UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to_____

Commission File Number: 001-41184

ZYVERSA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**86-2685744**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2436 N. Federal Highway, Suite 466 Lighthouse Point, FL 33064	**33064**
(Address of principal executive offices)	(Zip Code)

(754) 231-1688
(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	ZVSA	*

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: ☐ No: ☒

Indicate by check mark if the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: ☒ No: ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes: ☒ No: ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark if the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes: ☐ No: ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

* The Company's common stock is quoted on the OTCQB® Venture Market under the symbol "ZVSA."

As of June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of shares of the registrant's common stock held by non-affiliates of the registrant (based upon the closing sales price of $0.68 for such shares on the Nasdaq Capital Market on June 30, 2025) was approximately $3.3 million. For purposes of calculating the aggregate market value of shares held by non-affiliates, we have assumed that all outstanding shares are held by non-affiliates, except for shares held by each of our executive officers, directors, and 5% or greater stockholders. In the case of 5% or greater stockholders, we have not deemed such stockholders to be affiliates unless there are facts and circumstances which would indicate that such stockholders exercise any control over our company, or unless they hold 10% or more of our outstanding common stock. These assumptions should not be deemed to constitute an admission that all executive officers, directors, and 5% or greater stockholders are, in fact, affiliates of our company, or that there are not other persons who may be deemed to be affiliates of our company. Further information concerning shareholdings of our officers, directors, and principal stockholders is included or incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

As of March 25, 2026, the number of shares outstanding of the registrant's common stock, $0.0001 par value per share, was 8,095,921.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our ability to continue as a going concern;
- the costs associated with our business;
- our financial and business performance, including financial projections and business metrics;
- our ability to achieve and maintain profitability in the future
- our ability to effectively grow and expand operations;
- the risk of disruption to our current plans and operations;
- the potential for business or economic disruptions, including those caused by catastrophic events;
- our ability to maintain the quotation of our securities on the OTCQB® Venture Market, and the potential liquidity and trading of our securities;
- our ability to recognize the anticipated benefits of our business, which may be affected by, among other things, the ability to grow and manage our research and development and clinical activity, and retain key employees;
- the impact of changes to applicable laws or regulations;
- our future capital requirements and sources and uses of cash, including the ability to access sources of capital or raise financing in the future;
- the strength of our network, effectiveness of its technology, and quality of the offerings provided through our platform;
- the projected financial information, growth rate, strategies, and market opportunities for our business;
- our ability to maintain our existing license agreements and other collaborative arrangements;

- our ability to obtain and maintain regulatory approval for our product candidates, and any related restrictions and limitations of any approved products in the future;
- the success, cost and timing of our research and development strategies and activities;
- our ability to successfully launch our product candidates and be accepted by the market;
- our ability, assessment of, and strategies to compete with our competitors;
- our ability to attract and retain talent and the effectiveness of our compensation strategies and leadership;
- our ability to maintain our licenses and operate in the heavily regulated pharmaceutical industries;
- our ability to prevent and guard against cybersecurity attacks;
- our reliance on third-party service providers for processing payments, web and mobile operating systems, software, background checks, and insurance policies;
- our ability to establish and maintain an effective system of internal controls over financial reporting;
- the outcome of any known and unknown litigation and regulatory proceedings, including the occurrence of any event, change or other circumstances, including the outcome of any legal proceedings that may be instituted against us that could impact our business;
- our ability to maintain and protect our brand and intellectual property; and
- other factors detailed under the section entitled "*Risk Factors*."

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in such forward-looking statements. Please see "Part I—Item 1A—Risk Factors" for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaims any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

PART I

ITEM 1. BUSINESS

All references in this report to "ZyVersa," the "Company," "we," "us," or "our" mean ZyVersa Therapeutics, Inc. and its subsidiaries unless we state otherwise, or the context otherwise indicates.

Company Overview

We are a clinical stage biopharmaceutical company leveraging proprietary technologies to develop drugs for patients with chronic renal or inflammatory diseases with high unmet medical needs. Our mission is to develop drugs that optimize health outcomes and improve patients' quality of life.

We have two proprietary globally licensed drug development platforms, each of which was discovered by research scientists at the University of Miami, Miller School of Medicine (the "University of Miami" or "University"). These development platforms are:

- Cholesterol Efflux Mediator™ VAR 200 (2-hydroxypropyl-beta-cyclodextrin or "2HPβCD") is an injectable drug in clinical development for treatment of renal diseases. VAR 200 was licensed from L&F Research LLC on December 15, 2015. L&F Research was founded by the University of Miami research scientists who discovered the use of VAR 200 for renal diseases.

- Inflammasome ASC Inhibitor IC 100 is a humanized monoclonal antibody in preclinical development for treatment of inflammatory conditions. IC 100 was licensed from InflamaCore, LLC on April 18, 2019. InflamaCore, LLC was founded by the University of Miami research scientists who invented IC 100.

We believe that each of our product candidates has the potential to treat numerous indications in their respective therapeutic areas. Our strategy is to focus on indication expansion to maximize commercial potential.

Our renal pipeline is initially focused on rare, chronic glomerular diseases. Our lead indication for VAR 200 is focal segmental glomerulosclerosis ("FSGS"). We plan to initiate a Phase 2a basket trial in FSGS and Alport syndrome patients in Q2-2026. VAR 200 has pharmacologic proof-of-concept data in animal models representative of FSGS, Alport Syndrome, and diabetic kidney disease.

Our Inflammasome ASC Inhibitor IC 100 focuses on chronic inflammatory diseases. Our lead indication for IC 100 is cardiometabolic conditions associated with obesity. IC 100's preclinical development is nearing completion. Our focus is on advancing IC 100 toward a currently planned IND submission in Q4-2026, followed by initiation of a Phase 1 trial in healthy overweight patients with a BMI between 27 – 30 at risk for cardiometabolic conditions. We are preparing to initiate IND-enabling preclinical studies in an animal model of diet-induced obesity, which develops metabolic complications, and an animal model representative of an orphan renal disease in Q2-2026.

About Chronic Kidney Disease (CKD)

Chronic kidney disease ("CKD") is an increasing public health problem which affects over 750 million people worldwide, and approximately 37 million in the United States. The National Kidney Foundation estimates that approximately 80 million adults are at risk for kidney disease in the United States. With no disease modifying drug therapies commercially available, a sizeable percentage of kidney patients progress to end-stage renal disease ("ESRD"), requiring dialysis or transplant to survive. According to the Centers for Disease Control and Prevention, in 2018, approximately 131,600 people in the United States started treatment for ESRD, and nearly 786,000 people are currently living with ESRD in the United States (of those 786,000 people, approximately 71% are on dialysis, and 29% are living with a kidney transplant). Further, the economic burden associated with chronic kidney disease is substantial, with Medicare Fee-for-Service spending of $130 billion in 2018 according to the National Kidney Foundation. We believe the high incidence level and the steep monetary burden caused by CKD create a need for effective, disease modifying drug therapies. We believe that VAR 200 has the potential to help reduce the number of patients developing renal failure by mediating removal of excess renal cholesterol and lipids that contribute to kidney damage and dysfunction,

Our lead renal indication is FSGS, which is a progressive form of kidney disease with no approved drug therapies. Approximately 40-60% of FSGS patients develop end stage kidney disease within 10-20 years, requiring dialysis and ultimately kidney transplant to survive. FSGS is an orphan disease affecting approximately 40,000 people in the United States. It is characterized by injury to the kidneys' filtration system or "glomerular podocytes" leading to scarring that is focal (i.e., affecting only some glomerulus) and segmental (i.e., affecting only part of glomerulus). Accumulation of cholesterol and lipids in renal glomeruli, which has been associated with structural damage and impaired kidney function, has been seen in FSGS patient biopsies and in representative FSGS animal models. Damage to the glomeruli causes protein to leak into urine, a condition known as proteinuria. As the level of protein increases in the urine, patients develop a specific set of symptoms known as nephrotic syndrome. Proteinuria is strongly associated with kidney disease progression, and nephrotic syndrome is generally predictive of a poor prognosis. Approximately 70% of FSGS patients present with nephrotic syndrome at diagnosis. By mediating removal of excess cholesterol from renal glomeruli, we believe that VAR 200 has the potential to preserve renal structure and function and thereby reduce proteinuria that leads to FSGS progression.

About Inflammatory Diseases

Chronic inflammatory diseases have been recognized as one of the most significant causes of death in the world today, with more than 50% of all deaths worldwide attributable to inflammation-related diseases such as ischemic heart disease, stroke, cancer, diabetes mellitus, chronic kidney disease, non-alcoholic fatty liver disease ("NAFLD"), and autoimmune and neurodegenerative conditions. Excessive and persistent activation of inflammasomes have been linked to the pathophysiology of these types of chronic diseases.

Inflammasomes are comprised of 3 proteins: (i) one of several types of sensor molecules, (ii) an apoptosis-associated speck-like protein containing a caspase recruitment domain ("ASC"), and (iii) proinflammatory caspase-1 ("pro-caspase-1"). There are multiple types of inflammasomes that trigger inflammation. They are named based on their associated sensor molecule, such as NLRP1, NLRP2, NLRP3, NLRC4, AIM2, and Pyrin. Numerous inflammatory diseases are often associated with activation of multiple types of inflammasomes. For example, obesity is associated with activation of AIM2 and NLRP3, insulin resistance is associated with AIM2, NLRP3, and NLRC4 and diabetic nephropathy is associated with activation of AIM2, NLRP3, and NLRC4. The ASC component of inflammasomes is a promising drug target since it is a component of the six most common types of inflammasomes referenced above. We believe targeting ASC is more effective than targeting a specific sensor protein such as NLRP3, that inhibits only one type of inflammasome. In addition to its pivotal role in inflammasome formation and activation required for initiation of an inflammatory response, ASC also plays a role in the perpetuation of inflammation associated with extracellular release of ASC specks. By targeting ASC, we believe IC 100 has potential to effectively control inflammation in a multitude of inflammatory diseases.

Our Pipeline

The goal of our pipeline is to target renal and inflammatory indications with high unmet medical needs, which we believe can be addressed by our mechanisms of action. We intend to further enhance and expand our product portfolio through the development of multiple indications for VAR 200 and IC 100 each, and through potential in-licensing of promising renal and anti-inflammatory product candidates.

Our current pipeline consists of the following:

Development Phase: Phase in which a drug formulation is developed that ensures the proper drug delivery parameters are met

Preclinical Phase: Phase in which *in vitro* (laboratory) and *in vivo* (animal) studies are conducted to gather evidence to justify clinical trials in humans

Phase 1: First testing in healthy humans, primarily to test safety

Phase 2: Testing in a small number of patients to assess safety, monitor how a drug is metabolized, and gather initial data on efficacy

Phase 3: Large trial in patients to test efficacy and safety that are used for regulatory approval

Business Strategy

We seek to be recognized as a leading biopharmaceutical company at the forefront of innovation for patients with high unmet medical needs. We are committed to restoring health and transforming the lives of patients through development of biopharmaceutical products. Our strategy is to:

- ***Advance development of Cholesterol Efflux Mediator^{TM} VAR 200.*** We intend to advance development of VAR 200 by initiating a small Phase 2a trial in FSGS and Alport syndrome patients in Q2-2026.

- ***Advance development of Inflammasome ASC Inhibitor IC 100.*** We intend to advance our IC 100 preclinical program toward a planned IND submission Q4-2026, followed by initiation of a Phase 1 trial in healthy patients with a BMI between 27 – 30 at risk for cardiometabolic conditions. In preparation for IND submission, we are preparing to initiate an IND-enabling preclinical study in a diet-induced obesity animal model,that develops cardiometabolic conditions.

- ***Capitalize on our indication expansion strategy to maximize the commercial potential for each of our product platforms by developing multiple indications in their respective therapeutic areas.*** Our current pipeline includes three potential indications for our Cholesterol Efflux Mediator^{TM} VAR 200 Platform, FSGS (lead indication), Alport Syndrome, and diabetic kidney disease. Two near-term potential indications for our Inflammasome ASC inhibitor IC 100 platform are cardiometabolic conditions associated with obesity (lead indication) and an orphan renal disease. We intend to leverage our knowledge from preclinical and clinical programs from both product platforms to identify other opportunities for indication expansion.

- ***Maintain rights to develop and commercialize our product candidates.*** We intend to maintain the rights to develop and commercialize our product candidates in the United States, while pursuing strategic alliances and collaborations with other pharmaceutical companies to accelerate development, share risk, supplement our resources and maximize potential outside the United States.

- ***Expand our product candidate portfolio.*** We plan to expand our product portfolio by leveraging our expertise in development and commercialization to identify and in-license additional drug candidates with significant clinical and commercial potential. In addition to indication expansion for our VAR 200 and IC 100 platforms, our business strategy includes identifying and opportunistically acquiring development and commercialization rights to technologies relating to the treatment of kidney and inflammatory diseases.

- ***Continue to strengthen and expand our intellectual property portfolio.*** The intellectual property for VAR 200 is comprised of a portfolio of issued and pending patents in the United States and other countries. We have 2 patent families covering glomerular disorders and disease, and diabetic kidney disease. Likewise, we plan to seek orphan drug designation for FSGS and Alport Syndrome, which would provide 7 years exclusivity in United States and 10 years in European Union, if approved in each of those jurisdictions. Intellectual Property for IC 100 is comprised of a portfolio of issued and pending patents in the United States and other countries. We have 5 patent families covering composition of matter, biomarkers, and methods of use. Additionally, we plan to seek orphan exclusivity for any rare disease indications we develop for IC 100. For both product platforms, our proprietary position is reinforced by additional technical know-how and trade secrets. We plan to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates by filing for patents or other applicable intellectual property protection covering new or enhanced proprietary technology, and new formulations, dosing regimens, and administration routes in development.

The dates and events reflected in the foregoing are estimates only, and there can be no assurances that the events included will be completed on the anticipated timeline presented, or at all. Further, there can be no assurances that we will be successful in the development of any of our product candidates, or any other products or product candidates we may develop in the future, or that any product candidate we may develop in the future, will receive FDA approval for any indication.

Our Product Candidates

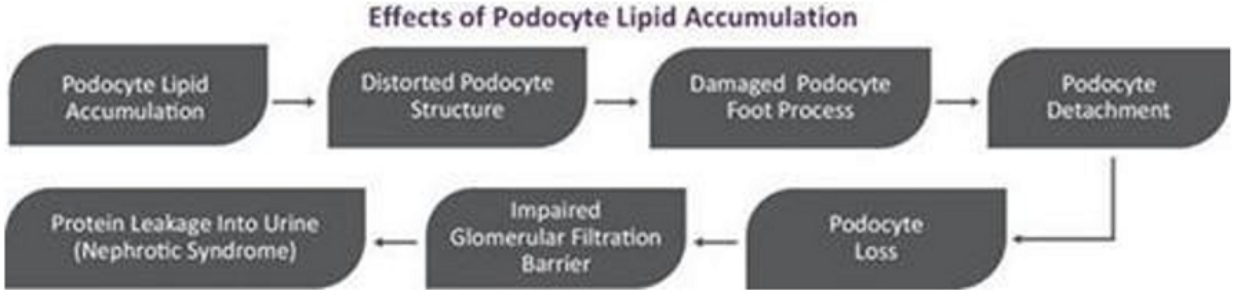
Cholesterol Efflux Mediator ^{TM} VAR 200 (2-hydroxypropyl-beta-cyclodextrin, 2HPβCD)

Cholesterol Efflux Mediator VAR 200 is an injectable drug in clinical development for treatment of chronic glomerular diseases, initially focusing on FSGS as the lead. Alport syndrome and diabetic kidney disease indications may be pursued based on our indication expansion strategy.

VAR 200 was developed to mediate removal of excess cholesterol that damages renal glomeruli, with the intent to preserve renal structure and function and reduce proteinuria that leads to glomerular disease progression. We are planning to initiate a small Phase 2a basket trial in FSGS and Alport syndrome patients in Q2-2026.

Role of Cholesterol and Lipid Accumulation in Glomerular Diseases (Including FSGS, Alport Syndrome, and Diabetic Kidney Disease)

In chronic glomerular diseases, cholesterol and lipids accumulates in glomerular podocytes, due in part to impaired transport out of the cell, or "efflux," resulting from reduced expression of the cholesterol transporters ABCA1 and ABCG1. Glomerular lipid accumulation has been demonstrated in *in vitro* podocyte studies, human biopsy data, and in animal models of various kidney diseases, including FSGS, Alport syndrome, and diabetic kidney disease. As shown below, the lipid accumulation causes distorted podocyte structure, damaged podocyte foot processes, and podocyte detachment and loss, which impairs kidney filtration resulting in proteinuria and disease progression. Preclinical animal models with VAR 200 show that reduction in podocyte cholesterol and lipids protects against ongoing kidney damage and progression of disease, which we hypothesize will translate to patients with kidney disease and potentially reduce or delay the need for dialysis and ultimately transplant.

