ZyVersa Therapeutics Reports Second Quarter 2023 Corporate and Financial Results

Aug 21, 2023

Key Highlights*:*

- Advanced clinical development initiatives for Cholesterol Efflux Mediator™ VAR 200, with planned initiation of a Phase 2a clinical trial in diabetic kidney disease (DKD) in the first quarter of 2024
- Granted a European patent covering Phase 2a-ready Cholesterol Efflux Mediator™ VAR 200 (2-hydroxypropyl-beta-cyclodextrin) for use in diabetic nephropathy/diabetic kidney disease
- Published new white paper detailing the critical role of inflammasome ASC in inflammatory diseases, and the potential of Inflammasome ASC Inhibitor IC 100 to address multiple CNS and non-CNS diseases
- Added Dr. Douglas Golenbock to ZyVersa's Inflammatory Disease Scientific Advisory Board to support advancement of Inflammasome ASC Inhibitor IC 100

WESTON, Fla., Aug. 21, 2023 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq-GM: 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 second quarter of 2023 ending June 30, 2023.

"The second quarter of 2023 was a period of continued progress at ZyVersa as we completed key corporate, developmental, regulatory and financial initiatives designed to position the company to achieve value-building milestones involving our Cholesterol Efflux Mediator™ VAR 200 and Inflammasome ASC Inhibitor IC 100," said Stephen C. Glover, Co-founder, Chairman, Chief Executive Officer, and President of ZyVersa. "We are pleased to report our VAR 200 program is progressing as planned, and we anticipate initiation of a Phase 2a clinical trial in diabetic kidney disease (DKD) in the first quarter of 2024. For our Inflammasome ASC Inhibitor IC 100, we are completing final preclinical activities to enable submission of an Investigational New Drug ("IND") application and initiation of a first-in-human clinical trial in 2024."

Mr. Glover concluded: "This is a very exciting time for ZyVersa as we seek to create shareholder value through the development of first-in-class drugs at the forefront of renal and inflammatory diseases. Significant value-building milestones are expected to be achieved for Cholesterol Efflux Mediator™ VAR 200 and Inflammasome ASC Inhibitor IC 100 over the remainder of 2023 and early 2024 to increase shareholder value."

SECOND QUARTER AND RECENT PROGRAM UPDATES

Phase 2a-Ready Cholesterol Efflux Mediator™ VAR 200

- European patent was granted covering VAR 200 for use in diabetic nephropathy/diabetic kidney disease
- Planning and key initiatives are underway to initiate a Phase 2a clinical trial in patients with DKD, with initial patient enrollment expected by first quarter 2024

Inflammasome ASC Inhibitor IC 100

- Continued to provide support for the mechanism of action of Inflammasome ASC Inhibitor IC 100 with consistent evidence across peer-reviewed academic literature on the role of inflammasomes in the pathogenesis of a broad range of diseases including Parkinson's disease, Alzheimer's disease, lupus nephritis, peripheral arterial disease, juvenile idiopathic arthritis, and alcoholic hepatitis
- Enhanced Inflammatory Disease Scientific Advisory Board with the addition of Dr. Douglas Golenbock, a pioneer and internationally recognized authority in the field of innate immunity
    - Dr. Golenbock is The Neil and Margery Blacklow Chair in Infectious Diseases and Immunology and Professor and Chief, Division of Infectious Diseases and Immunology at the UMass Chan Medical School

SECOND QUARTER FINANCIAL RESULTS

Since its inception in 2014 through June 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 expect our cash of $0.2 million as of June 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 $1.2 million for the three months ended June 30, 2023, an increase of $0.5 million or 69.7% from the three

months ended June 30, 2022. The increase is primarily attributable to an increase of $0.5 million in the costs of manufacturing of IC 100.

General and administrative expenses were $3.9 million for the three months ended June 30, 2023, an increase of $2.8 million or 237.5% from the three months ended June 30, 2022. The increase is primarily attributable to $1.2 million of common stock granted to certain stockholders in exchange for increasing the duration of their lockup period for certain common stockholdings, $0.5 million in professional fees associated with being a public company, a $0.5 million increase in marketing costs for investor and public relations, $0.4 million in director and officer insurance, and $0.2 million for bonus accruals.

