ZyVersa Therapeutics Reports Fourth Quarter and Year-End 2022 Corporate and Financial Results

April 3, 2023

Key Highlights:

- Closed business combination with Larkspur Health Acquisition Corp. in December 2022 and began trading on Nasdaq Global Market under the ticker symbol “ZVSA”
- Planning underway with nephrologists for an investigator-initiated clinical trial in focal segmental glomerulosclerosis (“FSGS”) and up to two other renal populations to gain human proof-of-concept for Cholesterol Efflux Mediator™ VAR 200
- Recently published data in peer-reviewed journals detail the mechanism of action of inflammasome ASC inhibitor IC 100, and support its CNS activity in preclinical models of aging and Alzheimer’s disease
- Added three new Board members and three new members to Renal Scientific Advisory Board

WESTON, Fla., April 03, 2023 (GLOBE NEWSWIRE) -- ZyVersa Therapeutics, Inc. (Nasdaq: ZVSA, or "ZyVersa"), a clinical-stage specialty biopharmaceutical company developing first-in-class drug candidates for the treatment of renal and inflammatory diseases with high unmet medical needs, today provides a corporate update and reported financial results for the fourth quarter and full year ended December 31, 2022.

“This is a very exciting time in the growth and evolution of ZyVersa. We seek to create shareholder value through the 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 ZyVersa to target numerous, underserved disease indications.”

Mr. Glover continued: “Our lead clinical product candidate, Cholesterol Efflux Mediator™ VAR 200 is being developed for potential treatment of multiple renal indications including FSGS, a progressive form of kidney disease for which no approved disease-specific treatment options exist. An investigator-initiated trial to evaluate VAR 200 in up to three renal indications including FSGS, is expected to initiate in the fourth quarter of 2023. Additionally, ZyVersa plans to complete IC 100’s preclinical program this year, with an Investigational New Drug (“IND”) submission anticipated in second quarter of 2024.”

Mr. Glover concluded: “We believe that 2023 offers the potential to be a year of significant progress at ZyVersa based on the value-building milestones that we expect to achieve over the next 12 to 18 months. Our leadership team and Board members are focused on executing our business and clinical development strategy designed to position ZyVersa as a leading and innovative company developing transformative drugs for underserved patients with renal and inflammatory diseases.”

FOURTH QUARTER AND RECENT PROGRAM UPDATES

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

- Planning investigator-initiated trial (“IIT”) with nephrologists in up to three renal indications, including FSGS, with trial initiation expected in the fourth quarter of 2023. Data from the IIT is expected to validate FSGS as the lead indication and will guide protocol development for a Phase 2a clinical trial
- Added three members to ZyVersa’s Renal Scientific Advisory Board

Inflammasome ASC Inhibitor IC 100: Blocks Initiation and Perpetuation of Damaging Inflammation Associated with Multiple Sclerosis and CNS and Other Inflammatory Diseases

- Preparing 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
- Plan to expand research program beyond proof-of-concept for multiple sclerosis and acute respiratory distress syndrome to evaluate additional indications
- Completed initial toxicology studies with IC 100 in rodents and non-human primates demonstrating no significant safety issues at doses up to 300mg/kg
- Awarded a grant from The Michael J. Fox Foundation to determine if IC 100 inhibition of microglial inflammasome

activation in a Parkinson's disease ("PD") model blocks neuroinflammation driving PD pathology
    - The research is underway at the University of Miami Miller School of Medicine in the labs of IC 100 inventors, Drs. Robert W. Keane and Juan Pablo de Rivero Vaccari

- Researchers at the University of Miami Miller School of Medicine published two peer-reviewed papers in *Translational Research:*
    - The first demonstrates that IC 100 gains access into cells, binds to ASC, and alters the structure of ASC specks, inhibiting activation and release of IL-1β to attenuate heightened inflammation associated with disease
    - The second indicates that IC 100 reduces CNS inflammasome activation in a mouse model for Alzheimer's disease following traumatic brain injury

- Those researchers also published a third peer-reviewed paper in *Frontiers in Molecular Neuroscience* which showed that IC 100 reduces brain inflammation in an aging mouse model

Closed Business Combination with Larkspur Health Acquisition Corp. and Began Trading on the Nasdaq Global Market

- Completed business combination with Larkspur Health Acquisition Corp., a blank-check special purpose acquisition company, in December 2022

- Initiated trading on the Nasdaq Global Market under the ticker symbol "ZVSA" on December 13, 2022

Mr. Glover commented: "Our business combination with Larkspur Health Acquisition Corp in December was a major inflection point for ZyVersa, providing a gateway to the Nasdaq Global Market, which we believe will serve to increase long-term shareholder value by augmenting our visibility and broadening our engagement with investors, further enabling our R&D initiatives. It was the culmination of several months of hard work by our executive team during a very challenging period for the capital markets and biotechnology industry. We believe that our ability to complete the deal is a testimony to senior management's deep biopharma experience, and the tenacity and creativity we bring to ZyVersa every day."