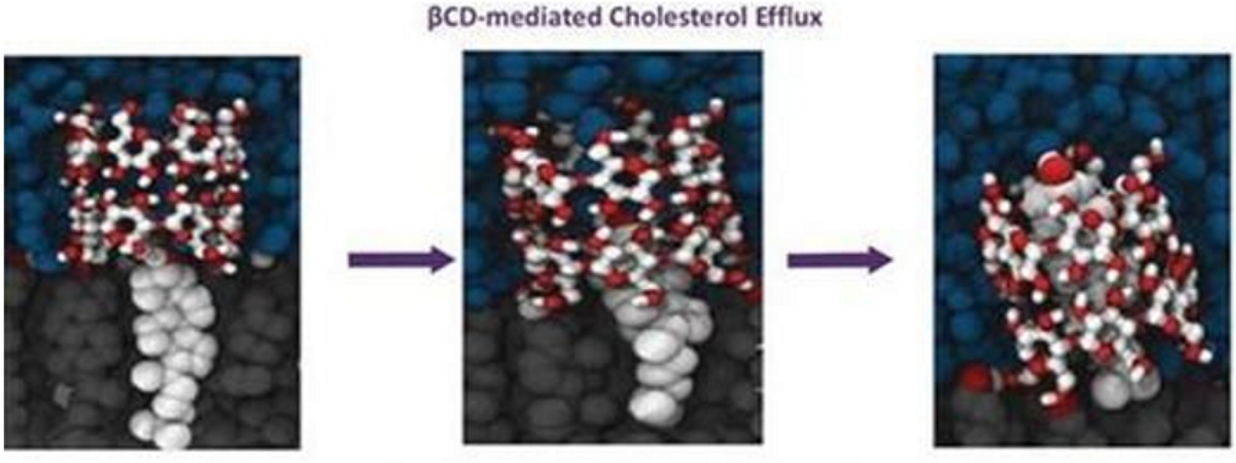


VAR 200 Mechanism of Action

VAR 200's active ingredient, 2HβCD, is comprised of seven sugar molecules bound together in a 3-D ring with a hydrophobic core and hydrophilic exterior. VAR 200 mediates cholesterol and lipid efflux both passively and actively by interacting with hydrophilic components of the glomerular membrane.

Passive Cholesterol Efflux

Passive cholesterol efflux occurs with formation of 2HPβCD dimers, which bind to the cell membrane surface and incorporate cholesterol into its hydrophobic core as an inclusion complex. Release of the 2HPβCD/cholesterol inclusion complex from the cell membrane surface brings the cholesterol into solution for transfer to cholesterol acceptors, such as high-density lipoprotein ("HDL").



Lopez CA, de Vries AH, Marrink SJ (2011) Molecular Mechanism of Cyclodextrin Mediated Cholesterol Extraction. PLoS Comput Biol 7(3): e1002020.

Active Cholesterol Efflux

Active cholesterol efflux occurs through mediating metabolism of free cholesterol into oxysterols. Oxysterols activate the liver X receptor ("LXR")-transcription factors, resulting in induction of cellular cholesterol efflux pathways, including upregulation cholesterol efflux transporters, ABCA1 and ABCG1, which transport free cholesterol outside the cell to cholesterol acceptors, such as HDL.

Preclinical Support for VAR 200

We believe that VAR 200 has an established benefit/risk profile supported by IND-enabling preclinical studies demonstrating safety and proof of concept, which led to FDA clearance to progress into Phase 2 clinical trials. Data from animal models representing FSGS, Alport Syndrome, and diabetic kidney disease consistently demonstrate that VAR 200 promotes cholesterol and lipid removal from podocytes, protecting the kidney's filtration system from damage and reducing protein spillage into the urine or "proteinuria." These types of outcomes are thought to be key to delaying or preventing progression of kidney disease. For a detailed overview of VAR 200's preclinical data, refer to the VAR 200 White Paper at https://www.zyversa.com/renal-lipids/white-paper-renal-lipids-in-the-pathogenesis-of-kidney-disease.

Inflammasome ASC Inhibitor IC 100

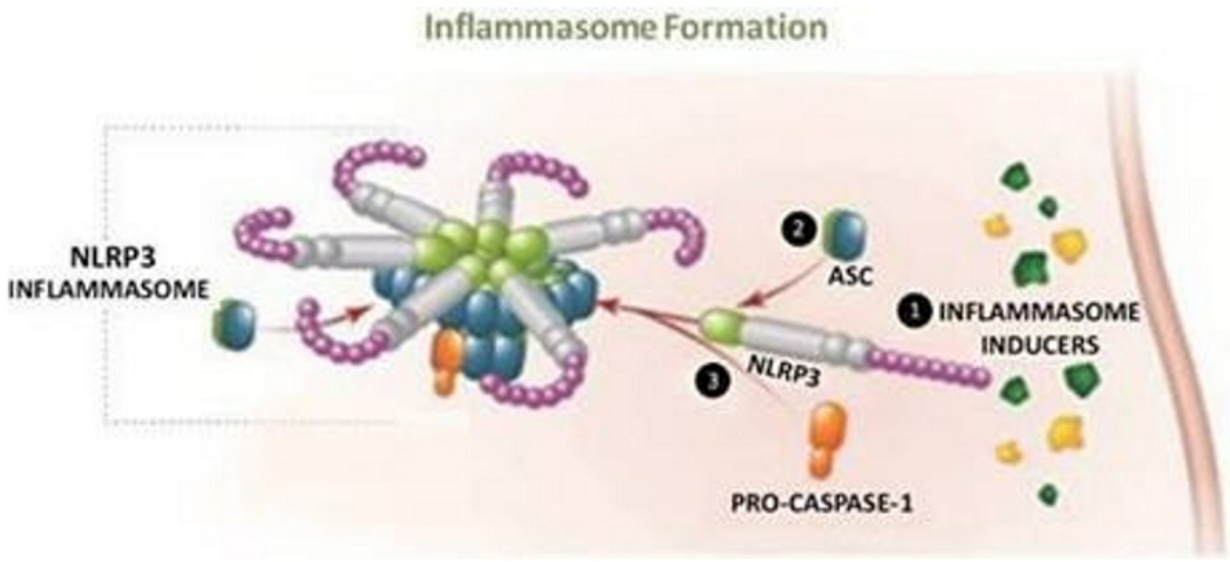
IC 100 is a humanized monoclonal antibody inflammasome ASC inhibitor in preclinical development for the treatment of numerous inflammatory diseases, with cardiometabolic conditions associated with obesity as the lead. IC 100 was developed with the intent of attenuating chronic aberrant inflammation that is pathogenic in a multitude of inflammatory diseases by attenuating initiation and perpetuation of inflammation to stop disease progression and improve quality of life.

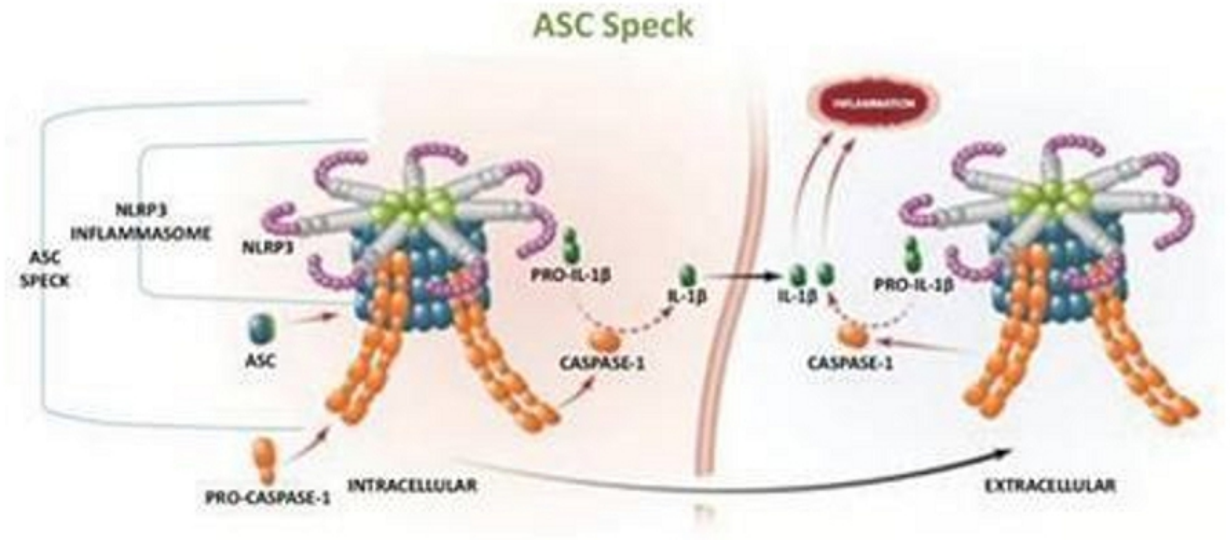
Our focus is on advancing IC 100 toward a planned IND submission in Q4-2026, following which we intend to initiate a Phase 1 trial in healthy subjects who are overweight (BMI 27 -30) and at risk of cardiometabolic conditions. Non-GLP toxicology data with IC 100 in mice and non-human primates ("NHP") demonstrate no adverse effects nor anti-drug antibodies at doses as high as 300 mg/kg. We are preparing to initiate IND-enabling preclinical studies in an animal models of diet-induced obesity that develops metabolic complications, and an animal model representative of an orphan renal disease in Q2-2026.

Role of Inflammasomes in Inflammatory Diseases

Excessive and persistent activation of inflammasomes have been linked to the pathophysiology of inflammatory diseases. Inflammasomes are multiprotein complexes that initiate an immune response to pathogens or internal danger signals. They are comprised of three basic proteins: (i) one of several types of sensor molecules (e.g., NLRP1, NLRP2, NLRP3, NLRC4, AIM2, and Pyrin), (ii) adaptor protein, ASC, and (iii) pro-caspase 1. Each sensor molecule responds to different pathogens or internal danger signals. Inflammasomes are named by their sensor molecule (e.g., NLRP3 inflammasome).

As depicted below, in the presence of harmful pathogens or cell damage, an intracellular sensor molecule (e.g., NLRP3) is triggered, stimulating recruitment of adaptor ASC, which in turn recruits pro-caspase-1 to form an inflammasome. The inflammasome is the organizing center that recruits additional ASC and polymerizes in a prion-like structure to form a large filamentous signaling platform, known as an ASC Speck. ASC Specks provide a scaffold for pro-caspase-1 recruitment, which triggers conversion of pro-caspase-1 to active caspase-1, which in turn converts the cytokine pro-IL-1ß to its active form IL-1ß, initiating the inflammatory response. Activated caspase-1 also drives cleavage of Gasdermin D, which triggers pyroptosis, a form of programmed cell death, releasing active cytokines and ASC Specks into the extracellular space, with continued activation of pro-IL-1ß, heightening and perpetuating the inflammatory response in neighboring cells and tissues. Although inflammasome triggering of the innate immune response is essential for protection against pathogens, persistent overactivation of inflammasomes can lead to chronic inflammation underlying a multitude of inflammatory conditions and diseases. Numerous inflammatory diseases are associated with activation of multiple types of inflammasomes. For example, obesity is triggered by AIM2 and NLRP3 and Parkinson's disease is triggered by NLRP1, NLRP3, and AIM2.

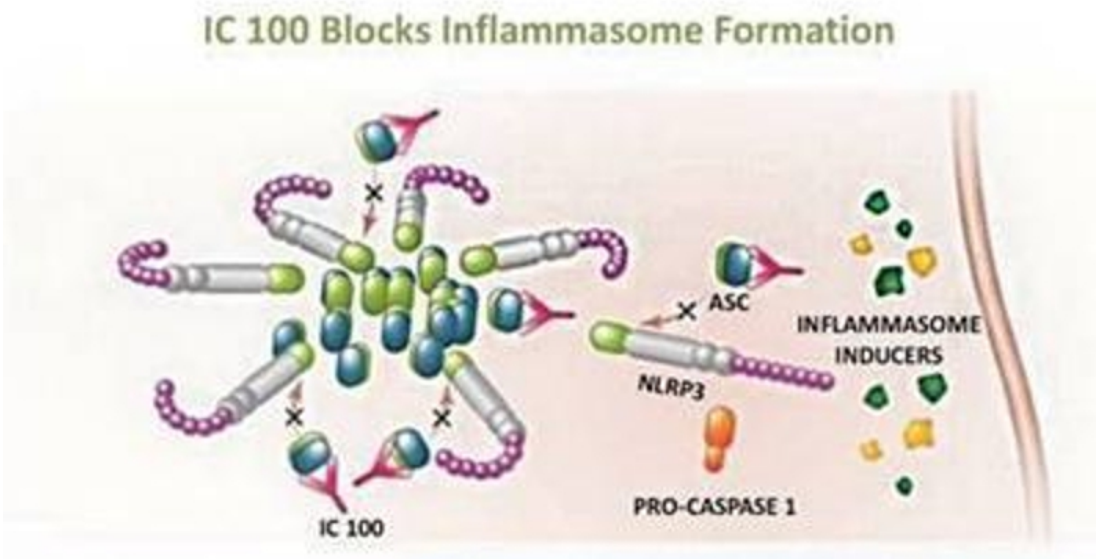


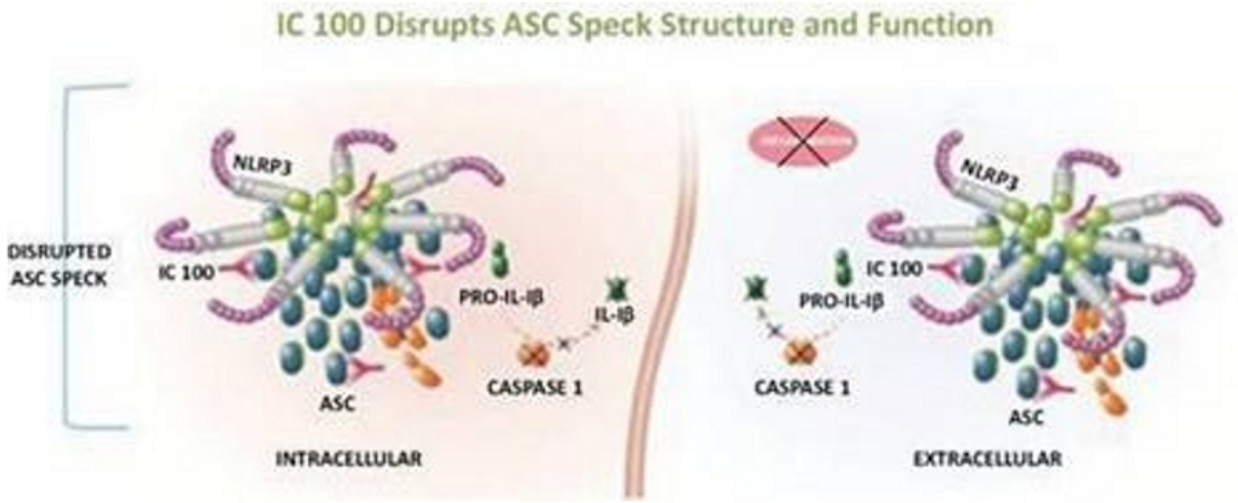


Inflammasome ASC Inhibitor IC 100 Mechanism of Action

IC 100 was designed to bind to key amino acids in adaptor protein ASC that govern ASC recruitment into the inflammasome complex and ASC Speck formation:

- By inhibiting ASC recruitment into the inflammasome complex, inflammasome formation is inhibited thereby blocking initiation of the inflammatory cascade; and
- By disrupting ASC Speck formation, both intracellularly and extracellularly, damaging perpetuation of inflammation is blocked.





Inflammasome Activation in One Condition Can Impact Another

A paper published in Translational Research demonstrates that inflammasome activity and signaling proteins triggered by one unique inflammatory condition can impact and potentially interact with another. The authors provided extensive evidence that traumatic brain injury (TBI) and Alzheimer's disease (AD) are linked by activation of multiple types of inflammasomes (NLRP3, NLRP1, and AIM2). In each condition, inflammasome activation leads to cell death and release of active cytokines and ASC specks to neighboring cells allowing for one condition to potentially exacerbate the other. For example, individuals with a history of moderate TBI have a 2.3 times greater risk of developing AD. Likewise, AD pathology is potentially exacerbated by inflammasome activation in patients with TBI through IL-18 and pathological ASC speck interactions with amyloid beta and phosphorylated tau, hallmarks of AD. The authors reported that inflammasome ASC represents a promising therapeutic target for TBI and AD because of ASC's unique role in heightening and perpetuating inflammation in neighboring cells, and its pathological interactions with amyloid beta and phosphorylated tau. In a subsequent study, also published in Translational Research by several of the same authors, researchers evaluated if blocking inflammasome activity by inhibiting ASC with IC 100 reduces the elevated inflammatory response in AD mice after TBI. Data demonstrated that IC 100 resulted in reduction of inflammasome-mediated cytokine IL-1β in the injured cortex of AD mice at 1-week post-injury.

