ZyVersa Therapeutics Reports Third Quarter 2023 Corporate Update and Financial Results

Nov 14, 2023

Key Corporate Highlights:

- *Progressing toward Q1-2024 initiation of a proof-of-concept clinical trial with Cholesterol Efflux Mediator™ VAR 200 in patients with diabetic kidney disease (DKD).*
- *Granted a European patent covering use of VAR 200 (2-hydroxypropyl-beta-cyclodextrin) in diabetic nephropathy/diabetic kidney disease.*
- *Nearing completion of pre-clinical requirements for GLP toxicology studies and subsequent IND submission.*

WESTON, Fla., Nov. 14, 2023 (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, today provides a corporate update, and reports financial results for the third quarter of 2023 ending September 30, 2023.

"The third quarter of 2023 marks substantial progress toward meeting a key milestone at ZyVersa, initiation of the first clinical trial with Cholesterol Efflux Mediator™ VAR 200 in patients with diabetic kidney disease, planned for Q1-2024. We have identified our clinical research organization ("CRO") and study site, manufactured clinical product, and started preparing our IND amendment for submission in December," said Stephen C. Glover, Co-founder, Chairman, Chief Executive Officer, and President of ZyVersa. "Regarding Inflammasome ASC Inhibitor IC 100, we are nearing completion of pre-clinical requirements for conduct of our GLP toxicology studies, the final phase of our preclinical program before submitting an IND."

Mr. Glover added: "We remain committed to our goals of developing first-in-class drugs at the forefront of innovation for patients with renal and inflammatory diseases. With the development progress achieved for VAR 200 and IC 100 in 2023, we expect 2024 to be a year to accomplish significant value-building milestones that we believe will drive growth for our shareholders as we seek to improve the lives of patients living with challenging renal and inflammatory diseases."

THIRD QUARTER AND RECENT PROGRAM UPDATES

Phase 2a-Ready Cholesterol Efflux Mediator™ VAR 200

- On track to begin a proof-of-concept clinical trial in patients with DKD planned for Q1-2024.
- Granted European patent for use of VAR 200 in diabetic nephropathy/diabetic kidney disease.
- Highlighted review article providing further scientific support for VAR 200's rationale for mediating transport of cholesterol and lipids out of kidney cells.

Inflammasome ASC Inhibitor IC 100

- Nearing completion of pre-clinical requirements for conduct of GLP toxicology studies and subsequent IND submission.
- Substantiated IC 100's rationale for targeting ASC to inhibit multiple types of inflammasomes with published data demonstrating that NLRP3 inhibition alone is insufficient to attenuate inflammation in diseases associated with activation of multiple inflammasome pathways.
- Reinforced IC 100's rationale for targeting ASC with multiple peer-reviewed papers addressing the critical need to attenuate inflammation spread to surrounding tissues and organs to minimize development of co-morbidities.

THIRD QUARTER FINANCIAL RESULTS

Since its inception in 2014 through September 30, 2023, ZyVersa has not generated any revenue and has incurred significant operating losses and negative cash flows from its operations. Based on our current operating plan, we have limited our research and development spending, and we expect our cash of $1.6 million as of September 30, 2023, will only be sufficient to fund our operating expenses and capital expenditure requirements on a month-to-month basis. ZyVersa will need additional financing to support its continuing operations. ZyVersa will seek to fund its operations through public or private equity or debt financings or other sources, which may include government grants and collaborations with third parties.

Research and development expenses were $0.7 million for the three months ended September 30, 2023, a decrease of $1.7 million or 71.1% from the three months ended September 30, 2022. This is primarily attributable to a decrease of $1.7 million in the costs of manufacturing materials for IC 100 as compared to the three months ended September 30, 2022.

General and administrative expenses were $2.2 million for the three months ended September 30, 2023, an increase of $1.2 million or 110.1% from the three months ended September 30, 2022. This is primarily attributable to an increase of $0.4 million in professional fees associated with being a public company, a $0.3 million increase in director and officer insurance, a $0.2 million increase for bonus accruals, and $0.1 million increase in

marketing costs for investor and public relations.

