ZyVersa Therapeutics Reports First Quarter 2025 Financial Results and Highlights Pipeline Progress

May 12, 2025

KEY HIGHLIGHTS

- First patient expected to start therapy by end of Q2-2025 in Phase 2a proof-of concept clinical trial for Cholesterol Efflux Mediator™ VAR 200 in patients with diabetic kidney disease (DKD).
- Obesity-associated cardiometabolic preclinical proof-of-concept study with Inflammasome ASC Inhibitor IC 100 planned to begin by end of Q2-2025.
- Investigational New Drug Application (IND) for IC 100 anticipated to be submitted H2-2025, followed by initiation of a Phase 1 clinical trial in healthy overweight subjects at risk of cardiometabolic diseases.
- Groundbreaking data demonstrating IC 100 blocks microglial inflammasome activation and reduces neurotoxic alpha-synuclein accumulation — both key contributors to neurodegeneration and Parkinson's disease (PD) progression — recently published (study sponsored by Michael J. Fox Foundation, MJFF).
- Invited MJFF grant request submitted for funding PD animal model proof-of-concept studies; response expected in June 2025.
- Raised approximately $2.0 million in Q1-2025.

WESTON, Fla., May 12, 2025 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA, or "ZyVersa"), a clinical-stage specialty biopharmaceutical company developing first-in-class drugs for the treatment of renal and inflammatory diseases with high unmet medical needs, reports financial results for the quarter ended March 31, 2025, and provides pipeline update.

"2025 is off to a good start. We have newly published data showing that our Inflammasome ASC Inhibitor IC 100 attenuates microglial inflammasome activation and accumulation of alpha-synuclein, which leads to neurodegeneration in Parkinson's disease. Additionally, thanks to the efforts of kidney disease experts and the FDA as part of the PARASOL Initiative, it is expected that shorter clinical trials with fewer patients will be required to demonstrate drug efficacy for FSGS, our lead indication for VAR 200. The PARASOL team recommended reduced proteinuria over a two-year period as a surrogate endpoint for full approval of FSGS drugs," stated Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. "I am also pleased to report that we have made great progress in development of our renal and anti-inflammatory drug pipelines. Our first-in-human Phase 2a clinical study with Cholesterol Efflux Mediator™ VAR 200 in patients with diabetic kidney disease is anticipated to begin treating the first patient around the end of June/early July of this year. Likewise, we expect to initiate our first-in-human Phase 1 trial with Inflammasome ASC Inhibitor IC 100 in overweight healthy subjects at risk of cardiometabolic diseases in the first half of 2026. This trial will be supported by an IC 100 preclinical study in a diet-induced mouse model, with an interim data read-out expected in the second half of 2025. We look forward to reporting our near-term data read-outs, and the anticipated value they will bring to our shareholders."

PIPELINE UPDATE

Cholesterol Efflux Mediator™ VAR 200

Kidney Disease (Global Drug Market: $18 Billion in 2024; $30 Billion Projected by 2034)

The first patient is expected to be treated in a phase 2a clinical trial in patients with DKD by the end of June of 2025. The intent of the study is to obtain renal patient proof-of-concept for VAR 200 prior to initiating a larger phase 2a/b for VAR 200's lead indication, FSGS. The DKD study will evaluate VAR 200's safety and efficacy (% change in proteinuria from baseline to week 12) in eight patients with type 2 diabetes who have diabetic kidney disease. This data will provide insights for designing the subsequent phase 2a/b FSGS study. The DKD study will be conducted at two clinical research sites.

Inflammasome ASC Inhibitor IC 100

Inflammatory Diseases (Global Biologics Market: $105 Billion in 2024; $186 Billion Projected by 2034)

Obesity with Cardiometabolic Complications

In preparation for filing an IND for IC 100, planned for the second half of 2025, we will initiate a diet-induced obesity (DIO) mouse model study, anticipated to begin by the end of June 2025. The study will evaluate the effects of IC 100 on body weight, body composition, and changes in cardiovascular, metabolic, and inflammatory parameters in comparison to semaglutide, and when administered concurrently with semaglutide. We expect a preliminary data read-out in the second half of 2025.

Following IND clearance, a phase 1 trial will be initiated with IC 100 in healthy overweight people (BMI: 27 – 30) at risk of cardiometabolic diseases to evaluate the safety of 3 different doses of IC 100, and to get a signal on the degree of weight loss, and changes in cardiometabolic biomarkers that can be expected with each dose. Results are anticipated in the first half of 2026.