Preclinical Support for IC 100

Non-GLP toxicology studies in mice and non-human primates demonstrate that IC 100 has a good safety profile. There were no drug-related adverse events at doses up to 300 mg/kg in either species. Likewise, epigenetic screening demonstrates a lower immunogenicity potential than many biologics. Based on our preclinical study in an animal model representing MS, inflammation was attenuated without immunosuppression.

IC 100 has preclinical data substantiating its mechanism of action in both CNS and Non-CNS diseases, summarized below. For a detailed overview of IC 100's preclinical data, refer to the IC 100 White Paper at https://investors.zyversa.com/static-files/64964310-ab95-4a06-bc47-dd44c63dc5c7.

IC 100 Preclinical Data Substantiates Its MOA in Both CNS and Non-CNS Diseases

Parkinson's Disease (PD)	• Inflammasome-induced Inflammation and alpha-synuclein accumulation are key contributors to PD progression • IC 100 reduced microglial inflammation and decreased alpha-synuclein that contribute to neurodegeneration
Multiple Sclerosis (MS)	• MS is characterized by an inflammatory response sustained by innate and adaptive immune mechanisms dependent on lymphocyte and myeloid cell activation • IC 100 at 30 mg/kg resulted in a lower number of activated myeloid cells in the spinal cord and spleen, a lower number of microglial cells in the spinal cord, and improved clinical outcomes consistent with these changes
Spinal Cord Injury (SCI)	• Following SCI, expression of NLRP1 inflammasome signaling molecules, including ASC, are increased and NLRP1 inflammasome is activated in spinal cord neurons, triggering an inflammatory response • ASC inhibition decreased inflammasome activation, reduced spinal lesions, and improved behavioral outcomes
Age-related Inflammation	• Inflammasome signaling proteins, NLRP1, ASC, caspase-1, caspase-8, and IL-1β, are significantly increased in the cortex of aged mice • IC 100 inhibits both canonical and non-canonical NLRP1 inflammasome activation that occurs in aged mice • IC 100 significantly reduced ASC Specks, IL-1β, and inflammasome protein expression (NLRP1, ASC, caspase-1, and caspase-8)
Penetrating Ballistic-Like Brain Injury Model (PBBI)	• Following PBBI, expression of inflammasome signaling molecules, including ASC, are increased and inflammasomes are activated in microglia triggering an inflammatory response and pyroptosis • IC 100 decreased inflammasome activation and pyroptosis when compared with vehicle control
Fluid Percussion Brain Injury Model (FPI)	• Following FPI, expression of inflammasome signaling molecules, including ASC, are increased and inflammasomes are activated in cerebral cortex neurons triggering an inflammatory response • ASC neutralization reduced inflammasome activation and decreased brain contusion volume associated with inflammation when compared with IgG control
Acute Respiratory Distress Syndrome (ARDS)	• Inflammasome activation and inflammation play a central role in the pathomechanism of lung injury in ARDS • IC 100 inhibited inflammasome activation and improved histopathological outcomes in lung tissue
Retinopathy of Prematurity	• Inflammasome activation is associated with the pathogenesis of ocular diseases (e.g., diabetic retinopathy, age related macular degeneration) • IC 100 Attenuated Retinal Inflammation in OIR Mice and Restored Retinal Structure and Function
Diabetic Nephropathy	• A link between NLRP3 inflammasome activity and glomerular injury in the kidneys of people with diabetic nephropathy is now well established • IC 100 (5 mg/kg) significantly reduced fasting blood glucose, ACR, and BUN in Mouse Model of Type 2 Diabetic Nephropathy (BTBR ob/ob Mice)
Stroke-related Cardiovascular Injury	• Catecholamine surge after stroke activates AIM2 inflammasomes in the heart, triggering inflammation resulting in damage and dysfunction • IC 100 administered post-stoke reduced cardiac inflammation and attenuated cardiac dysfunction (shortened action potential duration)

For a detailed overview of IC 100's preclinical data, refer to the IC 100 White Paper at https://investors.zyversa.com/static-files/64964310-ab95-4a06-bc47-dd44c63dc5c7.

Market and Commercial Opportunity

We believe that each of our product candidates has potential for treatment of numerous diseases with significant unmet medical needs. VAR 200 has potential to treat Alport syndrome, diabetic nephropathy, and other glomerular diseases in addition to its lead indication, focal segmental glomerulosclerosis (FSGS). IC 100 has potential to treat multiple and diverse inflammatory diseases, including, but not limited to orphan renal diseases, Parkinson's and Alzheimer's diseases, in addition to its lead indication, cardiometabolic conditions associated with obesity.

Cholesterol Efflux Mediator™ VAR 200 Opportunity

According to a report from Precedence Research, the global renal drug market was $20 billion in 2024 and projected to reach $30 billion by 2034. There are two key drivers of this growth. The first is the significant increase in obesity and diabetes which lead to renal disease. The second is a resurgence in development of innovative new drug therapies resulting from the increasing economic and societal burdens of chronic kidney disease, as well as advances in technology facilitating a better understanding of the molecular mechanisms underlying kidney disease. A more recent growth driver is data from the Parasol project supporting use of 2-year changes in proteinuria as an endpoint for approval of FSGS drugs, that will shorten the regulatory path. The Parasol project, co-chaired by Dr. Aliza Thompson, Director of the Cardio-Renal Division at the FDA, was prompted by the urgent need to develop safe and effective therapies for people with FSGS since there are no approved drug therapies. The goal of Parasol was to define a traditional or reasonably likely surrogate endpoint for use in FSGS clinical trials to enable accelerated approval of novel therapies and expedite access to effective treatments for this rare but devastating glomerular disorder. PARASOL was a partnership among NephCure, the National Kidney Foundation, the International Society of Glomerular Disease, and the Kidney Health Initiative, who brought together all the relevant parties - patients, clinical nephrologists, industry sponsors, basic scientists, biostatisticians, and regulatory authorities. PARASOL's analysis of 1600 FSGS patients found that a reduction in proteinuria over 24 months was strongly associated with a reduced risk of kidney failure. Based on the data, Parasol recommended proteinuria as a surrogate endpoint for full regulatory approval of FSGS drugs.

Following is a summary of the market for VAR 200's current pipeline.

Renal Indications	Overview	U.S. Prevalence	Unmet Needs
Focal Segmental Glomerulosclerosis*	Rare disease that attacks the kidney's filtration system (glomeruli) causing serious scarring, leading to permanent kidney damage and kidney failure	40,000[1]	Current drugs don't effectively delay/halt disease progression leading to dialysis and transplant
Alport Syndrome*	Rare genetic disorder characterized by progressive kidney disease and abnormalities of the inner ear and the eye	30,000 – 60,000[2]	Current drugs don't effectively delay/halt disease progression leading to dialysis and transplant
Diabetic Kidney Disease	Progressive kidney disease that's a complication of type 1 diabetes and type 2 diabetes – leading cause of kidney disease in U.S.	Up to 12 Million[3]	Current drugs don't effectively delay/halt disease progression leading to dialysis and transplant

*Orphan Indications

References:
1. Nephcure
2. National Organization for Rare Disorders
3. National Kidney Foundation

IC 100 Opportunity

Anti-Inflammatory Biologics Market

According to a report from Precedence Research, the global anti-inflammatory biologics market was valued at $104.81 billion in 2024, and it is projected to reach $185.51 billion by 2034. This growth is driven by the rising incidence of chronic inflammatory diseases associated with population aging, lifestyle changes, and environmental factors. The growth trajectory is expected to accelerate over time with R&D focus on use of anti-inflammatory biologics, such as inflammasome inhibitors, as add-on to GLP-1 drugs to treat the inflammatory comorbidities of obesity. According to Morgan Stanley, global sales of GLP-1 drugs were $6 billion in 2023. With the surging demand seen in 2024, they project global sales to reach between $105 to $144 billion by 2030. Key drivers are the unsurpassed weight loss achieved and the broadening evidence that these drugs have potential to improve outcomes in numerous obesity-related comorbidities. Following is a summary of the market for IC 100's current pipeline.

Inflammatory Disease Indications	Overview	U.S. Prevalence	Unmet Needs
Cardiometabolic Diseases Related to Obesity	Heart attack, stroke, heart failure, coronary artery disease, insulin resistance, type 2 diabetes, dyslipidemia, chronic kidney disease, fatty liver diseases triggered by obesity-driven chronic inflammation	38 Million[1]	Although incretin therapy dramatically reduces weight, they don't address the chronic inflammation that contributes to cardiometabolic comorbidities.
Orphan Renal Diseases	FSGS, Alport syndrome, IgA Nephropathy - driven by hypertension, lipotoxicity, and inflammation	150,000[2-4]	No approved disease-modifying drugs

References
1. Prevalence of Cardiovascular-Kidney-Metabolic Syndrome Stages in US Adults, May 8, 2024
2. Nephcure
3. National Organization for Rare Diseases
4. DeCongelio M, Ali SN, Furegato M, et al. The incidence and prevalence of immunoglobulin A nephropathy in the United States. Clin Nephrol. 2024;103(1):19

Other Development Candidates

We continue to seek to identify and acquire commercialization rights to other technologies relating to renal and inflammatory diseases.

Strategic Alliances and Arrangements

Unless otherwise specifically provided herein, all share and per share information (including information relating to warrants) reflect the 1-for-35 reverse stock split and the 1-for-10 reverse stock split that we effected on December 4, 2023, and April 25, 2024, respectively.

L&F Research LLC License Agreement

We entered into a License Agreement with L&F Research LLC ("L&F Research") effective December 15, 2015, as amended (the "L&F License Agreement"), pursuant to which L&F Research granted us an exclusive, royalty-bearing, worldwide, sublicensable license under the patent and intellectual property rights and know-how specific to and for the development and commercialization of VAR 200, for the treatment, inhibition or prevention of kidney disease in humans and symptoms thereof, including FSGS. L&F Research was founded by the VAR 200 inventors and researchers at the University of Miami Miller School of Medicine, who licensed the intellectual property from the University of Miami. Pursuant to the L&F License Agreement, we (i) paid L&F Research an upfront license fee of $200,000 upon signing; (ii) agreed to make additional payments to L&F Research upon the achievement of certain development milestones up to an aggregate maximum of $21.5 million; and (iii) agreed to pay L&F Research royalty payments on net sales of any resulting product upon the achievement of certain net sales milestones, ranging from 5% to 10% based on certain annual net sales thresholds. In addition, upon the signing of and pursuant to the L&F License Agreement, we issued to L&F Research four (4) warrants (the "L&F Warrants"), of which one (1) warrant was exercised for 200 shares of common stock and the remaining three (3) warrants are exercisable in the aggregate for 300 shares of our common stock upon certain terms and conditions set forth in the L&F License Agreement and the L&F Warrants.

On December 23, 2022, we entered into a Second Amendment to Waiver of Certain Rights under License Agreement (the "Second Amendment") with L&F Research LLC ("L&F Research"), amending the previously disclosed Waiver of Certain Rights under License Agreement, dated March 2, 2022, between ZyVersa Therapeutics, Inc., a Florida corporation ("Old ZyVersa") and L&F Research, as amended (the "Waiver Agreement"). The Second Amendment further extended to March 31, 2023, the period that L&F Research waived its right to terminate the License Agreement and exercise any other remedies thereunder, with respect to $1,500,000 of aggregate milestone payments due to L&F Research pursuant to the L&F License Agreement (the "Milestone Payments").

On February 28, 2023, we entered into an Amendment and Restatement Agreement (the "Restatement") with L&F Research, amending and restating the Waiver Agreement, as amended. The Restatement provides that, with respect to the Milestone Payments, L&F Research waives its right to terminate the L&F License Agreement and exercise any other remedies thereunder, until (a) March 31, 2023, as to $1,000,000 of such Milestone Payments ("Waiver A"), and (b) January 31, 2024, as to $500,000 of such Milestone Payments ("Waiver B"). Waiver A is contingent upon (i) forgiveness by the Company of $351,579 in aggregate principal amount outstanding under the previously disclosed Promissory Note, dated December 13, 2020, between L&F Research, as the borrower, and Old ZyVersa, as the lender (the "Note"), and (ii) a cash payment by the Company to L&F Research in the amount of $648,421, in each case, to be effectuated on or before March 31, 2023. Waiver B is contingent upon a cash payment by the Company to L&F Research in the amount of $500,000 to be effectuated on or before the earlier of (x) January 31, 2024, and (y) ten business days from the date that the Company receives net proceeds of at least $30,000,000 from the issuance of new equity capital. All other terms of the L&F License Agreement remain in effect.

On March 29, 2023, the Company paid the $648,421 of cash to L&F, thus meeting the conditions of Waiver A, which also had the effect of canceling the Note Receivable and the Put Option.

On January 30, 2024, the Company paid $500,000 of cash to L&F, thus meeting the conditions of Waiver B.

The L&F License Agreement will terminate at the expiration of the last-to-expire of all royalty payment obligations under the L&F License Agreement and we have the right to terminate the L&F License Agreement upon 60 days' notice.

The L&F License is terminable by either party if the other party is in material breach of the agreement, and has not cured the breach within 60 days of notice. If we fail to make payments under the agreement, L&F Research may terminate the agreement on 10 days' notice. Further, L&F Research has the right to terminate the L&F License Agreement immediately upon written notice to us if we directly, or through assistance granted to a third party, commence any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Licensor Patent Right (as defined in the agreement).

In the event we do not complete the Throughput Milestones by the Throughput Milestone Completion Date (as each term is defined in the agreement), L&F Research may elect upon 90 days written notice to us to either (a) terminate the agreement in its entirety; or (b) terminate the exclusivity provisions of the agreement and convert the license to non-exclusive. However, before L&F Research terminates the agreement or terminates exclusivity, the parties will negotiate in good faith to agree upon a revised date for the relevant Throughput Milestone if we fail to achieve a particular Throughput Milestone by the specified time occurs because of a Force Majeure Event or a Significant Change (as those terms are defined in the agreement). In the event we cannot agree as to whether a Force Majeure Event or Significant Change has occurred by the later of the date of failure to meet the original Throughput Milestone Completion Date or 15 days after our notice that a Force Majeure Event or Significant Change has occurred, L&F Research may exercise its termination rights.

InflamaCORE, LLC License Agreement

We entered into a License Agreement with InflamaCORE, LLC ("InflamaCORE") effective as of April 18, 2019 (the "InflamaCORE License Agreement"), pursuant to which InflamCORE granted us an exclusive, worldwide, royalty-bearing, sublicensable license to patents, intellectual property rights, technology, and know-how to and for the development and commercialization of IC 100, in all therapeutic and diagnostic uses in all diseases and conditions. InflamaCORE was founded by the IC 100 inventors and researchers at the University of Miami Miller School of Medicine, who licensed the intellectual from the University of Miami and Selexis SA, a cell line development company in Switzerland. Pursuant to the InflamaCORE License Agreement, we (i) paid InflamaCORE an upfront license fee of $346,321.08 upon signing; (ii) agreed to make additional payments to InflamaCORE upon the achievement of certain development milestones up to an aggregate maximum of $22.5 million; (iii) agreed to pay InflamaCORE royalty payments on net sales of certain resulting products upon the achievement of certain net sales milestones, ranging from 5% to 10% depending on the level of net sales; (iv) agreed to pay University of Miami royalty payments on net sales of certain resulting products upon the achievement of certain net sales milestones, ranging from 3% to 6% of net sales, depending on the level of net sales; and (v) were granted a sublicense to all third-party technologies, including the Selexis cell line technology, and agreed to pay to InflamaCORE the obligations of their Selexis license. Pursuant to the Selexis license, we paid an upfront license fee to Selexis of CHF 50,000. We are also obligated to pay to Selexis (through reimbursement of InflamaCORE) (i) an annual maintenance fee of CHF 10,000, (ii) payments upon the achievement of certain development milestones up to an aggregate maximum of approximately CHF 1.1 million, and (iii) a royalty payment on net sales equal to a low single digit. Additionally, upon the execution of and pursuant to the InflamaCORE License Agreement, we issued (i) 114 shares of our common stock to the University of Miami, (ii) and four (4) warrants to InflamaCORE (the "InflamaCORE Warrants") of which one (1) warrant exercisable for 227 shares of common stock expired in April 2024 and the remaining three (3) warrants are exercisable in the aggregate for 342 shares of our common stock upon certain terms and conditions set forth in the InflamaCORE License Agreement and the InflamaCORE Warrants.

The InflamaCORE License Agreement will terminate at the expiration of the last-to-expire of all royalty payment obligations under the InflamaCORE License Agreement and we have the right to terminate the InflamaCORE License Agreement upon 60 days' notice. The license may be terminated by either party if the other party is in material breach of the agreement, and has not cured the breach within 60 days of notice. If we fail to make payments under the agreement, InflamaCORE may terminate the agreement on 10 days' notice. Further, the agreement may be terminated by a party upon the bankruptcy or insolvency of the other party.