Net losses were approximately $2.9 million for the three months ended September 30, 2023, which were $0.8 million or 21.4% less than net losses of approximately $3.7 million for the three months ended September 30, 2022. The net loss improvement was primarily due to lower costs incurred in connection with our research and development programs.

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 developed to ameliorate renal lipid accumulation that damages the kidneys' filtration system in patients with glomerular kidney diseases, and Inflammasome ASC Inhibitor IC 100, targeting damaging inflammation associated with numerous 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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ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	Successor	
	September 30, 2023	**December 31, 2022**
	(Unaudited)	
Assets		
Current Assets:		
Cash	$ 1,578,721	$ 5,902,199
Prepaid expenses and other current assets	426,519	225,347
Vendor deposits	-	235,000
Total Current Assets	2,005,240	6,362,546
Equipment, net	9,533	17,333
In-process research and development	30,806,158	100,086,329

Goodwill	-	11,895,033
Security deposit	-	46,659
Operating lease right-of-use asset	31,078	98,371
Total Assets	$ 32,852,009	$ 118,506,271
Liabilities, Temporary Equity and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 8,897,534	$ 6,025,645
Accrued expenses and other current liabilities	2,775,485	2,053,559
Operating lease liability	34,349	108,756
Total Current Liabilities	11,707,368	8,187,960
Deferred tax liability	1,440,982	10,323,983
Total Liabilities	13,148,350	18,511,943
Commitments and contingencies		
Successor redeemable common stock, subject to possible redemption, 0 and 65,783 shares outstanding as of September 30, 2023 and December 31, 2022, respectively	-	331,331
Stockholders' Equity:		
Successor preferred stock, $0.0001 par value, 1,000,000 shares authorized:		
Series A preferred stock, 8,635 shares designated, 50 and 8,635 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	-	1
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of September 30, 2023 and December 31, 2022	1	1
Successor common stock, $0.0001 par value, 110,000,000 shares authorized; 43,517,560 and 9,016,139 shares issued at September 30, 2023 and December 31, 2022, respectively, and 43,515,401 and 9,016,139 shares outstanding as of September 30, 2023 and December 31, 2022, respectively	4,353	902
Additional paid-in-capital	109,587,097	104,583,271
Accumulated deficit	(89,880,624)	(4,921,178)
Treasury stock, at cost, 2,159 and 0 shares at September 30, 2023 and December 31, 2022, respectively	(7,168)	-
Total Stockholders' Equity	19,703,659	99,662,997
Total Liabilities, Temporary Equity and Stockholders' Equity	$ 32,852,009	$ 118,506,271

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

	Successor For the Three Months Ended September 30, 2023	Predecessor For the Three Months Ended September 30, 2022	Successor For the Nine Months Ended September 30, 2023	Predecessor For the Nine Months Ended September 30, 2022
Operating Expenses:				
Research and development	$ 673,943	$ 2,334,120	$ 2,950,462	$ 4,120,477
General and administrative	2,228,735	1,061,046	9,694,097	4,526,428
Impairment of in-process research and development	-	-	69,280,171	-
Impairment of goodwill	-	-	11,895,033	-
Total Operating Expenses	2,902,678	3,395,166	93,819,763	8,646,905
Loss From Operations	(2,902,678)	(3,395,166)	(93,819,763)	(8,646,905)
Other (Income) Expense:				
Interest (income) expense	210	69,352	(555)	377,820
Change in fair value of derivative liabilities	-	228,100	-	420,600

Pre-Tax Net Loss	(2,902,888)	(3,692,618)	(93,819,208)	(9,445,325)
Income tax benefit	485	-	8,859,762	-
Net Loss	(2,902,403)	(3,692,618)	(84,959,446)	(9,445,325)
Deemed dividend to preferred stockholders	(32,373)	(9,684,637)	(7,948,209)	(10,015,837)
Net Loss Attributable to Common Stockholders	$ (2,934,776)	$ (13,377,255)	$ (92,907,655)	$ (19,461,162)
Net Loss Per Share				
- Basic and Diluted	$ (0.09)	$ (0.55)	$ (4.79)	$ (0.81)
Weighted Average Number of Common Shares Outstanding				
- Basic and Diluted	30,978,540	24,167,257	19,403,027	24,167,257