Pre-tax losses were $86.3 million for the three months ended June 30, 2023, an increase of $84.3 million compared to a pre-tax loss of approximately $2.0 million, for the three months ended June 30, 2022. The higher net loss reported for the three months ended June 30, 2023 is primarily due to the impairment of in-process research and development and impairment of goodwill of $69.3 million and $11.9 million, respectively, compared to none for the three months ended June 30, 2022. The impairment is a result of the decline in ZyVersa's market capitalization as of June 30, 2023.

Net losses were $78.5 million for the three months ended June 30, 2023, an increase of $76.5 million compared to a net loss of approximately $2.0 million for the three months ended June 30, 2022. A deferred tax benefit of $7.8 million for the three months ended June 30, 2023, compared to no tax benefit or expense during the three months ended June 30, 2022, resulted from the impairment of the in-process research and development.

About ZyVersa Therapeutics, Inc.

ZyVersa (Nasdaq-GM: 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 additional financing 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

	Successor	
	June 30, 2023	**December 31, 2022**

		(Unaudited)
Assets		
Current Assets:		
Cash	$ 228,693	$ 5,902,199
Prepaid expenses and other current assets	886,911	225,347
Vendor deposits	-	235,000
Total Current Assets	1,115,604	6,362,546
Equipment, net	12,133	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	53,898	98,371
Total Assets	$ 31,987,793	$ 118,506,271
Liabilities, Temporary Equity and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 8,144,033	$ 6,025,645
Accrued expenses and other current liabilities	2,281,026	2,053,559
Operating lease liability	59,625	108,756
Total Current Liabilities	10,484,684	8,187,960
Deferred tax liability	1,441,467	10,323,983
Total Liabilities	11,926,151	18,511,943
Commitments and contingencies (Note 8)		
Successor redeemable common stock, subject to possible redemption, 0 and 65,783 shares outstanding as of June 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, 200 and 8,635 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	-	1
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of June 30, 2023 and December 31, 2022	1	1
Successor common stock, $0.0001 par value, 110,000,000 shares authorized; 23,669,074 and 9,016,139 shares issued at June 30, 2023 and December 31, 2022, respectively, and 23,666,915 and 9,016,139 shares outstanding as of June 30, 2023 and December 31, 2022, respectively	2,367	902
Additional paid-in-capital	107,044,663	104,583,271
Accumulated deficit	(86,978,221)	(4,921,178)
Treasury stock, at cost, 2,159 and 0 shares at June 30, 2023 and December 31, 2022, respectively	(7,168)	-
Total Stockholders' Equity	20,061,642	99,662,997
Total Liabilities, Temporary Equity and Stockholders' Equity	$ 31,987,793	$ 118,506,271

ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

Successor	Predecessor	Successor	Predecessor
For the Three Months Ended June 30, 2023	For the Three Months Ended June 30, 2022	For the Six Months Ended June 30, 2023	For the Six Months Ended June 30, 2022

Operating Expenses:				
Research and development	$ 1,220,576	$ 719,395	$ 2,276,519	$ 1,786,357
General and administrative	3,929,225	1,164,013	7,465,362	3,465,382
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	86,325,005	1,883,408	90,917,085	5,251,739
Loss From Operations	(86,325,005)	(1,883,408)	(90,917,085)	(5,251,739)
Other (Income) Expense:				
Interest (income) expense	314	140,404	(765)	308,468
Change in fair value of derivative liabilities	-	(19,600)	-	192,500
Pre-Tax Net Loss	(86,325,319)	(2,004,212)	(90,916,320)	(5,752,707)
Income tax benefit	7,812,226	-	8,859,277	-
Net Loss	(78,513,093)	(2,004,212)	(82,057,043)	(5,752,707)
Deemed dividend to preferred stockholders	(7,915,836)	(331,200)	(7,915,836)	(331,200)
Net Loss Attributable to Common Stockholders	$ (86,428,929)	$ (2,335,412)	$ (89,972,879)	$ (6,083,907)
Net Loss Per Share - Basic and Diluted	$ (4.84)	$ (0.10)	$ (6.66)	$ (0.25)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	17,855,762	24,167,257	13,517,314	24,167,257