ZyVersa Therapeutics Reports First Quarter, 2024 Financial Results and Provides Business Update

May 15, 2024

Key Highlights:

- Second research site selected to enhance enrollment in the Phase 2a clinical trial for Cholesterol Efflux Mediator™ VAR 200 in patients with diabetic kidney disease planned to begin H1-2024.
- GLP toxicology studies for Inflammasome ASC Inhibitor IC 100 scheduled to begin H1-2024, with planned Investigational New Drug (IND) submission Q4-2024, and Phase 1 clinical trial initiation Q1-2025.Atherosclerosis preclinical data readout for Inflammasome ASC Inhibitor IC 100 on schedule for H1-2024.
- Initiation of preclinical study to assess Inflammasome ASC Inhibitor IC 100 for obesity-associated metabolic comorbidities scheduled to begin Q2-2024 with completion expected by year's end.
- Raised $2.7 million from exercising of investor warrants.

WESTON, Fla., May 15, 2024 (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, 2024 and provides business update.

"We are pleased to announce that ZyVersa is on track to achieve key development milestones over the next 3 quarters," stated Stephen C. Glover, ZyVersa's Co-founder, Chairman, CEO, and President. "Our Phase 2a clinical trial with Cholesterol Efflux Mediator ™ VAR 200 in diabetic kidney disease is expected to enroll the first patient(s) within the next few months, with initial data read-out in the second half of the year. Inflammasome ASC Inhibitor IC 100's indication expansion studies are nearing completion for atherosclerosis, expected to conclude in June, and obesity-associated metabolic comorbidities, expected to conclude by year's end. IND preparation has been initiated for IC 100, with submission targeted for year's end, and initiation of a phase 1 clinical trial in first quarter 2025. We believe achievement of these milestones is a key inflection point for ZyVersa and for shareholder value."

BUSINESS Update

CHOLESTEROL EFFLUX MEDIATOR™ VAR 200 FOR RENAL DISEASE

- Phase 2a clinical trial in diabetic kidney disease is on target to begin H1-2024
  - CRO, George Clinical, was engaged in December 2023 to initiate and manage the trial.
  - A central Institutional Review Board (IRB) approved the clinical trial protocol for trial initiation.
  - Two clinical research sites have been selected, with contracting nearing completion.
  - Enrollment of first patient(s) is expected in the next few months.

INFLAMMASOME ASC INHIBITOR IC 100 FOR INFLAMMATORY DISEASES

- Inflammasome ASC Inhibitor IC 100's preclinical program nearing completion, with GLP toxicology studies expected to begin H1-2024. IND submission is planned for Q4-2024, followed by initiation of a Phase 1 clinical trial in Q1-2025.
- Data from a scientific collaboration with an undisclosed partner to assess the potential of Inflammasome ASC Inhibitor IC 100 as a treatment for atherosclerosis in a well-established animal model is expected in June.
- A scientific collaboration with inflammasome and neurology experts at University of Miami Miller School of Medicine to assess the potential of Inflammasome ASC Inhibitor IC 100 as a treatment for obesity-associated metabolic comorbidities is expected to begin in Q2-2024, with completion in Q4-2024.
- In vitro preclinical research funded by The Michael J. Fox Foundation (MJFF) and conducted by researchers at University of Miami (UM) Miller School of Medicine supported Inflammasome ASC Inhibitor IC 100's mechanism of action and potential to block damaging neuroinflammation that induces neural degeneration in Parkinson's disease. At the suggestion of MJFF, UM researchers are developing a grant request to further the research in an established animal model.

FIRST QUARTER FINANCIAL RESULTS

Net losses were approximately $2.8 million for the three months ended March 31, 2024, with an improvement of $0.7 million or 20.2% compared to a net loss of approximately $3.5 million, for the three months ended March 31, 2023.

Based on its current operating plan, ZyVersa expects its cash of $2.0 million as of March 31, 2024 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 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. During Q1, ZyVersa raised approximately $2.7 million from investors exercising in-the-money warrants.

Research and development expenses were $0.5 million for the three months ended March 31, 2024, a decrease of $0.5 million or 51.4% from $1.1 million for the three months ended March 31, 2023. The decrease is attributable to lower manufacturing costs of IC 100 of $0.4 million and lower research and development payroll costs of $0.2 million due to fewer employees. This was offset by an increase in CRO fees of $0.1 million for VAR 200.

General and administrative expenses were $2.3 million for the three months ended March 31, 2024, a decrease of $1.2 million or 34.6% from $3.5 million for the three months ended March 31, 2023. The decrease is primarily attributable to a decrease of $0.4 million in payments for the Effectiveness Failure related to the PIPE shares, a decrease of $0.4 million for bonus accruals, a $0.2 million decrease in accounting fees and a $0.1 million decrease in director and officer insurance.

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 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.

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.

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, 2024 (Unaudited)	December 31, 2023
Assets		
Current Assets:		
Cash	$ 2,033,576	$ 3,137,674

Prepaid expenses and other current assets	866,476	215,459
Total Current Assets	2,900,052	3,353,133
Equipment, net	4,333	6,933
In-process research and development	18,647,903	18,647,903
Vendor deposit	98,476	98,476
Operating lease right-of-use asset	-	7,839
Total Assets	$ 21,650,764	$ 22,114,284
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 8,127,746	$ 8,431,583
Accrued expenses and other current liabilities	1,454,970	1,754,533
Operating lease liability	-	8,656
Total Current Liabilities	9,582,716	10,194,772
Deferred tax liability	844,914	844,914
Total Liabilities	10,427,630	11,039,686
Commitments and contingencies		
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, 2024 and December 31, 2023	-	-
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of March 31, 2024 and December 31, 2023	1	1
Common stock, $0.0001 par value, 250,000,000 shares authorized; 834,903 and 405,212 shares issued as of March 31, 2024 and December 31, 2023, respectively, and 834,896 and 405,205 shares outstanding as of March 31, 2024 and December 31, 2023, respectively	83	40
Additional paid-in-capital	117,276,079	114,300,849
Accumulated deficit	(106,045,861)	(103,219,124)
Treasury stock, at cost, 7 shares at March 31, 2024 and December 31, 2023, respectively	(7,168)	(7,168)
Total Stockholders' Equity	11,223,134	11,074,598
Total Liabilities and Stockholders' Equity	$ 21,650,764	$ 22,114,284

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

	For the Three Months Ended March 31,	
	2024	**2023**
Operating Expenses:		
Research and development	$ 512,937	$ 1,055,943
General and administrative	2,313,699	3,536,136
Total Operating Expenses	2,826,636	4,592,079
Loss From Operations	(2,826,636)	(4,592,079)
Other (Income) Expense:		
Interest (income) expense	101	(1,078)
Pre-Tax Net Loss	(2,826,737)	(4,591,001)

Income tax benefit	-	1,047,051
Net Loss	(2,826,737)	(3,543,950)
Net Loss Per Share		
- Basic and Diluted	$ (4.53)	$ (135.88)
Weighted Average Number of Common Shares Outstanding		
- Basic and Diluted	623,600	26,081