Upon any termination of the InflamaCORE License Agreement, the license granted to us will automatically terminate and revert back to InflamaCORE.

Manufacturing

We do not currently own or operate any facilities to formulate, manufacture, test, store, package or distribute VAR 200, IC 100 and any other product candidate that we are developing or may seek to develop and do not currently have the capabilities to conduct such activities. We currently rely on third parties to manufacture, store and test VAR 200, IC 100 and any other product candidate that we may seek to develop. We will depend on third-party suppliers and manufacturing organizations for all our required raw materials and drug substance and to formulate, manufacture, test, store, package and distribute clinical trial quantities of VAR 200, IC 100 and any other product candidate that we may seek to develop. We plan to continue developing our network of third-party suppliers and manufacturing organizations, but in the future we may decide to consider investing in our own manufacturing and supply capabilities if there is a technical need or a strategic or financial benefit.

We have internal personnel and utilizes consultants with extensive technical, manufacturing, analytical and quality experience to oversee our contract manufacturing and testing activities. Manufacturing is subject to extensive regulations that impose procedural and documentation requirements, including, but not limited to, record-keeping, manufacturing processes and controls, personnel, quality control and quality assurance. Our systems, procedures and contractors are required to be in compliance with these regulations and are assessed through regular monitoring and formal audits.

Research and Development

We spent approximately $1.1 million for the year ended December 31, 2025, and $1.8 million for the year ended December 31, 2024. For the year ended December 31, 2025, there was an $18.6 million impairment charge related to in-process research and development ("IPR&D"), which was recorded upon the determination that the carrying value of our IPR&D intangible asset may not be recoverable.

Sales and Marketing

We currently have no marketing, sales or distribution capabilities. To commercialize any product that is approved for commercial sale, we must either develop our own sales, marketing and distribution infrastructure or collaborate with third parties that have such commercial infrastructure and relevant marketing and sales experience. We expect to be able to build our commercial infrastructure over time in advance of any anticipated launch of our products, and we may rely on licensing, co-sale and co-promotion agreements with strategic partners for the commercialization of our products. If we establish the commercial infrastructure to support the potential marketing of VAR 200, IC 100 and any other product candidate that we may seek to develop, such commercial infrastructure could be expected to include a targeted sales force supported by sales management, internal sales support, a market access group, an internal marketing group and distribution support. To establish the proper commercial infrastructure, we would need to invest significant financial and management resources prior to any approval of VAR 200, IC 100 and any other product candidate that we may seek to develop.

Competition

The pharmaceutical and biotechnology industry is highly competitive. These competitors include many public and private companies, universities, governmental agencies and other research organizations actively engaged in the research and development of products that may be similar to our product candidates that we seek to develop or address similar indications. Many competitors have substantially greater financial, technical and human resources than we possess and may be better equipped to develop, manufacture and market their products. We also expect that the number of companies seeking to develop products and therapies similar to our products may increase over time. Competitive factors in the pharmaceutical and biotechnology industry include product efficacy, safety, ease of use, price, demonstrated cost-effectiveness, marketing effectiveness, stakeholder support, service, reputation, and access to technical information. Any products that we develop and seek to commercialize may not be able to compete with the products of our competitors with respect to one or more of these considerations.

For instance, there are currently several other companies with drugs in clinical development for FSGS, targeting inflammation, hypertension, and fibrosis. Among our competitors, there are products in various phases of development, including compounds in Phase 2 and Phase 3 of development. However, we believe that VAR 200 may be the only drug currently in development that lipotoxicity. The current treatment algorithm for renal disease includes multiple drug therapies to address the various pathways contributing to renal disease. We believe that VAR 200 could potentially be used in combination with other treatment modalities addressing other pathogenic pathways.

Additionally, there are a number of other companies developing drugs targeting inflammasome pathways, mainly NLRP3 inflammasome pathways, some of which have clinical trials underway in multiple indications. Indications being evaluated in current Phase 2 clinical trials include obesity-related cardometabolic comorbidities, obesity-related osteoarthritis, recurrent pericarditis, and Parkinson's disease. We believe that IC 100 may be the only monoclonal antibody targeting the ASC component of the inflammasome, which can potentially inhibit multiple types of inflammasomes and disrupt the structure and function of ASC specks to prevent initiation and perpetuation of inflammation.

Intellectual Property

We seek to protect our products and technologies through a combination of patents, regulatory exclusivity, and proprietary know-how. Our goal is to obtain, maintain, and enforce patent protection for our products, formulations, processes, methods, and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current compositions and methods and any future compositions and methods under development, proprietary information, and proprietary technology through a combination of contractual arrangements and patents, where applicable, both in the United States and abroad. However, even patent protection may not always afford complete protection against competitors who seek to circumvent our patents. For additional information, see section entitled "*Risk Factors — Risks Related to Our Intellectual Property.*"

Pursuant to the L&F License Agreement, we have an exclusive, sublicensable, worldwide license to the inventions relating to 2-hydroxypropyl-beta-cyclodextrin ("2HPβCD") for the treatment of kidney disease in humans, including FSGS, as described in certain method-of-use patents and pending applications filed in the United States and selected foreign countries (Canada, China, Europe, Japan, and Mexico) from two international patent applications filed pursuant to the provisions of the Patent Cooperation Treaty ("PCT"). Currently, there are 4 issued United States patents and 12 foreign granted or allowed applications. These patents, and any patents that issue from the pending applications, are anticipated to have a term to at least 2033, absent of any patent term adjustments or extensions.

Pursuant to the InflamaCORE License Agreement, we have an exclusive, sublicensable, worldwide license to the inventions relating to recognition, diagnosis, and treatment of inflammatory responses and inflammation mediated by inflammasomes and components thereof, including but not limited to IC 100 which is a humanized IgG4 antibody directed against a specific amino acid sequence of the pyrin domain of Apoptosis-associated speck-like protein ("ASC"). The patent portfolio for IC 100 includes 5 patent families covering composition of matter, biomarker, and method-of-use patents and their related national stage filings in the United States and selected foreign countries (Australia, Brazil, Canada, Chile, China, Colombia, Europe, India, Indonesia, Israel, Japan, Malaysia, Mexico, Philippines, Singapore, South Africa, South Korea, Thailand, Vietnam). Currently, there are 6 issued United States patents, 14 foreign granted patents or allowed applications, and 59 pending applications. These patents, including composition of matter patents that have a term until December 2037, and any patents that issue from the pending applications are anticipated to have a term until at least 2028, absent of any patent term adjustments or extensions.

At this time, ZyVersa has no patents or patent applications outside of those connected to the L&F or InflamaCORE License Agreements.

Even though we have licensed issued patents, there is no guarantee that the validity of the patents will be upheld if challenged by a third party. There can be no assurance that any of our intellectual property rights will afford us any protection from competition.

We use the trade names Cholesterol Efflux Mediator™ and Lipid Efflux Mediator™ in association with our VAR 200 pharmaceutical preparations and plan to seek federal trademark protection in the United States and foreign national trademark protection where available and when appropriate. No other applications for trademark protection have been filed for any names or logos for products or technologies in development. We intend to use these marks in connection with our pharmaceutical product candidates currently in development as added levels of intellectual property protection for our proprietary technologies.

Regulatory Matters

In the United States, the FDA regulates drug products, biological products, and medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA"), and other federal laws and regulations. These FDA-regulated products are also subject to state and local statutes and regulations, as well as applicable laws or regulations in foreign countries. The FDA, and comparable regulatory agencies in state and local and local jurisdictions and in foreign countries, impose substantial requirements on the research, development, testing, manufacture, quality control, labeling, packaging, storage, distribution, record-keeping, approval, post-approval monitoring, advertising, promotion, marketing, sampling and import and export of FDA-regulated products.

Government Regulation

Any product development activities related to VAR 200, IC 100, and any other product candidates that we may seek to develop or acquire in the future will be subject to extensive regulation by various government authorities, including the FDA and other federal, state and local statutes and regulations and comparable regulatory authorities in other countries, which regulate the design, research, clinical and non-clinical development, testing, manufacturing, storage, distribution, import, export, labeling, advertising and marketing of pharmaceutical products and devices. Generally, before a new drug can be sold, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority. The data is often generated in two distinct development states: pre-clinical and clinical. VAR 200, IC 100, and any other product candidates that we may seek to develop or acquire in the future must be approved by the FDA through the New Drug Application ("NDA"), Biologic Licensing Application ("BLA") or other applicable approval process before they may be legally marketed in the United States.

The clinical stages of development can generally be divided into three sequential phases that may overlap: Phase 1, Phase 2 and Phase 3 clinical trials. In Phase 1, generally, small numbers of healthy volunteers are exposed to single escalating doses and then multiple escalating doses of the product candidate. The primary purpose of these studies is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug. Phase 2 trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected. In some instances, formal Phase 1 and Phase 2 trials may not be deemed necessary or required by the FDA. Such is often the case when the safety and efficacy of an API is considered to be well understood by the FDA. In Phase 3 studies, the drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely. Under established regulatory pathways, pharmaceutical products with APIs equal or similar to those known by the FDA often enter more streamlined development programs than compounds entirely new to the agency.

Post-approval studies, sometime referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These studies may be used to gain additional experience from the treatment of patients in the intended therapeutic condition or to gain additional indications for a medication. In certain instances, the FDA may mandate the performance of Phase 4 studies.

Development of Drugs and Biological Products in the United States

In the United States, the process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawal from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties.

Prior to the start of human clinical studies for a new drug or biological product in the United States, pre-clinical laboratory and animal tests are often performed under the FDA's Good Laboratory Practices regulations. The Sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data and literature and a proposed clinical protocol to the FDA as part of the Investigational New Drug ("IND") application. Similar filings are required in other countries. The amount of data that must be supplied in the IND depends on the phase of the study. Phase 1 studies typically require less data than larger Phase 3 studies. A clinical plan must be submitted to the FDA prior to commencement of a clinical trial. If the FDA has concerns about the clinical plan or the safety of the proposed study, they may suspend or terminate the study at any time. Studies must be conducted in accordance with good clinical practice and regular reporting of study progress and any adverse experiences is required. Studies are also subject to review by independent institutional review boards responsible for overseeing studies at particular investigator sites and protecting human research study subjects. An independent institutional review board may also suspend or terminate a study once initiated. Accordingly, submission of an IND does not guarantee approval by the FDA allowing clinical trials to begin, or, once begun, that issues will not arise that could cause the trial to be suspended or terminated.

Review and Approval of Drugs and Biological Products in the United States

Following completion of Phase 3 trials, data from the trials are analyzed to determine safety and effectiveness. Complete development data is then filed with the FDA in a NDA or BLA, along with proposed labeling for the product and information about the manufacturing and testing processes and facilities that will be used to ensure product quality. The NDA and BLA applications are the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical product for sale and marketing in the United States. The NDA or BLA must contain proof of safety, purity, potency and efficacy, which entails extensive pre-clinical and clinical testing. The data gathered during the animal studies and human clinical trials of an IND become part of the NDA or BLA.

The review and evaluation of an NDA or BLA by the FDA may take several years to complete. The FDA may conduct pre-approval inspections of the manufacturing facilities for the new product to determine whether they comply with cGMP requirements and may also audit data from clinical and pre-clinical trials.

The FDA may place conditions on approvals including the requirement for a risk evaluation and mitigation strategy ("REMS") to assure the safe use of the agent. If the FDA concludes a REMS is needed, the Sponsor of the application must submit a proposed REMS, which may include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

IND and Clinical Trials of Drugs and Biological Products

Prior to commencing a human clinical trial of a drug or biological product, an IND, which contains the results of preclinical studies along with other information, such as information about product chemistry, manufacturing and controls and a proposed protocol, must be submitted to the FDA. An IND is a request for authorization from the FDA to administer an investigational drug or biological product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA within the 30-day time period raises concerns or questions about the conduct of the clinical trial. In such a case, the IND sponsor must resolve any outstanding concerns with the FDA before the clinical trial may begin. A separate submission to the existing IND must be made for each successive clinical trial to be conducted during drug development.

An independent Institutional Review Board ("IRB") for each site proposing to conduct the clinical trial must review and approve the investigational plan for the trial before it commences at that site. Informed written consent must be obtained from each trial subject.

Human clinical trials for drug and biological products typically are conducted in sequential phases that may overlap:

- *Phase I:* The investigational drug/biologic is given initially to healthy human subjects or patients with the target disease or condition in order to determine metabolism and pharmacologic actions of the drug in humans, side effects and, if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational drug/biologic's pharmacokinetics and pharmacologic effects may be obtained to permit the design of well-controlled and scientifically valid Phase II clinical trials.

- *Phase II:* Clinical trials are conducted to evaluate the effectiveness of the drug/biologic for a particular indication or in a limited number of patients in the target population to identify possible adverse effects and safety risks, to determine the efficacy of the drug/biologic for specific targeted diseases and to determine dosage tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the Sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials.

- *Phase III:* When Phase II clinical trials demonstrate that a dosage range of the drug/biologic appears effective and has an acceptable safety profile, and provide sufficient information for the design of Phase III clinical trials, Phase III clinical trials in an expanded patient population at multiple clinical sites may begin. They are intended to further evaluate dosage, effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug/biologic and to provide an adequate basis for product labeling and approval by the FDA. In most cases, the FDA requires two adequate and well-controlled Phase III clinical trials to demonstrate the efficacy of the drug in an expanded patient population at multiple clinical trial sites.

All clinical trials must be conducted in accordance with FDA regulations, including good clinical practice ("GCP") requirements, which are intended to protect the rights, safety and well-being of trial participants, define the roles of clinical trial sponsors, administrators and monitors and ensure clinical trial data integrity. Regulatory authorities, including the FDA, an IRB, a data safety monitoring board or the Sponsor, may suspend or terminate a clinical trial at any time on various grounds, including a finding that the participants are being exposed to an unacceptable health risk or that the clinical trial is not being conducted in accordance with FDA requirements.

During the development of a new drug or biologic, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase II clinical trials, and before a NDA or BLA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the Sponsor to share information about the data gathered to date, for the FDA to provide advice and for the Sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the end-of-Phase II clinical trials meetings to discuss their Phase II clinical trials results and present their plans for the pivotal Phase III registration trial that they believe will support approval of the new drug/biologic.

An investigational drug product that is a combination of two different drugs in the same dosage form must comply with an additional rule that requires that each component make a contribution to the claimed effects of the drug product. This typically requires larger studies that test the drug against each of its components.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, biologics, and devices, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial, is made public as part of the registration. Sponsors also are obligated to discuss summary results of their clinical trials on clinicaltrials.gov within 1 year after primary completion (the date when the last data point for the primary outcome measure is collected from the last enrolled participant). Disclosure of the clinical trial results can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

The NDA and Biologics License Application (BLA) Approval Processes

Our drug or biological products must be approved by the FDA through the NDA and BLA approval processes, respectively, before they may be legally marketed in the U.S. These FDA-required processes for drugs or biological products to be marketed in the U.S. generally involve the following:

- completion of non-clinical laboratory tests, in the case of a NDA, completion of animal studies and formulation studies conducted according to good laboratory practice or other applicable regulations;
- submission of an IND application;
- performance of human clinical trials conducted in accordance with GCP to establish the safety and efficacy of the proposed drug or biological product for its intended use or uses;
- submission to the FDA of a NDA or BLA (as applicable) after completion of all pivotal clinical trials;
- FDA pre-approval inspection of manufacturing facilities and audit of clinical trial sites; and
- FDA approval of a NDA or BLA, as applicable.

In order to obtain approval to market a drug or biological product in the U.S., a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. The cost of preparing and submitting a NDA or BLA is substantial. Each NDA or BLA submission requires a user fee payment (exceeding $2.5 million in fiscal year 2019), unless a waiver or exemption applies. The manufacturer or sponsor of an approved BLA is also subject to annual establishment fees. The application includes all relevant data available from pertinent non-clinical studies, or preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other information. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators that meet GCP requirements.

Companies also must develop additional information about the characteristics of the drug or biological product and finalize a process for the NDA or BLA sponsor's manufacturing the product in compliance with current good manufacturing practice ("cGMP") requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate, and the manufacturer must develop methods for testing the finished drug or biological product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf-life.

The results of drug or biological product development, non-clinical studies and clinical trials, along with descriptions of the manufacturing process, tests conducted on the drug or biological product, proposed labeling and other relevant information are submitted to the FDA as part of a NDA or BLA requesting approval to market the product.

The FDA reviews all NDAs or BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. FDA may request additional information rather than accept a NDA or BLA for filing. In this event, the NDA or BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. The FDA has 60 days from its receipt of a NDA or BLA to conduct an initial review to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review.

Once the NDA or BLA submission is accepted for filing, the FDA begins an in-depth review of the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to ensure the product's identity, strength, quality and purity. The FDA has agreed to specific performance goals on the review of NDAs and BLA's and seeks to review standard NDAs or BLAs within 12 months and prior review biologics within 8 months from submission of the respective applications. The review process may be extended by the FDA for three additional months to consider certain late submitted information or information intended to clarify information already provided in the submission.