First Quarter 2025 FINANCIAL RESULTS

Net losses were approximately $2.3 million for the three months ended March 31, 2025, with an improvement of $0.5 million or 20.2% compared to a net loss of approximately $2.8 million, for the three months ended March 31, 2024.

Based on its current operating plan, ZyVersa expects its cash of $1.6 million as of March 31, 2025 will be sufficient to fund its operating expenses and capital expenditure requirements on a month-to-month basis. ZyVersa will need additional financing to support its continuing operations, pay its current liabilities, and to meet its stated milestones. ZyVersa will seek to fund its operations and clinical activity through public or private equity or debt financings or other sources, which may include government grants, collaborations with third parties or outstanding warrant exercises.

Research and development expenses were $259 thousand for the three months ended March 31, 2025, a decrease of $254 thousand or 49.5% from the three months ended March 31, 2024. The decrease is attributable to lower manufacturing costs of IC 100 of $62 thousand, lower CRO fees of $106 thousand for VAR 200 and lower research and development consultant costs of $95 thousand due to fewer consultants.

General and administrative expenses were $1.9 million for the three months ended March 31, 2025, a decrease of $428 thousand or 18.5% from the three months ended March 31, 2024. The decrease is primarily attributable to a decrease of $156 thousand in stock-based compensation expense due to options becoming fully amortized in January 2025, a decrease of $143 thousand due to a lower premium for director and officer insurance, and a $119 thousand decrease in investor and public relations marketing expense due to less engagement of service providers.

ABOUT ZYVERSA THERAPEUTICS, INC.

ZyVersa (Nasdaq: ZVSA) is a clinical stage specialty biopharmaceutical company leveraging advanced, proprietary technologies to develop first-in-class drugs for patients with renal and inflammatory diseases who have significant unmet medical needs. The Company is currently advancing a therapeutic development pipeline with multiple programs built around its two proprietary technologies – Cholesterol Efflux Mediator™ VAR 200 for treatment of kidney diseases, and Inflammasome ASC Inhibitor IC 100, targeting damaging inflammation associated with numerous CNS and peripheral 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 27A of the Securities Act of 1933, as amended, 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 ability to obtain the funding necessary to advance the development of our product candidates and maintain its business operations; 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; 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.

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 law.

This press release does not constitute an offer to sell, or the solicitation of an offer to buy, any securities.

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ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2025 (Unaudited)	December 31, 2024
Assets		
Current Assets:		

Cash	1,611,532	1,530,924
Prepaid expenses and other current assets	498,778	184,873
Total Current Assets	2,110,310	1,715,797
In-process research and development	18,647,903	18,647,903
Vendor deposit	178,476	178,476
Deferred offering costs	48,852	57,238
Total Assets	20,985,541	20,599,414
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	9,604,568	9,337,267
Accrued expenses and other current liabilities	2,398,964	1,894,041
Total Current Liabilities	12,003,532	11,231,308
Deferred tax liability	851,659	851,659
Total Liabilities	12,855,191	12,082,967
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 1,000,000 shares authorized:		
Series A preferred stock, 8,635 shares designated, 50 shares issued and outstanding as of March 31, 2025 and December 31, 2024	-	-
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of March 31, 2025 and December 31, 2024	1	1
Common stock, $0.0001 par value, 250,000,000 shares authorized; 2,568,198 and 2,508,198 shares issued as of March 31, 2025 and December 31, 2024, respectively, and 2,568,191 and 2,508,191 shares outstanding as of March 31, 2025 and December 31, 2024, respectively	257	251
Additional paid-in-capital	123,026,749	121,155,922
Accumulated deficit	(114,889,489)	(112,632,559)
Treasury stock, at cost, 7 shares at March 31, 2025 and December 31, 2024,	(7,168)	(7,168)
Total Stockholders' Equity	8,130,350	8,516,447
Total Liabilities and Stockholders' Equity	20,985,541	20,599,414

ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended March 31,	
	2025	**2024**
Operating Expenses:		
Research and development	$ 258,876	$ 512,937
General and administrative	1,885,695	2,313,699
Total Operating Expenses	2,144,571	2,826,636
Loss From Operations	(2,144,571)	(2,826,636)
Other (Income) Expense:		
Interest expense	119,559	101
Change in fair value of equity payable	(7,200)	-
Net Loss	$ (2,256,930)	$ (2,826,737)
Net Loss Per Share		

- Basic and Diluted	$ (0.73)	$ (4.53)
Weighted Average Number of Common Shares Outstanding		
- Basic and Diluted	3,106,928	623,600