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

Nov 14, 2024

KEY BUSINESS HIGHLIGHTS

- Phase 2a clinical trial for Cholesterol Efflux Mediator™ VAR 200 in patients with diabetic kidney disease expected to begin Q1-2025.
- New Obesity, Metabolic & Inflammatory Disease Scientific Advisory Board (SAB) was formed in October 2024 to support development of Inflammasome ASC Inhibitor IC 100 for obesity with metabolic complications.
- Two obesity proof-of-concept studies with IC 100 in diet-induced obesity (DIO) mouse models are planned, which will include assessment of various metabolic parameters. At least one of the studies is targeted to begin Q4-2024.
- IC 100 Investigational New Drug (IND) submission is planned for Q2-2025, and once cleared, will be followed by initiation of a Phase 1 clinical trial in healthy overweight subjects at risk for certain metabolic complications (Q2/Q3-2025), with safety data expected H2-2025.
- Raised approximately $3.9 million from the beginning of Q3-2024 to present.

WESTON, Fla., Nov. 14, 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 September 30, 2024, and provides business update.

“We are pleased to announce the progress that ZyVersa has made toward achieving our key near-term development milestones,” 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 begin Q1-2025, with an initial data read-out around mid-year 2025. In preparation for an IND submission for Inflammasome ASC Inhibitor IC 100 and a subsequent Phase 1 trial in healthy overweight subjects at risk for certain metabolic complications, we are initiating two proof-of-concept studies with IC 100 in obesity DIO models. At least one of the studies is expected to begin in Q4-2024. One study will evaluate IC 100 as monotherapy compared to semaglutide, and the other will evaluate IC 100 in combination with semaglutide. Our newly formed Obesity, Metabolic & Inflammatory Disease SAB has been instrumental in designing these two studies to optimize the parameters to be evaluated. We are pleased with the level of scientific evidence from our preclinical program and published third party data that support the potential of IC 100 to control the damaging obesity-driven inflammation and its associated comorbidities. Unlike NLRP3 inhibitors in development for obesity with metabolic complications, IC 100 targets ASC to inhibit multiple inflammasomes, including NLRP3 and AIM2 associated with obesity. More importantly, IC 100 uniquely disrupts the function of ASC specks to attenuate chronic, systemic inflammation leading to obesity comorbidities. We are excited about the promise of our two lead compounds in development to improve health and transform lives. We believe our near-term milestone achievement will be a key inflection point for ZyVersa that will drive shareholder value.”

BUSINESS UPDATE

CHOLESTEROL EFFLUX MEDIATOR™VAR 200 FOR RENAL DISEASE

Phase 2a clinical trial in diabetic kidney disease planned to begin Q1-2025.

- All necessary regulatory preparation has been completed by ZyVersa, our CRO, George Clinical, and our two clinical sites who are gearing up for site initiation and patient recruitment in the new year.

INFLAMMASOME ASC INHIBITOR IC 100 FOR OBESITY WITH METABOLIC COMPLICATIONS

IC 100 IND submission planned for Q2-2025, to be followed by initiation of a Phase 1 clinical trial in healthy overweight patients at risk for certain metabolic complications. Safety data expected before year end 2025.

- New Obesity, Metabolic & Inflammatory Disease SAB established to provide expert advice on IC 100’s obesity clinical program.
  - SAB comprised of five top tier experts in the areas of obesity and metabolic diseases, and four world-renowned inflammasome experts and inventors of IC 100 from University of Miami Miller School of Medicine who have provided advisory support for IC 100 since its license.
- Two IC 100 obesity proof-of-concept studies in DIO mouse models designed with expert advice from SAB.
  - One will evaluate IC 100 monotherapy in comparison to semaglutide, and the other will evaluate IC 100 in combination with semaglutide.

- At least one of the DIO model studies is planned to begin Q4-2024.
- Data read-outs expected within six months of initiation.

- IC 100 GLP toxicology studies are anticipated to begin Q4-2024/Q1-2025

THIRD QUARTER FINANCIAL RESULTS

Net losses were approximately $2.4 million for the three months ended September 30, 2024, with an improvement of approximately $0.5 million or 17.3% compared to a net loss of approximately $2.9 million for the three months ended September 30, 2023.

Based on its current operating plan, ZyVersa expects its cash of approximately $0.1 million as of September 30, 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.