After the FDA evaluates the NDA or BLA, it will issue either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the drug or biologic product with specific prescribing information for specific indications. A complete response letter indicates that the application is not ready for approval. A complete response letter may require additional clinical data and/or an additional pivotal clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. The FDA may also refer applications for novel drug or biological products or drug or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations carefully and generally follows such recommendations when making decisions.

Before approving a NDA or BLA, the FDA typically will inspect the facilities where the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either the approval letter or the complete response letter. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, its complete response letter typically will outline the deficiencies and often will request additional testing or information, which may include additional large-scale clinical testing or information in order for the FDA to reconsider the application. This may significantly delay further review of the application.

If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP regulations, the FDA may determine the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA or BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue the approval letter. The FDA has committed to reviewing such resubmissions in 2 or 6 months depending on the type of information included. An approval letter authorizes commercial marketing and distribution of the product with specific prescribing information for specific indications. As a condition of approval, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy after a product is approved, including additional clinical trials and may impose other conditions, including labeling restrictions, which can materially affect the product's potential market and profitability. These so-called Phase IV or post-approval clinical trials may be a condition for continuing drug approval. The results of Phase IV clinical trials can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA now has express statutory authority to require sponsors to conduct post-marketing trials to specifically address safety issues identified by the agency. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems or safety issues are identified following initial marketing.

The FDA also has authority to require a REMS to ensure that the benefits of a drug or biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the NDA submission. The need for a REMS is determined as part of the review of the NDA or BLA. Elements of a REMS may include "dear doctor letters," a medication guide, more elaborate targeted educational programs, and in some cases elements to assure safe use ("ETASU"), which is the most restrictive REMS. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. These elements are negotiated as part of the NDA or BLA approval, and in some cases the approval date may be delayed. Once implemented, REMS are subject to periodic assessment and modification.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, device components or manufacturing processes or facilities, may require submission and FDA approval of a new NDA or BLA, or NDA or BLA supplement before the change can be implemented. A NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA or BLA supplements as it does in reviewing NDAs or BLAs.

Even if a product candidate receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution or post-marketing trial requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for our products, or obtaining approval but for significantly limited use, would harm our business. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products in development. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Hatch-Waxman Act

Under the Drug Price Competition and Patent Term Restoration Act of 1984, as amended, commonly known as the Hatch-Waxman Act, a portion of a product's U.S. patent term that was lost during clinical development and regulatory review by the FDA may be restored. The Hatch-Waxman Amendments also provide a process for listing patents pertaining to approved products in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) and for a competitor seeking approval of an application that references a product with listed patents to make certifications pertaining to such patents. In addition, the Hatch-Waxman Amendments provide for a statutory protection, known as non-patent exclusivity, against the FDA's acceptance or approval of certain competitor applications.

Patent Term Restoration

Patent term restoration can compensate for time lost during drug development and the regulatory review process by returning up to five years of patent life for a patent that covers a new product or its use. This period is generally one-half the time between the effective date of an IND (falling after issuance of the patent) and the submission date of a NDA, plus the time between the submission date of a NDA and the approval of that application, provided the Sponsor acted with diligence. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended and the extension must be applied for prior to expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Orange Book Listing

In seeking approval for a drug through a NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed by the NDA holder in the drug's application or otherwise are published in the FDA's Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application ("ANDA"). An ANDA permits marketing of a drug product that has the same active ingredient(s) in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical studies or clinical trials to prove the safety or effectiveness of their drug product. Drugs approved under and ANDA are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (i) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (ii) such patent has expired; (iii) the date on which such patent expires; or (iv) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant also may elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the reference NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the notice of the paragraph IV certification, the expiration of the patent, when the infringement case concerning each such patent was favorably decided in the applicant's favor or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the thirty-month stay. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

Market Exclusivity

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain drug applications. The Hatch-Waxman Act establishes periods of regulatory exclusivity for certain approved drug products, during which the FDA cannot approve (or in some cases accept) an ANDA or 505(b)(2) application that relies on the branded reference drug. For instance, the FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of a NDA for a new chemical entity ("NCE"). A drug is a NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a Paragraph IV certification. The Hatch- Waxman Act also provides three years of marketing exclusivity to the holder of a NDA (including a 505(b)(2) NDA) for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) conducted or sponsored by the applicant were deemed by the FDA to be essential to the approval of the application, including, for example, new indications, dosages or strengths of an existing drug. This three- year exclusivity period protects against FDA approval of ANDAs and 505(b)(2) NDA for drugs that include the innovation that required the new clinical data, but does not prohibit the FDA from approving ANDAs for drugs containing the original active ingredient. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA is required to conduct or obtain a right of reference to all of the non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Biosimilar Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") creates an abbreviated approval pathway for biosimilar products under section 351(k) of the Public Health Service Act ("PHSA"). A biosimilar product or "biosimilar" is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-licensed reference product. Biosimilarity must be shown through analytical studies, animal studies, and at least one clinical study, absent a waiver. A biosimilar product may be deemed interchangeable with a prior licensed product if it is biosimilar and meets additional requirements under the BPCIA, including that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. An interchangeable product may be substituted for the reference product without the involvement of the prescriber.

Under the BPCIA, no section 351(k) application for a biosimilar may be submitted for four (4) years from the date of licensure of the reference product. Additionally, a reference biologic is granted twelve (12) years of exclusivity from the time of first licensure of the reference product, During this twelve (12)-year exclusivity period, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product submitted under section 351(a) of the PHSA containing the competing sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The first biologic product submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product may obtain exclusivity against a finding of interchangeability for other biologics for the same condition of use for the lesser of (i) one (1) year after first commercial marketing of the first interchangeable biosimilar; (ii) eighteen (18) months after the first interchangeable biosimilar is approved if there is no patent challenge; (iii) eighteen (18) months after resolution of a lawsuit over the patents of the reference biologic in favor of the first interchangeable biosimilar applicant; or (iv) forty-two (42) months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the forty-two (42)-month period.

Expedited Development and Review Programs

Fast Track Designation

Fast track designation may be granted for a product that is intended to treat a serious or life-threatening disease or condition for which preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. The sponsor of an investigational drug product may request that the FDA designate the drug candidate for a specific indication as a fast track drug concurrent with, or after, the submission of the IND for the drug candidate. The FDA must determine if the drug candidate qualifies for fast track designation within 60 days of receipt of the sponsor's request. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review is available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. At the time of NDA filing, the FDA will determine whether to grant priority review designation. Additionally, fast track designation may be withdrawn if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Breakthrough Therapy Designation

The FDA may also accelerate the approval of a designated Breakthrough Therapy, which is a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The sponsor of a Breakthrough Therapy may request the FDA to designate the drug as a Breakthrough Therapy at the time of, or any time after, the submission of a IND for the drug. If the FDA designates a drug as a Breakthrough Therapy, it must take actions appropriate to expedite the development and review of the application, which may include (i) holding meetings with the sponsor and the review team throughout the development of the drug; (ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; (iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; (iv) assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and (v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

Accelerated Approval

Accelerated approval may be granted for a product that is intended to treat a serious or life-threatening condition and that generally provides a meaningful therapeutic advantage to patients over existing treatments. A product eligible for accelerated approval may be approved on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is contingent on a sponsor's agreement to conduct additional post-approval confirmatory studies to verify and describe the product's clinical benefit. These confirmatory trials must be completed with due diligence and, in some cases, the FDA may require that the trial be designed, initiated, and/or fully enrolled prior to approval. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making the product for this type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation must be requested before submitting a NDA. After the FDA grants orphan drug designation, the identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The first NDA applicant to receive FDA approval for a particular active moiety to treat a rare disease for which it has such designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care, or in instances of drug supply issues. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Other benefits of orphan drug designation include tax credits for certain research and an exemption from the NDA user fee.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted, with certain exceptions.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity — patent or nonpatent — for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Marketing FDA Regulations

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA and other federal and state regulatory authorities, including, among other things, monitoring and record-keeping activities, reporting to applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling and distribution requirements, and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Modifications or enhancements to the products or labeling or changes of site of manufacture are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process.

The FDA, state and foreign regulatory authorities have broad enforcement powers. Failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include the following:

- untitled letters or warning letters;
- fines, disgorgement, restitution or civil penalties;
- injunctions (e.g., total or partial suspension of production) or consent decrees;
- product recalls, administrative detention, or seizure;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant requests for future product approvals or foreign regulatory approvals of new products, new intended uses, or modifications to existing products;

- withdrawals or suspensions of FDA product marketing approvals or foreign regulatory approvals, resulting in prohibitions on product sales;
- clinical holds on clinical trials;
- FDA refusal to issue certificates to foreign governments to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations. Such actions by government agencies could also require us to expend a large amount of resources to respond to the actions. Any agency or judicial enforcement action could have a material adverse effect on our business.

Prescription drug advertising is subject to federal, state and foreign regulations. In the United States, the FDA regulates prescription drug promotion, including direct-to-consumer advertising. Prescription drug promotion materials must be submitted to the FDA in conjunction with their first use. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act ("PDMA"), a part of the FDCA. Once a product is approved, its manufacture is subject to comprehensive and continuing regulations by the FDA. The FDA regulations require the products be manufactured in specific approved facilities and in accordance with cGMP, and NDA or BLA holders must list their products and register their manufacturing establishments with the FDA. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws.

NDA or BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms. These firms are subject to inspections by the FDA at any time, and the discovery of violations could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Newly-discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

Healthcare and Reimbursement Regulation

If VAR 200, IC 100 and any other product candidate that we seek to develop, are approved by the FDA, government coverage and reimbursement policies will both directly and indirectly affect our ability to successfully commercialize the product, and such coverage and reimbursement policies will be affected by future healthcare reform measures. Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for healthcare. In particular, in the United States, private health insurers and other third-party payors often provide reimbursement for products based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Many patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our products will therefore depend substantially, both domestically and abroad, to the extent they are reimbursed by government health administration authorities, such as Medicare and Medicaid, private health coverage insurers and other third-party payors. The market for our products will depend significantly on access to third-party payors' formularies, or lists of products or treatments for which third-party payors provide coverage and reimbursement. Also, third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. Coverage and reimbursements for therapeutic products can differ significantly from payor to payor. A third-party payors' decision to provide coverage for a medical product or service does not imply that an adequate reimbursement rate will be approved. One third-party payor's decision to cover a particular medical product or service does not assure that other payors will also provide coverage for the medical product or services, or to provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of or products to each payor separately, with no assurance that adequate coverage and reimbursement will be obtained.

In the United States and other potentially significant markets for VAR 200, IC 100 and any other product candidate that we seek to develop, government authorities and other third-party payors are developing increasingly sophisticated methods of controlling healthcare costs. For example, third-party payors are attempting to limit or regulate the price of medical products, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the United States will put additional pressure on product pricing, reimbursement and usage. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

The United States and some foreign jurisdictions have enacted or are considering a number of additional legislative and regulatory proposals designed to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including the Patient Protection and Affordable Care Act, or ACA, enacted in March 2010. In the future, there may be additional proposals relating to the reform of the United States health care system, some of which could further limit the prices we are able to charge for our products, or the amounts of reimbursement available for our products. If drug products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Further, if a drug product is reimbursed by Medicare, Medicaid or other federal or state healthcare programs, we, and our business activities, including but not limited to our sales, marketing and scientific/educational grant programs must comply with the False Claims Act, as amended, the federal Anti-Kickback Statute, as amended, other healthcare fraud and abuse laws and similar state laws. Additionally, if an outpatient prescription drug product is reimbursed by Medicare or Medicaid, pricing and rebate programs must comply with, as applicable, the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Medicare Prescription Drug Improvement and Modernization Act of 2003.

Other Regulatory Matters and Compliance Requirements

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services (“CMS”), other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency, and state and local governments. Sales, marketing and scientific/educational programs must also comply with federal and state fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair completion laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The Federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates"— independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. For example, California recently enacted legislation, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach.

Corruption Laws

The U.S. Foreign Corrupt Practices Act and similar foreign anti-corruption laws generally prohibit companies and their intermediaries from making improper payments or providing anything of value to improperly influence foreign government officials for the purpose of obtaining or retaining business, or obtaining an unfair advantage. In recent years, there has been a substantial increase in the global enforcement of anti-corruption laws. Our anticipated non-U.S. operations and our anticipated expansion into additional countries outside the United States, including in developing countries, could increase the risk of such violations. Violations of these laws may result in severe criminal or civil sanctions, could disrupt our business, and could adversely affect our reputation, business and results of operations or financial condition.

International Regulation of Drugs

Before we can market VAR 200, IC 100 and any other product candidate that we seek to develop, in any jurisdiction outside of the United States, we must obtain the necessary marketing authorizations in such jurisdiction. Many such jurisdictions require extensive safety and efficacy data similar to the data required by the FDA before granting marketing authorization. We may not be successful in obtaining marketing authorizations that we seek outside of the United States. If we are successful in obtaining marketing authorization in one jurisdiction, including the United States, that authorization does not ensure that we will receive marketing authorization in any other jurisdiction. The authorizations that are required to market a pharmaceutical product vary greatly from jurisdiction to jurisdiction. If we obtain marketing approval in any jurisdiction outside of the United States, we will be subject to ongoing regulation in such jurisdiction, consistent with the ongoing regulations to which we would be subject in the United States.

International Data Privacy and Security Laws

Certain non-U.S. laws, such as the GDPR govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, in Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of individuals within the EEA. The GDPR also increases the scrutiny of transfers of personal data from clinical trial sites located in the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws. Further, recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of information from the EEA to the United States. For example, on June 16, 2020, the Court of Justice of the European Union, or the CJEU, declared the EU-U.S. Privacy Shield framework, or the Privacy Shield, to be invalid. As a result, Privacy Shield is no longer a valid mechanism for transferring personal data from the EEA to the United States. Moreover, it is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature, which seems possible given the rationale behind the CJEU's concerns about U.S. law and practice on government surveillance. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Additionally, following the United Kingdom's withdrawal from the European Union and the EEA, companies have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. In Canada, PIPEDA and similar provincial laws impose obligations on companies with respect to processing personal information, including health-related information, and provides individuals certain rights with respect to such information, including the right to access and challenge the accuracy of their personal information held by an organization. Failure to comply with PIPEDA could result in significant fines and penalties.

Employees

As of December 31, 2025, we had six (6) full-time employees. We believe our relations with our employees are good. In addition, we utilize and will continue to utilize consultants, clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, manufacturing and regulatory functions.

Corporate Information

We were incorporated under the name "Larkspur Health Acquisition Corp." on March 17, 2021 under the laws of the State of Delaware for the purpose of effecting a merger, capital stock exchange, asset acquisition, stock purchase, reorganization or similar business combination, involving one or more other businesses. On December 12, 2022, we changed our name to "ZyVersa Therapeutics, Inc." in connection with the Business Combination (as hereinafter defined) with ZyVersa Therapeutics, Inc., a Florida corporation ("Old ZyVersa"). Our principal executive offices are located at 2200 North Commerce Parkway, Suite 208, Weston, Florida 33326. Our telephone number is (754) 231-1688 and our website address is *https://www.zyversa.com*. On our website, investors can obtain, free of charge, a copy of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Code of Business Conduct and Ethics, including disclosure related to any amendments or waivers thereto, other reports and any amendments thereto filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we file such material electronically with, or furnish it to, the U.S. Securities and Exchange Commission (the "SEC"). None of the information posted on our website is incorporated by reference into this Annual Report on Form 10-K. The SEC also maintains a website at http://www.sec.gov that contains reports, proxy and information statements and other information regarding the Company and other companies that file materials with the SEC electronically.

This Annual Report on Form 10-K and the information incorporated herein by reference contain references to registered or common law trademarks, service marks and trade names owned by us or other companies. Solely for convenience, such trademarks, service marks and trade names referred to in this report and the information incorporated herein, including logos, artwork, and other visual displays, may appear without the ® or ™ or ^{SM} symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks, service marks and trade names. We do not intend to use or display of other companies' trademarks, service marks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies. Other trademarks, service marks and trade names appearing in this report are the property of their respective owners.

Item 1A. RISK FACTORS

There have been no material changes as of the date of this Annual Report on Form 10-K to the risk factors set forth in our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 27, 2025, other than those described below.

We have never been profitable.

