

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **May 12, 2023**

ZYVERSA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-41184

(Commission
File Number)

86-2685744

(I.R.S. Employer
Identification No.)

2200 N. Commerce Parkway, Suite 208

Weston, Florida, 33326

(Address of principal executive offices) (Zip Code)

(754) 231-1688

(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbols	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	ZVSA	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02. Results of Operations and Financial Condition.

ZyVersa Therapeutics, Inc. (the “Company”) issued a press release on May 12, 2023, disclosing financial information and operating metrics for its first fiscal quarter ended March 31, 2023 and discussing its business outlook. A copy of the Company’s press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K under Item 2.02, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Press Release issued by ZyVersa Therapeutics, Inc. dated May 12, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: May 12, 2023

By: /s/ Stephen Glover

Name: Stephen C. Glover

Title: Chief Executive Officer

ZyVersa Therapeutics Reports First Quarter 2023 Corporate and Financial Results**Key Highlights:**

- Continued progress has been made in advancing an investigator-initiated clinical trial to gain human proof-of-concept for Cholesterol Efflux Mediator™ VAR 200 in patients with renal disease
- Announced publication of several peer-reviewed journal articles supporting ASC inhibition as a promising therapeutic target - data continue to demonstrate that multiple types of inflammasomes are activated in various conditions (Alzheimer's disease, traumatic brain injury, and injury from intracortical implants), and substantiate that extracellular release of ASC specks to neighboring cells heighten and perpetuate damaging inflammation leading to disease progression in conditions such as Parkinson's disease and alcoholic hepatitis
- Added three internationally recognized experts in the field of glomerular disease to Renal Scientific Advisory Board, and an internationally recognized authority in the field of innate immunity to our Inflammatory Disease Scientific Advisory Board
- Enhanced our Board of Directors with addition of three biopharmaceutical leaders with impeccable credentials and a proven track record of success

Weston, FL, May 12, 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, provides a corporate update and reports financial results for the first quarter of 2023 ending March 31, 2023.

“This is a very exciting time in the growth and evolution of ZyVersa as we seek to build shareholder value through development of first-in-class drugs at the forefront of innovation for renal and inflammatory diseases,” said Stephen C. Glover, Co-founder, Chairman, Chief Executive Officer, and President of ZyVersa. “We are currently advancing a dynamic pipeline of drug candidates with multiple programs built around our two proprietary technologies – Cholesterol Efflux Mediator™ VAR 200 for treatment of kidney diseases and Inflammasome ASC Inhibitor IC 100 for treatment of multiple CNS and other inflammatory diseases. We believe that both technologies have transformative potential, enabling development of drugs for patients who have limited or no therapeutic options.”

Mr. Glover continued: “Highlighting our Inflammasome ASC Inhibitor IC 100, ZyVersa expects to complete IC 100's preclinical program this year, with an Investigational New Drug (“IND”) submission anticipated in second quarter of 2024. We were pleased to report publication of data in several peer-reviewed journal articles demonstrating the role of ASC specks in heightening and perpetuating damaging inflammation in neurological conditions (Alzheimer's disease, Parkinson's disease, and traumatic brain injury), and in alcoholic hepatitis. These data support the therapeutic potential of inhibiting ASC and ASC specks with IC 100 to control inflammation associated with various inflammatory diseases.”

“Regarding Cholesterol Efflux Mediator™ VAR 200, ZyVersa continues to leverage relationships with experts in the field of renal disease,” stated Mr. Glover. “To that end, we welcomed three new members to our Renal Disease Scientific Advisory Board. We look forward to benefitting from their decades of experience as we advance our investigator-initiated trial to evaluate VAR 200 in patients with renal disease, expected to begin in the fourth quarter of 2023.”

