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

Aug 9, 2024

KEY HIGHLIGHTS

- Phase 2a clinical trial for Cholesterol Efflux Mediator™ VAR 200 in patients with diabetic kidney disease on track to begin H2-2024.
- Obesity with related metabolic complications selected as lead indication for Inflammasome ASC Inhibitor IC 100.
    - Supportive data from preclinical study in atherosclerosis, a common obesity-related metabolic complication, is expected to be available H2-2024.
- IC 100 Investigational New Drug (IND) submission planned for Q4-2024, to be followed by initiation of a Phase 1 clinical trial in obesity with metabolic complications expected to begin Q1-2025.
- Raised approximately $0.8 million from exercise of investor warrants.

WESTON, Fla., Aug. 09, 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 June 30, 2024, and provides business update.

“We are pleased to announce that ZyVersa remains 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 an initial data read-out around the end of the year. In preparation for the planned Q4-2024 IND submission and subsequent phase 1 trial for Inflammasome ASC Inhibitor, a lead indication has been selected, obesity with related metabolic complications. This selection was based on unmet needs and IC 100’s mechanism of action substantiated in its robust preclinical program. By inhibiting ASC, IC 100 targets all four inflammasome pathways associated with obesity and related metabolic complications. Importantly, IC 100 disrupts the structure and function of extracellular ASC specks which perpetuate and spread damaging inflammation leading to obesity-related metabolic complications. We believe our 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 is on target to begin H2-2024.
    - Clinical trial agreements have been successfully negotiated with both sites
    - Clinical trial Site IRB submissions have been approved for both sites
    - Clinical product and lab kits are ready to ship
    - Site initiation visits are scheduled
    - Enrollment of first patient(s) is expected in the next few months

INFLAMMASOME ASC INHIBITOR IC 100 FOR INFLAMMATORY DISEASES

- IND submission planned for Q4-2024, to be followed by initiation of a Phase 1 clinical trial in obese patients with metabolic complications expected to begin Q1-2025.
    - IC 100 preclinical study in obesity with associated metabolic complications planned to conclude by year’s end, with a second study evaluating concomitant treatment of IC 100 and a GLP-1 agonist to begin shortly thereafter
    - Supportive data read-out from preclinical study in atherosclerosis expected H2-2024
    - GLP toxicology studies scheduled to begin H2-2024
- ZyVersa has recruited six top-tiered experts in obesity and related metabolic complications for a scientific advisory board, which will be announced in the next few weeks, to guide clinical development plans for IC 100.
- Recently published preclinical study demonstrated that IC 100 attenuates retinal inflammation, abnormal retinal

vascularization, and retinal thinning, leading to restored retinal function in an animal model of retinopathy of prematurity (ROP).
    - ROP is the sixth indication with preclinical data demonstrating that IC 100 attenuates pathogenic inflammasome signaling pathways resulting in reduced inflammation and improved histopathological and/or functional outcomes
    - The other indications are early Alzheimer's disease, multiple sclerosis, acute respiratory distress syndrome, spinal cord injury, and traumatic brain injury
- Recently published preclinical study supports the potential of plasma ASC levels as a biomarker for early stages of cognitive decline, reinforcing the role of inflammasome-induced inflammation in the development of neurodegenerative conditions such as Alzheimer's and Parkinson's diseases, and the potential of inhibiting ASC with IC 100 as a treatment option.

SECOND QUARTER FINANCIAL RESULTS

Net losses were approximately $2.8 million for the three months ended June 30, 2024, with an improvement of $75.7 million or 96.5% compared to a net loss of approximately $78.5 million, for the three months ended June 30, 2023. This large improvement is due primarily to no further impact from our one-time impairment in 2023 of in-process research and development and goodwill.

Based on its current operating plan, ZyVersa expects its cash of $0.1 million as of June 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 $0.7 million for the three months ended June 30, 2024, a decrease of $0.5 million or 41.9% from $1.2 million for the three months ended June 30, 2023. The decrease is primarily attributable to a decrease of $0.4 million in the costs of manufacturing of IC 100 and a decrease in payroll expenses due to employee attrition of $0.1 million.

General and administrative expenses were $2.0 million for the three months ended June 30, 2024, a decrease of $1.9 million or 48.0% from the three months ended June 30, 2023. The decrease is primarily attributable to a one-time 2023 charge of $1.2 million for common stock granted to certain members of the SPAC merger sponsor in exchange for certain concessions to extend the duration of their holding period. Other reductions include professional fees, marketing costs, director and officer insurance totaling $0.6 million, and a $0.1 million decrease in stock-based compensation as a result of options becoming fully amortized in February 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 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

	June 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current Assets:		
Cash	$ 119,486	$ 3,137,674
Prepaid expenses and other current assets	521,906	215,459
Total Current Assets	641,392	3,353,133
Equipment, net	1,733	6,933
In-process research and development	18,647,903	18,647,903
Vendor deposit	178,476	98,476
Operating lease right-of-use asset	-	7,839
Total Assets	$ 19,469,504	$ 22,114,284
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 8,316,506	$ 8,431,583
Accrued expenses and other current liabilities	1,678,322	1,754,533
Operating lease liability	-	8,656
Total Current Liabilities	9,994,828	10,194,772
Deferred tax liability	854,621	844,914
Total Liabilities	10,849,449	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 June 30, 2024 and December 31, 2023, respectively	-	-
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of June 30, 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 at June 30, 2024 and December 31, 2023, respectively, and 834,896 and 402,205 shares outstanding as of June 30, 2024 and December 31, 2023, respectively	83	40
Additional paid-in-capital	117,436,743	114,300,849
Accumulated deficit	(108,809,604)	(103,219,124)
Treasury stock, at cost, 7 shares at June 30, 2024 and December 31, 2023, respectively	(7,168)	(7,168)
Total Stockholders' Equity	8,620,055	11,074,598
Total Liabilities and Stockholders' Equity	$ 19,469,504	$ 22,114,284

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Operating Expenses:				

Research and development	$ 709,049	$ 1,220,576	$ 1,221,987	$ 2,276,519
General and administrative	2,044,929	3,929,225	4,358,627	7,465,362
Impairment of in-process research and development	-	69,280,171	-	69,280,171
Impairment of goodwill	-	11,895,033	-	11,895,033
Total Operating Expenses	2,753,978	86,325,005	5,580,614	90,917,085
Loss From Operations	(2,753,978)	(86,325,005)	(5,580,614)	(90,917,085)
Other (Income) Expense:				
Interest (income) expense	58	314	159	(765)
Pre-Tax Net Loss	(2,754,036)	(86,325,319)	(5,580,773)	(90,916,320)
Income tax (provision) benefit	(9,707)	7,812,226	(9,707)	8,859,277
Net Loss	(2,763,743)	(78,513,093)	(5,590,480)	(82,057,043)
Deemed dividend to preferred stockholders	-	(7,915,836)	-	(7,915,836)
Net Loss Attributable to Common Stockholders	$ (2,763,743)	$ (86,428,929)	$ (5,590,480)	$ (89,972,879)
Net Loss Per Share - Basic and Diluted	$ (3.31)	$ (1,694.12)	$ (7.67)	$ (2,329.76)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	834,915	51,017	729,306	38,619