To date, we do not have data to support regulatory approval of any of our drug products, we have no products approved for commercial sale in any jurisdiction, and we have not generated any revenue from product sales. As a result, our ability to curtail our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never been profitable and do not expect to be profitable for the foreseeable future. As of December 31, 2025, our accumulated net loss was approximately $204 million, inclusive of the period prior to the Business Combination period. We have devoted most of our financial resources to our organizational and capital-raising activities and negotiating our license agreements, and other strategic partnerships and collaborations. We have not completed development of any product candidate through the receipt of marketing approval, and we have therefore not generated any revenues from product sales. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. We expect to incur increased expenses as we continue the clinical development of VAR 200 and preclinical development of IC 100 and other product candidates that we may seek to develop and for which we may seek marketing approval in the United States and elsewhere. We also expect an increase in our expenses associated with creating additional infrastructure (including hiring additional personnel) to commence clinical trials and continue the development and commercialization of VAR 200 and IC 100 and other product candidates that we may seek to develop. As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

To date, we have financed our operations through the sale of our equity securities. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If we are unable to develop and commercialize VAR 200, IC 100, or any other product candidates that we may seek to develop, either alone or with collaborators, or if revenues from any product candidate that receives marketing approval are insufficient, we may not be able to raise additional capital and will not achieve profitability. Current limitations on accessing capital in a risk-averse environment for the biotechnology sector, characterized by decreased investor appetite, market volatility, and regulatory uncertainty, have contributed to a sustained decline in our market capitalization. As a result, in September 2025, we determined that the carrying value of our in-process research and development intangible asset was not recoverable and recorded an $18.6 million impairment charge.

Our common stock has been delisted from The Nasdaq Capital Market.

Effective October 6, 2025, our common stock was delisted from The Nasdaq Capital Market. Our common stock is currently quoted on the OTCQB under the ticker symbol "ZVSA." We can provide no assurance that our common stock will continue to trade on this market, whether broker-dealers will continue to provide public quotes of our common stock on this market, whether the trading volume of our common stock will be sufficient to provide for an efficient trading market or whether quotes for our common stock will continue on this market in the future. Stocks trading in the OTC Markets generally have substantially less liquidity; consequently, it can be much more difficult for stockholders and broker/dealers to purchase and sell our shares in an orderly manner or at all. Due in part to the decreased trading price of our common stock and reduced analyst coverage, the trading price of our common stock may change quickly, and brokers may not be able to execute trades as quickly as they previously could when our common stock was listed on a national exchange.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Our use of information systems for using, transmitting and storing data is a vital aspect of our business operations. Information systems can be vulnerable to a range of cybersecurity threats that could potentially have a material impact on our business strategy, results of operations and financial condition.

Cybersecurity is a key category within our risk management efforts, and our cybersecurity risk management is intended to assist in assessing, identifying, and managing material risks from cybersecurity threats to the Company's information systems. Our cybersecurity risk management and strategy is based upon utilizing systems that are cloud based which require multifactor authentication to access. Due to our small size, we partner with a third-party service provider which utilizes multiple security operations centers. The security operations centers maintain, monitor, mitigate and alert on threats against the cloud systems that we utilize. If a risk is identified the security operations center has the ability to shut down access to any user in the organization.

The Audit Committee of our Board of Directors is responsible for oversight of the Company's cyber-risk management and management's role is to assist the Audit Committee in identifying and considering material cybersecurity risks, ensure implementation of management and employee level cybersecurity practices and training and provide the Audit Committee with unrestricted access to Company personnel and documents regarding any cybersecurity attacks or vulnerabilities.

We also require our employees to participate in cybersecurity training and awareness programs. Company's employees are expected to help safeguard the Company's information systems and to assist in the discovery and reporting of cybersecurity incidents. These programs are intended to decrease cybersecurity risks associated with human error and foster a culture of cybersecurity consciousness.

To date, the risks from cybersecurity threats, including as a result of any previous immaterial cybersecurity incidents, have not materially affected, or are reasonably likely to materially affect our business strategy, results of operations, or financial condition. While our insurance covers certain cybersecurity related matters, the costs related to cybersecurity threats or disruptions may not be fully insured.

ITEM 2. PROPERTIES

Our principal executive offices are located at 2200 North Commerce Parkway, Suite 208, Weston, Florida 33326. On January 18, 2019, we entered into a lease agreement (the "Lease") for 3,502 square feet of office space located at this facility, with a lease term of 60 months beginning in January 2019 and ending in January 2024. On January 15, 2024, the Company extended the lease for an additional year and on January 9, 2025, the Company extended the lease for an additional year. The lease agreement ended on January 31, 2026 and it was not extended.

ITEM 3. LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings; however, we may from time to time become a party to various legal proceedings arising in the ordinary course of our business. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this report, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is quoted on the OTCQB® Venture Market under the symbol "ZVSA". Any over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down, or commission, and may not necessarily represent actual transactions. Prior to July 17, 2025, our common stock traded on The Nasdaq Capital Market.

Holders

As of March 25, 2026, there were approximately 88 holders of record of our common stock. These numbers do not include beneficial owners whose shares were held in street name. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees.

Dividends

The Company has never declared dividends on the Company's equity securities, and currently does not plan to declare dividends on shares of the Company's common stock in the foreseeable future. The Company expects to retain future earnings, if any, for use in the operation and expansion of the Company's business. The payment of cash dividends in the future, if any, will be at the discretion of the board of directors and will depend upon such factors as earnings levels, capital requirements, overall financial condition and any other factors deemed relevant by the board of directors.

Recent Sales of Unregistered Securities

There were no unregistered sales of equity securities which have not been previously disclosed in a quarterly report on Form 10-Q or a current report on Form 8-K since January 1, 2024.

Penny Stock Regulations

The SEC has adopted Rule 15g-9, which establishes the definition of a "penny stock," for purposes relevant to the Company, as any equity security that has a market price of less than $5.00 per share or with an exercise price of less than $5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require: (i) that a broker or dealer approve a person's account for transactions in penny stocks, and (ii) that the broker or dealer receive from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased. In order to approve a person's account for transactions in penny stocks, the broker or dealer must (i) obtain financial information and investment experience and objectives of the person, and (ii) make a reasonable determination that the transactions in penny stocks are suitable for that person and that such person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks. The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prepared by the SEC relating to the penny stock market, which, in highlight form, (i) sets forth the basis on which the broker or dealer made the suitability determination, and (ii) confirms that the broker or dealer received a signed, written agreement from the investor prior to the transaction. Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading, and about commissions payable to both the broker-dealer and the registered representative, current quotations for the securities, and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

Because of these regulations, broker-dealers may encounter difficulties in their attempt to buy or sell shares of our common stock, which may affect the ability of our shareholders to sell their shares in the secondary market and have the effect of reducing the level of trading activity in the secondary market. These additional sales practice and disclosure requirements could impede the sale of our common stock in the marketplace. In addition, the liquidity for our common stock may be decreased, with a corresponding decrease in the price of our common stock. Our shares are likely to be subject to such penny stock rules for the foreseeable future.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Unless the context otherwise requires, all references in this section to "we," "us" or "our" refer to the combined business of ZyVersa Therapeutics, Inc., a Florida corporation, prior to the Business Combination and ZyVersa Therapeutics, Inc., a Delaware corporation, and its consolidated subsidiaries after giving effect to the Business Combination.

The following discussion and analysis provides information that management believes is relevant to an assessment and understanding of our consolidated results of operations and financial condition. You should read this discussion and analysis in conjunction with our consolidated financial statements and notes thereto included elsewhere in this Annual Report. Certain amounts may not foot due to rounding. This discussion and analysis contains forward-looking statements and involves numerous risks and uncertainties, including, but not limited to, those described under "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements." We assume no obligation to update any of these forward-looking statements. Actual results may differ materially from those contained in any forward-looking statements.

Business Overview

We are a clinical stage specialty biopharmaceutical company leveraging advanced proprietary technologies to develop first-in-class drugs for patients with renal or inflammatory diseases with high unmet medical needs.

Our renal drug candidate, which we refer to as Cholesterol Efflux Mediator^{TM} VAR 200 (2-hydroxypropyl-beta-cyclodextrin or "2HβCD"), is in development to treat multiple renal indications. The lead indication is focal segmental glomerulosclerosis (FSGS). Our anti-inflammatory drug candidate, which we refer to as Inflammasome ASC Inhibitor IC 100, is a humanized monoclonal IgG4 antibody targeting apoptosis-associated speck-like protein containing a caspase recruitment domain ("ASC") in development to treat multiple inflammatory diseases. The lead indication is obesity-related cardiometabolic comorbidities.

Financial Operations Overview

We have not generated any revenue to date and have incurred significant operating losses. Our net losses were $25.0 million for the period from January 1, 2025 through December 31, 2025, compared to $9.4 million for the period from January 1, 2024 through December 31, 2024. As of December 31, 2025, we had an accumulated deficit of approximately $137.6 million and cash of $0.1 million. We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses. We expect our expenses will increase in connection with our ongoing activities as we:

- progress development of VAR 200 and IC 100
- prepare and file regulatory submissions;
- begin to manufacture our product candidates for clinical trials;
- hire additional research and development, finance, and general and administrative personnel;
- protect and defend our intellectual property; and
- meet the requirements of being a public company.

We will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include government grants and collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenues to achieve profitability, and we may never do so.

Recent Developments

On July 15, 2025, we received a determination letter (the "Letter") from The Nasdaq Stock Market LLC ("Nasdaq") indicating that the Nasdaq Hearings Panel (the "Panel") has determined to deny our request to continue our listing on The Nasdaq Capital Market. Our common stock was delisted on October 6, 2025. As a result of the delisting, there may be a very limited market in which our shares are traded, our stockholders may find it difficult to sell their shares of our common stock, and the trading price of our securities, if any, may be adversely affected. We applied for trading on the OTCQB® Venture Market ("OTCQB") maintained by the OTC Markets Group Inc. to mitigate the risk of delisting from Nasdaq. Our application was approved on July 25, 2025, and our common stock began trading on OTCQB on July 28, 2025, under the symbol "ZVSA."

Components of Operating Results

Revenue

Since inception, we have not generated any revenue and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval, or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from collaboration or license agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist of costs incurred in the discovery and development of our product candidates, and primarily include:

- expenses incurred under third party agreements with contract research organizations ("CROs"), and investigative sites, that conducted or will conduct our clinical trials and a portion of our pre-clinical activities;
- costs of raw materials, as well as manufacturing cost of our materials used in clinical trials and other development testing;
- expenses, including salaries, stock-based compensation and benefits of employees engaged in research and development activities;
- costs of equipment, depreciation and other allocated expenses; and
- fees paid for contracted regulatory services as well as fees paid to regulatory authorities including the US Food and Drug Administration (the "FDA") for review and approval of our product candidates.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected in our financial statements as prepaid expenses or accrued expenses.

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase for the foreseeable future as we continue preclinical and clinical development for our product candidates. As products enter later stages of clinical development, they will generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. Historically, our research and development costs have primarily related to the development of VAR 200 and IC 100. As we advance VAR 200 and IC 100, as well as identify other potential product candidates, we will continue to allocate our direct external research and development costs to the products. We expect to fund our research and development expenses from our current cash and cash equivalents and any future equity or debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project resulting from many factors, including:

- the number of clinical sites included in the clinical trials;
- the length of time required to enroll suitable patients;
- the size of patient populations participating in the clinical trials;
- the number of doses a patient receives;
- the duration of patient follow-ups;
- the number and types of assessments;
- the development state of the product candidates; and
- the efficacy and safety profile of the product candidates.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of our product candidates. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Product commercialization will take years and likely millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, stock-based compensation and related costs for our employees in administrative, executive and finance functions. General and administrative expenses also include professional fees for legal, accounting, audit, tax and consulting services, insurance, human resources, information technology, office, and travel expenses.

We expect that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also expect to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax compliance services, director and officer insurance, and investor and public relations costs.

Results of Operations

As we continue to explore commercial opportunities and partners in both U.S. and international markets, we remain attentive to evolving global economic conditions, including uncertainties related to international trade policies, tariffs, and supply chain dynamics. Although these factors have not had a material impact on our operations to date, future changes in trade regulations, tariff structures, or logistical constraints could influence the cost, availability, or timing of materials, services and other components associated with the development of our product candidates and manufacturing capabilities. We continue to monitor these developments closely to maintain operational efficiency and help mitigate potential future impacts.

Comparison of the years ended December 31, 2025 and December 31, 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and December 31, 2024.

	For the Years Ended December 31,		Favorable (Unfavorable)	
(in thousands)	2025	2024	$ Change	% Change
Operating expenses:				
Research and development	$ 1,113	$ 1,779	$ 666	37.4%
General and administrative	5,732	7,358	1,626	22.1%
Impairment of in-process research and development	18,648	-	(18,648)	0.0%
Total Operating Expenses	25,493	9,137	(16,356)	(179.0)%
Loss from Operations	(25,493)	(9,137)	(16,356)	(179.0)%
Other (Income) Expense, Net	312	270	(42)	(100.0)%
Pre-tax net loss	(25,805)	(9,407)	(16,398)	(174.3)%
Income tax benefit	852	(6)	858	(100.0)%
Net loss	$ (24,953)	$ (9,413)	$ (15,540)	(165.1)%

Research and development expenses

Research and development expenses were approximately $1.1 million for the year ended December 31, 2025, a decrease of approximately $0.7 million or 37.4% from the year ended December 31, 2024. The decrease is attributable to fewer consultants utilized in 2025 for a decrease of $0.3 million, retirement of Chief Medical Officer in late 2025 for a net decrease of $0.1 million, decrease in VAR200 clinical patient trial expense of $0.1 million, as program paused in 2025, and a decrease in preclinical bioassay IC100 work of $0.1 million which was completed in 2024.

General and administrative expenses

General and administrative expenses were approximately $5.7 million for the year ended December 31, 2025, a decrease of approximately $1.6 million or 22.1% from the year ended December 31, 2024. The decrease is attributable to $0.5 million decrease in director and officer insurance due to reduced costs in the third year of being a public company, a $0.4 million decrease in stock-based compensation as a result of options becoming fully amortized in 2025, a $0.4 million decrease in marketing expense due to fewer investor relations and public relations firms used in 2025, and a $0.2 million decrease in Delaware franchise tax as a result of a decrease in total assets.

Impairment of in-process research and development

For the year ended December 31, 2025, impairment of in-process research and development was $18.6 million which is a result of a significant and sustained decline in the Company's market capitalization. There was no impairment for the year ended December 31, 2024.

Other (Income) Expense, Net

Other (income) expense, net was $312 thousand for the year ended December 31, 2025, an increase of $42 thousand from the year ended December 31, 2024. The increase in expense is attributable to $243 thousand increase in interest expense charged by a vendor for outstanding amounts owed offset by a decrease of $201 thousand for a mark to market adjustment in the fair value of equity payable due to the decreased price in stock.

Cash Flows

The following table summarizes our cash flows from operating and financing activities for the years ended December 31, 2025 and 2024:

	For the Years Ended December 31,		Increase
(in thousands)	2025	2024	(decrease)
Net cash provided by (used in)			
Operating activities	$ (5,114)	$ (7,560)	$ 2,446
Financing activities	3,685	5,953	(2,268)
Net Decrease in Cash	$ (1,429)	$ (1,607)	$ 178

Cash Flows from Operating Activities

Net cash used in operating activities was approximately $5.1 million and $7.6 million for the years ended December 31, 2025 and 2024, respectively. For the years ended December 31, 2025 and 2024, the net cash used in operating activities was primarily attributable to the net loss of approximately $25.1 million and $9.4 million, respectively, offset by $18.3 million and $0.9 million, respectively, of net non-cash expenses, and approximately $1.7 million and $1.0 million, respectively, of cash generated by the levels of operating assets and liabilities, respectively.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $3.7 million and $5.9 million for the years ended December 31, 2025 and 2024, respectively. Cash provided by financing activities during the year ended December 31, 2025 represented proceeds from the exercise of warrants and private placement of warrants. Cash provided by financing activities during the year ended December 31, 2024 represented proceeds from the exercise of warrants and at the market stock proceeds.

Liquidity and Capital Resources

The following table summarizes our total current assets, liabilities and working capital deficiency at December 31, 2025 and 2024, respectively:

(in thousands)	December 31, 2025	December 31, 2024
Current Assets	$ 348	$ 1,716
Current Liabilities	$ 12,735	$ 11,231
Working Capital Deficiency	$ (12,387)	$ (9,515)

Since our inception in 2014 through December 31, 2025, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. Based on our current operating plan, we expect our cash of $0.1 million as of December 31, 2025 will only be sufficient to fund our operating expenses and capital expenditure requirements on a month-to-month basis. It is difficult to predict our spending for our product candidates prior to obtaining FDA approval. Moreover, changing circumstances may cause us to expend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

Going Concern

Since inception we have been engaged in organizational activities, including raising capital and research and development activities. We have not generated revenues and have not yet achieved profitable operations, nor have we ever generated positive cash flow from operations. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. We are subject to those risks associated with any pre-clinical stage pharmaceutical company that has substantial expenditures for research and development. There can be no assurance that our research and development projects will be successful, that products developed will obtain necessary regulatory approval, or that any approved product will be commercially viable. In addition, we operate in an environment of rapid technological change and are largely dependent on the services of our employees and consultants. Further, our future operations are dependent on the success of our efforts to raise additional capital. These uncertainties raise substantial doubt about our ability to continue as a going concern for 12 months after the issuance date of our financial statements. The accompanying financial statements have been prepared on a going concern basis, which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability to continue as a going concern. We incurred a net loss of $25.0 million for the year ended December 31, 2025 and had an accumulated deficit of $137.6 million on December 31, 2025. We anticipate incurring additional losses until such time, if ever, that we can generate significant revenue from our product candidates currently in development. Our primary source of capital has been the issuance of debt and equity securities. On February 27, 2026, the Company entered into a Securities Purchase agreement and received approximately $1.0 million. We believe that current cash is only sufficient to fund operations and capital requirements on a month-to-month basis. Additional financing will be needed to fund our operations, to complete development of and to commercialize our product candidates. There is no assurance that such financing will be available when needed or on acceptable terms.