FIRST QUARTER AND RECENT PROGRAM UPDATES

Targeting Renal Disease with Phase 2a-Ready Cholesterol Efflux Mediator™ VAR 200

- Continued progress is being made to launch an investigator-initiated clinical trial in patients with renal disease to gain human proof-of-concept for Cholesterol Efflux Mediator™ VAR 200, with trial initiation expected in the fourth quarter of 2023
- Added to ZyVersa’s Renal Scientific Advisory Board (1) Dr. Daniel C. Cattran, Professor of Medicine, University of Toronto; (2) Dr. Fernando C. Fervenza, Professor of Medicine, Mayo Graduate School of Medicine and Director of the Nephrology Collaborative Group; and (3) Dr. Richard J. Glassock, Professor Emeritus, David Geffen School of Medicine, UCLA

Inflammasome ASC Inhibitor IC 100: Targeting Inflammation Associated with Multiple CNS and Other Inflammatory Diseases

- On track to complete IND-enabling preclinical studies by end of year, with the goal of filing an IND application with the U.S. Food and Drug Administration in the second quarter of 2024
- Highlighted peer-reviewed journal articles supporting the potential of ASC inhibition to control damaging inflammation associated with numerous diseases, including Alzheimer’s disease, Parkinson’s disease, traumatic brain injury, and alcohol induced hepatitis
- Added to ZyVersa’s Inflammatory Disease Scientific Advisory Board Dr. Douglas Golenbock, 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

FIRST QUARTER FINANCIAL RESULTS

Since its inception in 2014 through March 31, 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 \$1.3 million as of March 31, 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 consistent at approximately \$1.1 million for the three months ended March 31, 2023 (“Successor Period”), with an immaterial decrease of \$11 thousand or 1.0% from the three months ended March 31, 2022 (“Predecessor Period”).

General and administrative expenses were \$3.5 million for the three months ended March 31, 2023, an increase of \$1.2 million or 53.7% from \$2.3 million for the three months ended March 31, 2022. The increase is primarily attributable to an increase of \$0.4 million in director and officer insurance, a \$0.4 million increase in marketing costs for investor and public relations, and \$0.4 million in payments for the Effectiveness Failure related to the PIPE shares.

Net losses were approximately \$3.5 million for the three months ended March 31, 2023, with an improvement of \$0.2 million or 5.5% compared to a net loss of approximately \$3.7M, for the three months ended March 31, 2022. Net losses for the three months ended March 31, 2023 benefited from a \$1.0 Million deferred tax benefit compared to none for the year earlier period.

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.

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	
	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current Assets:		
Cash	\$ 1,278,073	\$ 5,902,199
Prepaid expenses and other current assets	1,321,551	225,347
Vendor deposits	235,000	235,000
Total Current Assets	2,834,624	6,362,546
Equipment, net	14,733	17,333
In-process research and development	100,086,329	100,086,329
Goodwill	11,895,033	11,895,033
Security deposit	46,659	46,659
Operating lease right-of-use asset	76,324	98,371
Total Assets	\$ 114,953,702	\$ 118,506,271
Liabilities, Temporary Equity and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 6,381,086	\$ 6,025,645
Accrued expenses and other current liabilities	2,112,812	2,053,559
Operating lease liability	84,507	108,756
Total Current Liabilities	8,578,405	8,187,960
Deferred tax liability	9,276,932	10,323,983
Total Liabilities	17,855,337	18,511,943
Commitments and contingencies		
Successor redeemable common stock, subject to possible redemption, 0 and 65,783 shares outstanding as of March 31, 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, 8,635 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	1	1
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	1	1
Successor common stock, \$0.0001 par value, 110,000,000 shares authorized; 9,211,922 and 9,016,139 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	922	902
Additional paid-in-capital	105,562,569	104,583,271
Accumulated deficit	(8,465,128)	(4,921,178)
Total Stockholders' Equity	97,098,365	99,662,997
Total Liabilities, Temporary Equity and Stockholders' Equity	\$ 114,953,702	\$ 118,506,271

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

	Successor	Predecessor
	For the Three	For the Three
	Months Ended	Months Ended
	March 31,	March 31,
	2023	2022
Operating Expenses:		
Research and development	\$ 1,055,943	\$ 1,066,962
General and administrative	3,536,136	2,301,369
Total Operating Expenses	4,592,079	3,368,331
Loss From Operations	(4,592,079)	(3,368,331)
Other (Income) Expense:		
Interest (income) expense	(1,078)	168,064
Change in fair value of derivative liabilities	-	212,100
Pre-Tax Net Loss	(4,591,001)	(3,748,495)
Income tax benefit	1,047,051	-
Net Loss	\$ (3,543,950)	\$ (3,748,495)
Net Loss Per Share		
- Basic and Diluted	\$ (0.39)	\$ (0.16)
Weighted Average Number of Common Shares Outstanding		
- Basic and Diluted	9,128,488	24,167,257