ZyVersa Therapeutics CEO, Stephen C. Glover, Issues Letter to Shareholders Providing Outlook for 2024

Jan 3, 2024

WESTON, Fla., Jan. 03, 2024 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA; “ZyVersa”), a clinical stage specialty biopharmaceutical company developing first-in-class drugs for treatment of patients with renal and inflammatory diseases who have unmet medical needs, announces that Stephen C. Glover, Co-Founder, Chairman, Chief Executive Officer, and President, has issued a Letter to Shareholders providing a corporate outlook with anticipated milestones for 2024. The full text of the letter follows.

A MESSAGE FROM OUR PRESIDENT AND CHIEF EXECUTIVE OFFICER

To my fellow shareholders,

Like so many in the biotech and pharmaceutical industry, we are looking forward to 2024 with great optimism for improved conditions in the financial markets and a milestone-rich year in the development of our lead renal and anti-inflammatory therapeutic candidates, which is expected to drive value for our shareholders. Our renal and inflammatory disease pipelines each have potential to address multiple indications. Combined, our two proprietary product platforms target a global total addressable market of around $75 billion.

On the financial front, various market watchers are seeing signals that the biotech and pharma investment environment is set to trend positively in 2024. Capital is again starting to flow to companies that are seeking to innovate through differentiated technologies or novel mechanisms of action. Near the end of 2023, we began to witness an increase in financings and an uptick in M&A across multiple sectors from inflammatory diseases to oncology. These were driven by investors targeting high upside opportunities and large pharma seeking to re-energize their product pipelines. Our team at ZyVersa shares this optimism, anticipating improved conditions as we focus our efforts on developing innovative, disease-modifying treatments to help improve patients’ quality of life.

We are looking forward to an active first quarter of this new year, including initiation of our first clinical trial for our Cholesterol Efflux Mediator^{TM} VAR 200. VAR 200 is designed to ameliorate renal lipid accumulation that damages the kidney’s filtration system. Currently there are no approved treatments that target lipid accumulation, which is known to contribute to structural damage, proteinuria, and progression of kidney disease. The current standard of care addresses glomerular hypertension and inflammation.

We are on schedule to initiate our Phase 2a clinical trial with VAR 200 in patients with diabetic kidney disease (DKD) in the first quarter of 2024. This will be an open label trial for real-time data reads. Initial data is anticipated to be available mid-year. DKD represents a significant area of unmet need, as it is the leading cause of end-stage kidney disease, requiring dialysis or kidney transplant for survival. Although substantial progress has been made in slowing progression of DKD with introduction of ACE inhibitors, ARBs, and most recently SGLT2 inhibitors, patients are still progressing to end-stage renal disease. We are optimistic that the protection against kidney injury, fibrosis, and disease progression that was demonstrated with VAR 200 in animal models of three different kidney diseases will translate to humans. Data from our initial Phase 2a trial will not only provide proof-of-concept for VAR 200 in renal patients, it will also provide valuable insights for designing future trials with VAR 200 in other planned renal indications, including two rare kidney diseases, focal segmental glomerulosclerosis (FSGS) and Alport syndrome.

We are equally excited about our progress in the development of our proprietary Inflammasome ASC Inhibitor IC 100, which is designed to block initiation and perpetuation of damaging inflammation that contributes to a multitude of inflammatory diseases. A growing body of scientific literature reinforces the central role of multiple types of inflammasomes in the development and progression of inflammatory diseases, and we continue to report on these developments as they are published. By inhibiting Inflammasome ASC rather than a sensor molecule such as NLRP3, IC 100 targets multiple types of inflammasome pathways (including NLRP3, NLRP1, and AIM2), which is expected to provide better control of damaging inflammation and its perpetuation.

The IC 100 preclinical program is nearing completion and IND submission is planned for the fourth quarter of 2024, with Phase 1 trial initiation expected shortly thereafter.

Two Platforms, Singular Vision

We view 2024 as a potentially transformative year for ZyVersa based on the value-building milestones that we expect to achieve over the next 12 to 15 months. I look forward to working with my leadership team and fellow Board members to execute a business and clinical strategy that has potential to position ZyVersa as a leading and innovative company developing transformative drugs for underserved patients with renal and inflammasome-mediated inflammatory diseases.

Though our platforms are independent from each other, our mission is singular – to develop drug therapies that can restore health and improve quality of life for patients living with the often debilitating symptoms of renal and inflammatory diseases. We look forward to embarking on what we believe will be a productive 2024. We thank you for your continued support.

Sincerely,
Stephen C. Glover
Co-Founder, Chairman, Chief Executive Officer, and President
ZyVersa Therapeutics

About ZyVersa Therapeutics, Inc.

ZyVersa is a clinical stage specialty biopharmaceutical company leveraging advanced, proprietary technologies to develop first-in-class drugs. Our focus is on patients with renal or inflammatory diseases who have significant unmet medical needs. Our development pipeline includes phase clinical stage Cholesterol Efflux Mediator™ VAR 200 in development to alleviate damaging accumulation of cholesterol and lipids in the filtering system of the kidneys. The lead indication is treatment of rare kidney disease, focal segmental glomerulosclerosis. VAR 200 has potential to treat other kidney diseases, including Alport syndrome and diabetic kidney disease. ZyVersa's pipeline also includes proprietary inflammasome ASC inhibitor IC 100 that blocks initiation and perpetuation of damaging inflammation associated with a multitude of inflammatory diseases. IC 100 has potential to treat many different CNS and other inflammatory diseases. For more information, please visit www.zyversa.com.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this press release regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995. These include statements regarding management's intentions, plans, beliefs, expectations, or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. ZyVersa Therapeutics, Inc ("ZyVersa") uses words such as "anticipates," "believes," "plans," "expects," "projects," "future," "intends," "may," "will," "should," "could," "estimates," "predicts," "potential," "continue," "guidance," and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions. Such forward-looking statements are based on ZyVersa's expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including ZyVersa's plans to develop and commercialize its product candidates, the timing of initiation of ZyVersa's planned preclinical and clinical trials; the timing of the availability of data from ZyVersa's preclinical and clinical trials; the timing of any planned investigational new drug application or new drug application; ZyVersa's plans to research, develop, and commercialize its current and future product candidates; the clinical utility, potential benefits and market acceptance of ZyVersa's product candidates; ZyVersa's commercialization, marketing and manufacturing capabilities and strategy; ZyVersa's ability to protect its intellectual property position; and ZyVersa's estimates regarding future revenue, expenses, capital requirements and need for additional financing. A discussion of these and other factors, including risks and uncertainties with respect to ZyVersa, is set forth in ZyVersa's filings with the Securities and Exchange Commission, including ZyVersa's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q.

New factors emerge from time-to-time, and it is not possible for ZyVersa to predict all such factors, nor can ZyVersa assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Forward-looking statements included in this press release are based on information available to ZyVersa as of the date of this press release. ZyVersa disclaims any obligation to update such forward-looking statements to reflect events or circumstances after the date of this press release, except as required by applicable law.

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