expenses. The Company records estimated expenses of research and development activities conducted by third-party service providers based on factors such as estimates of the work completed as provided to the Company by confirmations by such third-party service providers and provisions within agreements with such third-party service providers such as scope of work, payment, timeline and similar provisions. The Company's estimated research and development expenses recorded were higher than the actual expenses that were incurred. The net result of 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.

Once the Company has completed and filed the restated financial statements, the Company will notify shareholders of the new date and time for its Annual Meeting.

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.

About Enobosarm

Enobosarm (aka ostarine, MK-2866, GTx-024, and VERU-024), a novel daily oral selective androgen receptor modulator (SARM), has been previously studied in 5 clinical studies involving 968 older normal men and postmenopausal women as well as older patients who have muscle wasting because of advanced cancer. Advanced cancer simulates a "starvation state" where there is significant unintentional loss of both muscle and fat mass like that seen with GLP-1 RA treatment. The totality of the clinical data from these five clinical trials demonstrates that enobosarm treatment leads to preservation of muscle mass with improvements in physical function as well as significant reductions in fat mass.
Enobosarm has a large safety database, which includes 27 clinical trials involving 1581 men and women dosed with duration of treatment in some patients for up to 3 years. In this large safety database, enobosarm was generally well tolerated with no increase in gastrointestinal side effects. This is important as there are already significant and frequent gastrointestinal side effects with a GLP-1 RA treatment alone.

The efficacy and safety clinical data that were generated from five enobosarm clinical trials in both elderly patients and in patients with a cancer induced starvation-like state provide strong clinical rationale for enobosarm. The expectation is that enobosarm in combination with a GLP-1 RA would potentially augment the fat reduction with higher quality total weight loss while preserving muscle and physical function.

Planned Phase 2b enobosarm clinical trial design for potentially high quality weight loss

The Phase 2b, multicenter, double-blind, placebo-controlled, randomized, dose-finding clinical trial is designed to evaluate the safety and efficacy of enobosarm 3mg, enobosarm 6mg, or placebo as a treatment to preserve muscle and augment fat loss in 90 sarcopenic obese or overweight elderly (>60 years of age) patients receiving a GLP-1 RA who are at-risk for developing muscle atrophy and muscle weakness. The primary endpoint is lean body mass (muscle), and the key secondary endpoints are total body fat mass and physical function at 16 weeks. The IND has received FDA clearance, and the clinical study is expected to begin in April 2024 with the topline clinical results from the trial expected calendar year-end 2024.

After completing the efficacy dose-finding portion of the Phase 2b clinical trial, participants will then continue into a Phase 2b extension clinical trial where all patients will stop receiving a GLP-1 RA, but will continue taking placebo, enobosarm 3mg, or enobosarm 6mg for an additional 12 weeks. The Phase 2b extension clinical trial will evaluate whether enobosarm can maintain muscle and prevent the fat and weight rebound that occurs after stopping a GLP-1 RA drug. The topline results of the separate Phase 2b extension clinical study is expected in calendar Q2 2025.

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, whether enobosarm will enhance weight loss or preserve muscle in, or meet any unmet need for, obesity patients and whether it will enhance weight loss, whether the Company will be successful in its transformation into a late stage biopharmaceutical company focused on obesity and oncology, the expected timing of the Company’s completion and filing of restated financial statements and the net effect of such restatement on the Company’s historical financial statements and the timing for the determination of a new date and time for the Annual Meeting of Shareholders. The words “anticipate,” “believe,” “could,” “expect,” “intend,” “may,” “opportunity,” “plan,” “predict,” “potential,” “estimate,” “should,” “will,” “would” and similar expressions are intended to identify forward-looking 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 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, uncertainties related to work required to complete the restatement and the timing of completion of the restatement and the other risks that are 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.