FOURTH QUARTER AND YEAR END 2022 FINANCIAL RESULTS

Since its inception in 2014 through December 31, 2022, ZyVersa has not generated any revenue and has incurred significant operating losses and negative cash flows from its operations. Based on its current operating plan, ZyVersa expects its cash of $5.9 million as of December 31, 2022 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. 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 $0.4 million for the period from December 13, 2022, through December 31, 2022 (the "Successor" period) and $5.4 million for the period from January 1, 2022 through December 12, 2022 (the "Predecessor" period). Research and development expenses for the combined year ended December 31, 2022 were $5.8 million, an increase of $3.7 million or 173.4% from the $2.1 million for the Predecessor year ended December 31, 2021. The increase in research and development expenses was due to an overall increase in spending for batch manufacturing, analytical services, and for materials supplies for manufacturing.

General and administrative expenses were $0.4 million for the Successor period and $7.6 million for the Predecessor period. General and administrative expenses for the combined year ended December 31, 2022, were $8.0 million, an increase of $2.4 million or 43.8% from the $5.6 million for the Predecessor year ended December 31, 2021. The increase in general and administrative expenses is primarily due to transaction costs of $2.2 million directly related to preparations for the business combination**.**

Net losses were $75,018 for the Successor period and $14.0 million for the Predecessor period. Net loss for the combined year ended December 31, 2022 was $14.1 million, an increase of $6.0 million or 75% from the $8.1 million for the Predecessor year ended December 31, 2021. As noted above, the increase is primarily driven by manufacturing costs for research and development ($3.7 million) and general and administrative costs ($2.4 million) primarily related to transaction costs for the business combination.

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 for treatment of kidney diseases, and IC 100, a novel inflammasome ASC inhibitor to control 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 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.

Corporate and IR Contact:
Karen Cashmere
Chief Commercial Officer
kcashmere@zyversa.com
786-251-9641

Media Contacts
Tiberend Strategic Advisors, Inc.
Casey McDonald
cmcdonald@tiberend.com
646-577-8520

Dave Schemelia
dschemelia@tiberend.com
609-468-9325

ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	Successor December 31, 2022	Predecessor December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,902,199	$ 328,581
Prepaid and other current assets	460,347	483,201
Total current assets	6,362,546	811,782
Property and equipment, net	17,333	27,733
In-process research and development	100,086,329	-
Goodwill	11,895,033	-
Operating lease right-of-use asset	98,371	-
Other assets	46,659	286,659
Total assets	$ 118,506,271	$ 1,126,174
LIABILITIES, TEMPORARY EQUITY AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
Current liabilities:		
Accounts payable	$ 6,025,645	$ 2,000,100
Accrued expenses and other current liabilities	2,053,559	1,914,101
Operating lease liability	108,756	-
Derivative liabilities	-	560,600
Convertible notes payable	-	9,151,508
Total current liabilities	8,187,960	13,626,309
Deferred tax liability	10,323,983	-
Total liabilities	18,511,943	13,626,309
Commitments and contingencies		
Successor redeemable common stock, subject to possible redemption, 65,783 shares outstanding as of December 31, 2022	331,331	-
Predecessor redeemable common stock, subject to possible redemption, 331,331 shares outstanding as of December 31, 2021	-	331,331
Stockholders' equity (deficiency):		

Preferred stock, $0.0001 par value, 1,000,000 shares authorized:		
Successor Series A preferred stock, 8,635 shares designated,		
8,635 shares issued and outstanding as of December 31, 2022	1	-
Successor Series B preferred stock, 5,062 shares designated,		
5,062 shares issued and outstanding as of December 31, 2022	1	-
Successor common stock, $0.0001 par value, 110,000,000 shares authorized;		
9,016,139 shares issued and outstanding as of December 31, 2022	902	-
Predecessor common stock, $0.00001 par value, 75,000,000 shares authorized;		
24,167,257 shares issued and outstanding as of December 31, 2021	-	242
Additional paid-in-capital	104,583,271	40,065,109
Accumulated deficit	(4,921,178)	(52,896,817)
Total stockholders' equity (deficiency)	99,662,997	(12,831,466)
Total liabilities, temporary equity and stockholders' equity (deficiency)	$ 118,506,271	$ 1,126,174

ZYVERSA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Successor	Predecessor	
	For the period December 13 through December 31, 2022	For the period January 1 through December 12, 2022	For the year ended December 31, 2021
Operating Expenses:			
Research and development	$ 399,894	$ 5,407,859	$ 2,124,277
General and administrative	420,174	7,605,205	5,580,099
Total operating expenses	820,068	13,013,064	7,704,376
Loss from operations	(820,068)	(13,013,064)	(7,704,376)
Other (income) expense:			
Interest expense	-	427,542	821,366
Change in fair value of derivative liabilities	-	607,001	(228,100)
Gain on forgiveness of PPP Loan	-	-	(213,481)
Pre-Tax Net Loss	(820,068)	(14,047,607)	(8,084,161)
Income tax benefit	745,050	-	-
Net loss	(75,018)	(14,047,607)	(8,084,161)
Deemed dividend to preferred stockholders	-	(10,015,837)	-
Net loss attributable to common stockholders	$ (75,018)	$ (24,063,444)	$ (8,084,161)
Net loss per share basic and diluted	$ (0.01)	$ (0.99)	$ (0.33)
Weighted average common shares outstanding basic and diluted	9,016,139	24,194,270	24,167,257