Contractual Obligations

The following summarizes our contractual obligations as of December 31, 2025 that will affect our future liquidity. Based on our current operating plan, we plan to satisfy the obligations identified below from our current cash balance and future financing.

Cash requirements for our current liabilities as of December 31, 2025 are approximately $12.7 million for accounts payable and accrued expenses.

Future Capital Needs

We expect our cash on hand will enable us to invest in our continued development of VAR 200 and IC 100 on a month-to-month basis as cash is available. We intend to raise additional capital in the future to fund continued development.

We expect to raise additional capital by issuing equity, equity-linked securities, or debt in subsequent offerings. If we are unable to raise additional capital on terms favorable to us, we may not have sufficient liquidity to execute our business strategy. We have various warrants outstanding that can be exercised for our common stock, many of which must be exercised in exchange for cash by the holders of such warrants. If the market price of our common stock is less than the exercise price of a holder’s warrants, it is unlikely that holders will exercise their warrants. As such, we do not expect to receive significant proceeds in the near term from the exercise of most of our warrants based on the current market price of our common stock and the exercise prices of such warrants.

Our policy is to invest any cash exceeding our immediate requirements in investments designed to preserve the principal balance and provide liquidity while producing a modest return on investment.

We expect to continue to incur substantial additional operating losses for at least the next several years as we continue to develop our product candidates and seek marketing approval and, the eventual commercialization of our product candidates if approved. If we obtain marketing approval for our product candidates, we will incur significant sales, marketing and outsourced manufacturing expenses. In addition, we expect to incur additional expenses to add operational, financial, and information systems and personnel, to support our planned product development efforts, and other initiatives. We also expect to incur significant costs to comply with corporate governance, internal controls, and requirements applicable to public companies.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the initiation, progress, timing, costs and results of clinical development plans and clinical trials for our product candidates;
- the number and characteristics of product candidates that we develop or in-license;
- the terms of any collaboration agreements we may choose to execute;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA or other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us;
- the cost and timing of the implementation of commercial scale manufacturing activities; and
- the cost of establishing, or outsourcing, sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

To continue to grow our business over the longer term, we plan to commit substantial resources to research and development, clinical trials of our product candidates, and other operations and potential product acquisitions and in-licensing. We have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our plan to acquire or in-license approved or development products and develop additional products and product candidates to augment our internal development pipeline or expand our existing operations. Strategic transaction opportunities that we may pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. Strategic transactions may also be structured as a collaboration or partnering arrangement. We have no arrangements, agreements, or understandings in place at the present time to enter into any acquisition, in-licensing or similar strategic business transaction. We continue to evaluate commercial collaborations and strategic relationships with established pharmaceutical companies, which would provide us with more immediate access to marketing, sales, market access and distribution infrastructure.

If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any debt financing or additional equity that we raise may contain terms, such as liquidation and other preferences that are not favorable to us or our existing stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

JOBS Act Accounting Election

ZyVersa is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. The JOBS Act permits companies with emerging growth company status to take advantage of an extended transition period to comply with new or revised accounting standards, delaying the adoption of these accounting standards until they apply to private companies. ZyVersa expects to use this extended transition period to enable compliance with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date the Company (1) is no longer an emerging growth company or (2) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting standards as of public company effective dates.

In addition, the Company intends to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act.

Off-Balance Sheet Arrangements

There are no off-balance sheet arrangements with any other entity that have, or are reasonably likely to have, a current or future effect on financial conditions, changes in financial conditions, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to stockholders.

Critical Accounting Estimates

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, which require our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. Our critical accounting estimates are described below.

Impairment of In-Process Research and Development

The Company reviews for the impairment of in-process research and development at a minimum annually, but more frequently if events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company measures the carrying amount of the asset against the estimated undiscounted future cash flows associated with it. Should the sum of the expected future net cash flows be less than the carrying value of the asset being evaluated, an impairment loss would be recognized for the amount by which the carrying value of the asset exceeds its fair value.

During the year ended December 31, 2025, we determined that it was more likely than not that the Company's single reporting unit's fair value was below its carrying amount, due to significant and sustained decline in the Company's market capitalization. Current limitations on accessing significant capital in what is currently a risk averse environment for biotech (as evidenced by decreased investor appetite for risk, market volatility, regulatory uncertainty from a changing Food and Drug Administration and a challenging economic environment), resulted in a sustained decline in the Company's market capitalization, and the Company's ability to further finance the development of its drug candidates to the next milestone could be adversely impacted. Accordingly, the Company determined that the carrying value of its IPR&D intangible asset was not recoverable and it was fully impaired. Therefore, the Company recorded an $18.6 million impairment charge, reflected within operating expenses in the consolidated statements of operations for the year ended December 31, 2025.

The evaluation of asset impairment requires the Company to make assumptions about future cash flows over the life of the asset being evaluated. These assumptions require significant judgement, and actual results may differ from assumed and estimated amounts.

There are other items within our financial statements that require estimation but are not deemed critical, as defined above.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The amendments in this update address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This update also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments in ASU 2023-09 were adopted by the Company on a prospective basis effective January 1, 2025. There was no material impact to the Company's financial statements as a result of adopting ASU 2023-09. Refer to Note 6 – Income Taxes for the inclusion of new disclosures required.

Recently Issued Accounting Pronouncements

In November 2024, The FASB issued ASU 2024-03, Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220 – 04). This update requires an entity to disclose more detailed information regarding expenses for the entity. The amendments require that at each interim and the annual reporting period, the entity must disclose amounts related to purchases of inventory, employee compensation, depreciation, intangible asset amortization and depreciation, depletion, and amortization recognized as part of oil and gas- producing activities. Including the amounts, the entity is required to disclose and qualitative description of the amounts remaining in relevant expense captions, and to disclose the total amount of selling expenses and the definition of selling expenses. The amendments in this update should be applied prospectively to financial statements issued for reporting periods, and retrospectively to any prior periods presented in the financials. Although early adoption is permitted, the new guidance becomes effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Since this new ASU addresses only disclosures, the Company does not expect the adoption of this ASU to have any material effects on its financial condition, results of operations or cash flows.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements required to be filed pursuant to this Item 8 are found on pages F-1 through F-22 following the Exhibit Index of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in company reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer (who serve as our Principal Executive Officer and Principal Financial and Accounting Officer, respectively), to allow timely decisions regarding required disclosure.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer and Chief Financial Officer carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2025. Based upon their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025, based on the criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of the Effectiveness of Controls

Management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all errors and fraud. A control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to errors or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth certain information concerning our executive officers and directors.

Name	Age	Position
Stephen C. Glover	66	Chief Executive Officer, President and Chairman
Karen A. Cashmere	74	Chief Commercial Officer
Peter Wolfe	58	Chief Financial Officer and Secretary
Pablo A. Guzman, M.D.	76	Chief Medical Officer and Senior Vice President of Medical Affairs
Min Chul Park, Ph.D.	44	Director
James Sapirstein	64	Director
Gregory Freitag	64	Director

Management

Stephen C. Glover. Mr. Glover is one of our co-founders and has served as our Chief Executive Officer, President and Chairman since December 2022. Mr. Glover served as Chief Executive Officer and President of Old ZyVersa from March 2014 to December 2022, a member of the board of directors from March 2014 to September 2021, and Chairman from September 2021 to December 2022. Mr. Glover is formerly the Co-Founder of Coherus Biosciences where he was focused on business strategy, partnerships, product development efforts, and capitalization of the company. Prior to Coherus, he was the President of Insmed Therapeutic Proteins (from 2007 to 2010), as well as Chief Business Officer of Insmed Incorporated (from 2007 to 2010). At Insmed, Mr. Glover was responsible for the creation of the biosimilar business unit and the divestiture of the business to Merck. As Chief Business Officer he led Insmed's strategic review process which resulted in the merger of Insmed and Transave. Mr. Glover received his B.S. in Marketing from Illinois State University. Mr. Glover has multifaceted experience in Fortune 100, start up, and entrepreneurial environments and he serves on the board of PDS Biotechnology, The Coulter Foundation (University of Miami) and Asclepius Lifesciences. Mr. Glover was selected to serve on our board of directors based on his extensive experience in the therapeutics industry, his deep knowledge of ZyVersa and his ongoing experience as a board member of other life sciences companies. Mr. Glover was appointed to our board of directors by ZyVersa pursuant to the Business Combination Agreement.

Karen A. Cashmere. Ms. Cashmere has served as our Chief Commercial Officer since December 2022. Ms. Cashmere served in the same capacity at Old ZyVersa from January 2019 to December 2022, and as Acting Vice President, Development and Marketing from August 2014 to January 2019. Ms. Cashmere has more than 25 years' experience in business planning and execution for biopharmaceutical and medical device companies ranging in size from start-up to Fortune 100 companies. She formerly led the Marketing Communications function at Mako Surgical Corporation, an emerging robotic orthopedics company, where she was responsible for creating awareness and driving sales of Robotic Arm Systems priced at over $1 million each and their associated implants for partial knee and total hip arthroplasty.

Peter Wolfe. Mr. Wolfe has served as our Chief Financial Officer and Secretary since December 2022. Mr. Wolfe served as Senior Vice President, Finance and Administration at Old ZyVersa from 2019 to December 2022, and prior to that had served as Vice President of Finance from October 2015 to 2019. Mr. Wolfe has spent his career in various financial roles in the financial services, specialty finance, and the pharmaceutical/healthcare industries. Most recently Mr. Wolfe has spent his time cultivating start-up organizations in various healthcare entities, often dealing with complicated business models to develop a financial framework for success for many of these first of their kind businesses. Mr. Wolfe has spent the last 24 years of his career in the healthcare industry with one fourth of that time spent at Kos Pharmaceuticals, a publicly traded, fully-integrated specialty pharmaceutical company. Mr. Wolfe has his BBA from the University of Miami and his MBA from the University of Pittsburgh.

Pablo A. Guzman, M.D. Dr. Guzman has served as our Chief Medical Officer and Senior Vice President of Medical Affairs since January 2023. Prior to that, he was a consultant with us beginning January 2015. Since 2017, Dr. Guzman has served on the Scientific Advisory Board at Therapeutic Solutions International, Inc., a company focused on immune modulation. He received his Bachelor's degree in Biology from St Peter's University in Jersey City in 1971, his Medical Degree from the University of Puerto Rico School of Medicine in 1975, and his Interventional Cardiology Fellowship at The Johns Hopkins Hospital in Baltimore in 1980. He is Board certified in Internal Medicine (1978) and Cardiovascular Diseases (1981). He joined the staff at Johns Hopkins in 1980 and his duties included patient care, teaching, and both clinical and basic science research in the dog lab. He has over 30 articles in peer reviewed journals and many abstracts, some of them presented in national meetings including the American Heart Association and the American College of Cardiology. Dr. Guzman sits on the Board of Trustees at Holy Cross Health, a member of Trinity Health since 2015. He sits on the Scientific Advisory Board of Campbell Neurosciences Inc. and Therapeutics Solutions International.

Non-Executive Directors

Min Chul Park, Ph.D. Dr. Park has served as a member of our board of directors since December 2022. Mr. Park served in the same capacity at Old ZyVersa from May 2021 to December 2022. Dr. Park is an Assistant Professor at Inje University's College of Pharmacy. Dr. Park was formerly the Chief Executive Officer, and Director of Curebio Therapeutics, a biopharmaceutical company in Seoul, Korea, which develops peptide drugs for cancer, alopecia, and wound care, from October 2020 to April 2022. Dr. Park also served as Executive Vice President, CTO, and Director of Curebio from August 2017 to March 2022. Dr. Park served as an Adjust Professor at Korea University's Department of Pharmacy from March 2019 to February 2022. With 10 years in the pharmaceutical industry, Dr. Park has worked in the field of drug target discovery, assay development, and drug candidate optimization. He has expertise in basic and applied molecular and cellular biology. In his former role at Curebio Therapeutics, Dr. Park led financing and business development deals, including co-development agreements with three pharmaceutical companies, and one in-license deal. Additionally, he developed cosmetic peptides, and he co-developed antibodies, circulating tumor cell-based diagnostics, and a cancer stem cell assay system. Additionally, Dr. Park is a co-founder of TME Therapeutics, Co. and is currently on its Scientific Advisory Board. Until 2017, Dr. Park was CEO and Director at Neomics Co. in Seoul, Korea, where he helped expand the contract experiment and biomaterial business, and he led efforts to merge Neomics with Curebio and Bumyoung Bio Co., Ltd to form Curebio. Dr. Park developed cosmetic peptides, and a dermatology peptide drug candidate that he out-licensed. Dr. Park began his career as a Senior Research Associate at Medicinal Bioconvergence Research Center at Seoul National University, where he developed and led an out-licensing deal for an exosome isolation device, and he was responsible for two out-licensing deals for an anti-tumorigenic peptide. Dr. Park obtained his Ph.D. in pharmaceutical bioscience at the Seoul National University, Department of Pharmacy. Dr. Park was selected to serve on our board of directors based on his in-depth knowledge of the pharmaceutical industry and drug development technology. Dr. Park was appointed to our board of directors by ZyVersa pursuant to the Business Combination Agreement.

James Sapirstein. James Sapirstein has served as a member of our board of directors since January 2023. Mr. Sapirstein is currently the Chairman and Chief Executive Officer of 8 Prime Biosciences. He served as Chairman and CEO of Entero Therapeutics (ENTO:NASDAQ) from October 2019 until February 2025 and served as Chief Executive Officer of Contravir Pharmaceuticals from March 2014 until October 2018. Mr. Sapirstein served as the Chief Executive Officer of three NASDAQ listed companies. Mr. Sapirstein has raised over $600 Million dollars in venture capital and public capital markets financing in his various engagements as Chief Executive Officer. He was named as a Finalist for the Ernst & Young Entrepreneur of the Year award in 2015 as well as in 2016. He was Chairman of the Board for BioNJ, an association of biopharma industries in New Jersey from February 2017 to February 2019. In addition, he is a former member of the Board of Directors for BIO (Biotechnology Innovation Organization), the leading biotechnology trade organization promoting public policy and networking in the healthcare space, where he sat on several committees including the Emerging Companies Section Governing Board. Mr. Sapirstein was selected to serve as a member of the Board because of his extensive experience as an executive in the biotech and pharmaceutical sectors and as a director for multiple public companies in such sectors.

Gregory Freitag. Gregory Freitag has served as a member of our board of directors since January 2023. Mr. Freitag is currently a member of the board of directors of PDS Biotechnology Corporation (NASDAQ: PDSB), a clinical-stage immunotherapy company developing a growing pipeline of targeted cancer and infectious disease immunotherapies based on its proprietary Veramune and Infectimune T cell-activating platforms. He served from February 2011 until June 2024 as a member of the board of directors of Axogen, Inc. (NASDAQ: AXGN), a leading regenerative medicine company dedicated to peripheral nerve repair. Mr. Freitag was Axogen's Special Counsel from June 2020 until March 2021, General Counsel from September 2011 until June 2020, Chief Financial Officer from September 2011 until May 2014 and August 2015 until March 2016, and Senior Vice President Business Development from May 2014 until October 2018. Mr. Freitag holds a J.D. from the University of Chicago and a B.A. in Economics & Business and Law & Society from Macalester College, Minnesota. Mr. Freitag was selected to serve on the Board and as the chair of the Company's Audit Committee because of his proven leadership and experience as a senior-level executive, his particular knowledge of public companies, including reporting, compliance and financial markets related thereto, his finance management and legal expertise, his former position as a public company chief financial officer and over 30 years of experience in the life sciences sector.

Family Relationships

There are no family relationships between the officers and directors of the company.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has, during the past ten years, been involved in any legal proceedings which are required to be disclosed pursuant to the rules and regulations of the SEC.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our directors and executive officers, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Specific due dates for these reports have been established, and the Company is required to report any failure to comply therewith during the fiscal year ended December 31, 2025. During fiscal year ended December 31, 2025, Ms. Cashmere filed one late Form 4 with respect to one transaction.

To our knowledge, based solely on a review of the reports filed electronically with the SEC during the Company's most recent fiscal year and, where applicable, written representations that no other reports were required, we believe that all other Section 16(a) filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners were complied with in a timely manner during fiscal year ended December 31, 2025.