Research and development expenses were approximately $0.4 million for the three months ended September 30, 2024, a decrease of approximately $0.2 million or 35.3% from the three months ended September 30, 2023. The decrease is primarily attributable to a decrease of approximately $0.2 million in the costs of manufacturing, pre-clinical costs for IC 100, and clinical costs for VAR 200.

General and administrative expenses were approximately $1.8 million for the three months ended September 30, 2024, a decrease of approximately $0.4 million or 17.7% from the three months ended September 30, 2023. The decrease is attributable to an approximate $0.1 million decrease in professional fees due to reduced fees of public auditors and legal counsel, an approximate $0.2 million decrease in director and officer insurance due to reduced costs in the second year of being a public company, and an approximate $0.1 million decrease in stock-based compensation as a result of options becoming fully amortized in 2024.

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 inflammatory or kidney diseases with high unmet medical needs. We are well positioned in the rapidly emerging inflammasome space with a highly differentiated monoclonal antibody, Inflammasome ASC Inhibitor IC 100, and in kidney disease with phase 2 Cholesterol Efflux Mediator™ VAR 200. The lead indication for IC 100 is obesity and its associated metabolic complications, and for VAR 200, focal segmental glomerulosclerosis (FSGS). Each therapeutic area offers a “pipeline within a product,” with potential for numerous indications. The total accessible market is over $100 billion. 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 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, as well as ZyVersa’s ability to successfully complete any such 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

	September 30, 2024	December 31, 2023

		(Unaudited)
Assets		
Current Assets:		
Cash	$ 122,921	$ 3,137,674
Prepaid expenses and other current assets	267,494	215,459
Total Current Assets	390,415	3,353,133
Equipment, net	-	6,933
In-process research and development	18,647,903	18,647,903
Vendor deposit	178,476	98,476
Deferred offering costs	207,130	-
Operating lease right-of-use asset	-	7,839
Total Assets	$ 19,423,924	$ 22,114,284
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 9,284,631	$ 8,431,583
Accrued expenses and other current liabilities	2,257,372	1,754,533
Operating lease liability	-	8,656
Total Current Liabilities	11,542,003	10,194,772
Deferred tax liability	854,621	844,914
Total Liabilities	12,396,624	11,039,686
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 September 30, 2024 and December 31, 2023, respectively	-	-
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of September 30, 2024 and December 31, 2023	1	1
Common stock, $0.0001 par value, 250,000,000 shares authorized; 1,074,203 and 405,212 shares issued at September 30, 2024 and December 31, 2023, respectively, and 1,074,196 and 402,205 shares outstanding as of September 30, 2024 and December 31, 2023, respectively	107	40
Additional paid-in-capital	118,245,220	114,300,849
Accumulated deficit	(111,210,860)	(103,219,124)
Treasury stock, at cost, 7 shares at September 30, 2024 and December 31, 2023, respectively	(7,168)	(7,168)
Total Stockholders' Equity	7,027,300	11,074,598
Total Liabilities and Stockholders' Equity	$ 19,423,924	$ 22,114,284

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating Expenses:				
Research and development	$ 436,043	$ 673,943	$ 1,658,030	$ 2,950,462
General and administrative	1,833,578	2,228,735	6,192,205	9,694,097
Impairment of in-process research and development	-	-	-	69,280,171
Impairment of goodwill	-	-	-	11,895,033
Total Operating Expenses	2,269,621	2,902,678	7,850,235	93,819,763

Loss From Operations	(2,269,621)	(2,902,678)	(7,850,235)	(93,819,763)
Other Income (Expense):				
Interest (income) expense	131,635	210	131,794	(555)
Pre-Tax Net Loss	(2,401,256)	(2,902,888)	(7,982,029)	(93,819,208)
Income tax (provision) benefit	-	485	(9,707)	8,859,762
Net Loss	(2,401,256)	(2,902,403)	(7,991,736)	(84,959,446)
Deemed dividend to preferred stockholders	-	(32,373)	-	(7,948,209)
Net Loss Attributable to Common Stockholders	$ (2,401,256)	$ (2,934,776)	$ (7,991,736)	$ (92,907,655)
Net Loss Per Share - Basic and Diluted	$ (2.43)	$ (30.18)	$ (9.79)	$ (1,591.46)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	988,378	97,252	816,293	58,379