Code of Business Conduct

The Company has adopted a code of business conduct that applies to all of our directors, officers and employees, including its principal executive officer, principal financial officer and principal accounting officer, which is available on the Company's website. The Company's code of business conduct is a "code of ethics," as defined in Item 406(b) of Regulation S-K. Please note that the Company's Internet website address is provided as an inactive textual reference only. The Company will make any legally required disclosures regarding amendments to, or waivers of, provisions of its code of ethics on its corporate website.

Director Nominations

No material changes have been made to the procedures by which stockholders may recommend nominees to our board of directors.

Audit Committee

The audit committee consists of Gregory Freitag, serving as the chairperson, Robert G. Finizio, and James Sapirstein. Our board of directors has determined that each member of the audit committee qualifies as an independent director under applicable Nasdaq Listing Rules meets the independence requirements of Rule 10A-3 under the Exchange Act, and Mr. Frietag qualifies as an "audit committee financial expert," as that term is defined in Item 407(d)(5) of Regulation S-K. The purpose of the audit committee is to prepare the audit committee report required by the SEC to be included in any proxy statement or prospectus required to be filed by the Company under the rules and regulations of the SEC and to assist our board of directors in overseeing and monitoring (1) the quality and integrity of the financial statements; (2) compliance with legal and regulatory requirements; (3) the Company's independent registered public accounting firm's qualifications and independence; (4) the performance of the Company's internal audit function, if any; and (5) the performance of the Company's independent registered public accounting firm. Our board of directors has adopted a written charter for the audit committee, which is available free of charge on our corporate website (*www.zyversa.com*).

Insider Trading Policies

The Company has an Insider Trading Policy that prohibit directors and employees from engaging in short sales of the Company's securities; purchases or sales of puts, calls, or other derivative securities based on the Company's securities; or purchases of financial instruments (including prepaid variable forward contracts, equity swaps, collars and exchange funds) that are designed to hedge or offset any decrease in the market value of Company securities.

Our Insider Trading Policy also prohibits directors and employees from purchasing Company securities on margin, borrowing against Company securities held in a margin account, or pledging Company securities as collateral for a loan, subject to an exception for pledging Company securities as collateral for a loan (other than a margin loan) if the director or employee clearly demonstrates the financial capacity to repay the loan without resort to the pledged securities and upon approval by our Chief Financial Officer.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following Summary Compensation Table sets forth information regarding the compensation paid to, awarded to, or earned by our principal executive officer and certain other executive officers in 2025 and 2024 for services rendered in all capacities to us and our subsidiaries during 2025 and 2024.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards [1] ($)	Total Compensation ($)
Stephen C. Glover	2025	550,000	-	72,910	622,910
Co-Founder, Chief Executive Officer, President and Chairman	2024	550,000	-	-	550,000
Peter Wolfe	2025	395,000	-	32,008	427,008
Chief Financial Officer and Secretary	2024	395,000	-	-	395,000
Pablo A. Guzman, M.D.	2025	272,222	-	6,194	278,416
Chief Medical Officer and Senior Vice President of Medical Affairs	2024	350,000	-	-	350,000

(1) The amounts reported represent the aggregate grant date fair value of the stock options awarded under our 2022 Omnibus Equity Incentive Plan and 2014 Equity Incentive Plan in the years ended December 31, 2025 and December 31, 2024 respectively, calculated in accordance with FASB ASC Topic 718. See Note 9 to our financial statements for the assumptions used in calculating the grant date fair value.

Narrative Disclosure to Summary Compensation Table

Executive Employment Agreements

Stephen C. Glover

Effective September 13, 2022, we entered into an executive employment agreement with Stephen C. Glover (the "Glover Agreement"), which provides that Mr. Glover's employment is conditioned upon, among other things, his agreement and execution of a Proprietary Information & Restrictive Covenant Agreement.

Under the terms of the Glover Employment Agreement, Mr. Glover serves as our Chairman, President, and Chief Executive Officer and receives a base salary of $550,000 annually, subject to our standard payroll practices. Mr. Glover's base salary and future increases in compensation are subject to periodic review and approval by the board of directors. In addition, Mr. Glover is eligible to receive an annual performance-based cash bonus of up to fifty-five percent (55%) of Mr. Glover's base salary, the exact amount of which is subject to review and determination by the board of directors, based upon Mr. Glover's achievement of certain performance goals. Mr. Glover's receipt of an annual bonus is also contingent upon Mr. Glover's continued employment with us at the time such bonus is to be paid, otherwise the annual bonus is forfeited. In addition, pursuant to the terms of the Glover Employment Agreement, Mr. Glover may be eligible for certain grants of equity awards of our common stock, subject to vesting and other terms and conditions of our equity plan to which the award is granted and an agreement to be provided by us and entered into with Mr. Glover. Mr. Glover is also eligible to participate on the same basis as similarly situated employees in our benefit plans in effect from time during his employment.

Pursuant to the Glover Employment Agreement, we may terminate Mr. Glover's employment at any time without Cause (as that term is defined in the New Glover Agreement) upon 10 days' advance written notice to Mr. Glover. Provided Mr. Glover has not previously been notified of our intention to terminate his employment, Mr. Glover may resign from his employment with us for Good Reason (as that term is defined in the Glover Employment Agreement) upon 60 days' advance written notice to us, upon which notice we have 30 days to cure the conditions that Mr. Glover considers to be Good Reason, subject to certain conditions set forth in the Glover Employment Agreement.

If Mr. Glover resigns for Good Reason or Mr. Glover's employment is terminated without Cause, and, in each case, such resignation or termination constitutes a Separation from Service (as defined in the Glover Employment Agreement), then Mr. Glover shall be entitled to receive the Accrued Obligations (as defined in the Glover Employment Agreement) and, subject to Mr. Glover's compliance with his obligations under the Glover Employment Agreement, the following severance benefits: (i) payment of an amount equal to Mr. Glover's then current base salary for 24 months, paid in equal instalments; (ii) payment of an amount equal to any unpaid bonus earned for the year preceding Mr. Glover's Separation from Service; (iii) payment of an amount equal to the greater of (A) the bonus paid for the performance year ending prior to Mr. Glover's Separation from Service, and (B) the bonus that Mr. Glover would have earned for the performance year in which such Separation from Service occurs, in each case prorated for the period of Mr. Glover's employment through the Separation of Service date; (iv) immediate vesting of any equity awards issued to Mr. Glover that are outstanding as of the date of Mr. Glover's Separation of Service; and (iv) provided that Mr. Glover timely elects continued group health plan coverage under the Consolidated Omnibus Budget Reconciliation Act ("COBRA"), reimbursement for certain COBRA health benefits for up to 18 months, subject in each case to the terms and conditions of the Glover Employment Agreement and applicable laws and regulations.

Notwithstanding the above, if we (or any surviving or acquiring corporation) terminate Mr. Glover's employment without Cause or Mr. Glover resigns for Good Reason within 90 days before and 24 months following the effective date of a Change of Control (as defined in the Glover Employment Agreement), then Mr. Glover will be entitled to receive the Accrued Obligations and, subject to Mr. Glover's compliance with his obligations under the Glover Employment Agreement, the same severance benefits that Mr. Glover would receive if he had resigned for Good Reason or his employment terminated without Cause, except that Mr. Glover will receive a bonus in an amount equal to fifty-five percent (55%) of Mr. Glover's base salary in lieu of the amount set forth in (iii) in the above paragraph; provided however, that if the Change in Control is a change in ownership of a corporation, a change in the effective control of a corporation, or a change in ownership of a substantial portion of a corporation's assets, the cumulative amount of the severance payments payable (or remaining payable) for such termination or resignation shall be paid in a single lump sum on or within 30 days following such Change in Control.

Pursuant to the Glover Employment Agreement, we may terminate Mr. Glover's employment at any time for Cause upon 10 days' advance written notice to Mr. Glover. In the event Mr. Glover's employment is terminated at any time for Cause, Mr. Glover will not receive any severance compensation or benefits, except that, pursuant to our standard payroll policies, we shall pay to Mr. Glover the Accrued Obligations. Mr. Glover may resign from his employment with us at any time upon not less than 30 days' advance written notice to us of such resignation. In the event Mr. Glover resigns from employment with us for any reason (other than a resignation for Good Reason), Mr. Glover will not receive any severance compensation or benefits, except that we shall pay and provide the Accrued Obligations.

Mr. Glover's entitlement to receive certain severance benefits is conditioned upon, among other things, his obligation to sign and deliver an effective Release (as that term is defined in the New Glover Agreement) in a form acceptable to us by the 60th day following such termination or such earlier date as set forth in the Release.

Peter Wolfe

Effective as of September 13, 2022, we entered into an executive employment agreement with Peter Wolfe (the "Wolfe Employment Agreement") which , provides that Mr. Wolfe's employment is conditioned upon, among other things, his agreement and execution of a Proprietary Information & Restrictive Covenant Agreement.

Under the terms of the Wolfe Employment Agreement, Mr. Wolfe serves as our Chief Financial Officer and receives a base salary of $395,000 annually, subject to our standard payroll practices. Mr. Wolfe's base salary and future increases in compensation are subject to periodic review and approval by the board of directors. In addition, Mr. Wolfe is eligible to receive an annual performance-based cash bonus of up to forty percent (40%) of Mr. Wolfe's base salary, the exact amount of which is subject to review and determination by the board of directors, based upon Mr. Wolfe's achievement of certain performance goals. Mr. Wolfe's receipt of an annual bonus is also contingent upon Mr. Wolfe's continued employment with us at the time such bonus is to be paid, otherwise the annual bonus is forfeited. In addition, pursuant to the terms of the Wolfe Employment Agreement, Mr. Wolfe may be eligible for certain grants of equity awards of our common stock, subject to vesting and other terms and conditions of our equity plan to which the award is granted and an agreement to be provided by us and entered into with Mr. Wolfe. Mr. Wolfe is also eligible to participate on the same basis as similarly situated employees in our benefit plans in effect from time during his employment.

Pursuant to the Wolfe Employment Agreement, we may terminate Mr. Wolfe's employment at any time without Cause (as that term is defined in the Wolfe Employment Agreement) upon written notice to Mr. Wolfe. Provided Mr. Wolfe has not previously been notified of our intention to terminate his employment, Mr. Wolfe may resign from his employment with us for Good Reason (as that term is defined in the Wolfe Employment Agreement) upon 30 days' advance written notice to us, upon which notice we have 30 days to cure the conditions that Mr. Wolfe considers to be Good Reason, subject to certain conditions set forth in the Wolfe Employment Agreement

If Mr. Wolfe resigns for Good Reason or Mr. Wolfe's employment is terminated without Cause, and, in each case, such resignation or termination constitutes a Separation from Service (as defined in the Wolfe Employment Agreement), then Mr. Wolfe shall be entitled to receive the Accrued Obligations (as defined in the Wolfe Employment Agreement) and, subject to Mr. Wolfe's compliance with his obligations under the Wolfe Employment Agreement, the following severance benefits: (i) payment of an amount equal to Mr. Wolfe's then current base salary for 12 months paid in equal instalments; (ii) payment of an amount equal to any unpaid bonus earned for the year preceding Mr. Wolfe's Separation from Services; and (iii) provided that Mr. Wolfe timely elects continued group health plan coverage under COBRA, reimbursement for certain COBRA health benefits for up to 12 months, subject in each case to the terms and conditions of the Wolfe Employment Agreement and applicable laws and regulations.

Notwithstanding the above, if we (or any surviving or acquiring corporation) terminate Mr. Wolfe's employment without Cause or Mr. Wolfe resigns for Good Reason within 90 days before and 24 months following the effective date of a Change of Control (as defined in the Wolfe Employment Agreement), then Mr. Wolfe will be entitled to receive the Accrued Obligations and, subject to Mr. Wolfe's compliance with his obligations under the Wolfe Employment Agreement, the same severance benefits that Mr. Wolfe would receive if he had resigned for Good Reason or his employment terminated without Cause; provided, however, that if the Change in Control is a change in ownership of a corporation, a change in the effective control of a corporation, or a change in ownership of a substantial portion of a corporation's assets, the cumulative amount of the severance payments payable (or remaining payable) for such termination shall be paid in a single lump sum on or within 30 days following such Change in Control. In addition, Mr. Wolfe will be entitled to (i) receive a bonus equal to forty percent (40%) of Mr. Wolfe's then base salary, and (ii) an immediate vesting of any equity awards issued to Mr. Wolfe that are outstanding as of the closing of such Change in Control, provided that they are assumed or continued (in accordance with their terms) by the surviving entity in such Change in Control.

Pursuant to the Wolfe Employment Agreement, we may terminate Mr. Wolfe's employment at any time for Cause upon a 10 days' advance written notice to Mr. Wolfe. In the event Mr. Wolfe's employment is terminated at any time for Cause, Mr. Wolfe will not receive any severance compensation or benefits, except that, pursuant to our standard payroll policies, we shall pay to Mr. Wolfe the Accrued Obligations. Mr. Wolfe may resign from his employment with us at any time upon not less than 30 days' advance written notice to us of such resignation. In the event Mr. Wolfe resigns from employment with us for any reason (other than a resignation for Good Reason), Mr. Wolfe will not receive or any severance compensation or benefits, except that we shall pay and provide the Accrued Obligations.

Mr. Wolfe's entitlement to receive certain severance benefits is conditioned upon, among other things, his obligation to sign and deliver an effective Release (as that term is defined in the Wolfe Employment Agreement) in a form acceptable to us by the 60th day following such termination or such earlier date as set forth in the Release.

Pablo A. Guzman, M.D.

On January 26, 2023, we entered into an executive employment agreement with Dr. Pablo Guzman (the "Guzman Employment Agreement"), which provided that Dr. Guzman's employment is conditioned upon, among other things, his agreement and execution of a Proprietary Information & Restrictive Covenant Agreement.

Under the terms of the Guzman Employment Agreement, Dr. Guzman serves as our Chief Medical Officer and Senior Vice President of Medical Affairs and receives a base salary of $350,000 annually, subject to our standard payroll practices. Dr. Guzman's base salary and future increases in compensation are subject to periodic review and approval by the board of directors. In addition, Dr. Guzman is eligible to receive an annual performance-based cash bonus of up to thirty percent (30%) of Dr. Guzman's base salary, the exact amount of which is subject to review and determination by the board of directors, based upon Dr. Guzman's achievement of certain performance goals. Dr. Guzman's receipt of an annual bonus is also contingent upon Dr. Guzman's continued employment with us at the time such bonus is to be paid, otherwise the annual bonus is forfeited. In addition, pursuant to the terms of the Guzman Employment Agreement, Dr. Guzman may be eligible for certain grants of equity awards of our common stock, subject to vesting and other terms and conditions of our equity plan to which the award is granted and an agreement to be provided by us and entered into with Dr. Guzman. Dr. Guzman is also eligible to participate on the same basis as similarly situated employees in our benefit plans in effect from time during his employment.

Pursuant to the Guzman Employment Agreement, we may terminate Dr. Guzman's employment at any time without Cause (as that term is defined in the Guzman Employment Agreement) upon a 10 days' advance written notice to Dr. Guzman. Provided Dr. Guzman has not previously been notified of our intention to terminate his employment, Dr. Guzman may resign from his employment with us for Good Reason (as that term is defined in the Guzman Employment Agreement) upon 30 days written notice to us, upon which notice we have 30 days to cure the conditions that Dr. Guzman considers to be Good Reason, subject to certain conditions set forth in the Guzman Employment Agreement.

If Dr. Guzman resigns for Good Reason or his employment is terminated without Cause and, in each case, such resignation or termination constitutes a Separation from Service (as defined in the Guzman Employment Agreement), then Dr. Guzman shall be entitled to receive the Accrued Obligations (as that term is defined in the Guzman Employment Agreement), and subject to Dr. Guzman's compliance with his obligations under the Guzman Employment Agreement, the following severance benefits: (i) an amount equal to Dr. Guzman's then current base salary for 12 months paid in equal installments; (ii) an amount equal to any unpaid bonus earned for the year preceding Dr. Guzman's Separation from Services; and (iii) provided that Mr. Guzman timely elects continued group health plan coverage under COBRA reimbursement for certain COBRA health benefits for up to 12 months, subject in each case to the terms and conditions of the Guzman Employment Agreement and applicable laws and regulations.

Notwithstanding the above, if we (or any surviving or acquiring corporation) terminate Dr. Guzman's employment without Cause or Dr. Guzman resigns for Good Reason within 90 days before and 24 months following the effective date of a Change of Control (as defined in the Guzman Employment Agreement), then Dr. Guzman will be entitled to receive the Accrued Obligations and, subject to Dr. Guzman's compliance with his obligations under the Guzman Employment Agreement, the same severance benefits that Mr. Guzman would receive if he had resigned for Good Reason or his employment terminated without Cause; provided, however, that if the Change in Control is a change in ownership of a corporation, a change in the effective control of a corporation, or a change in ownership of a substantial portion of a corporation's assets, the cumulative amount of the severance payments payable (or remaining payable) for such termination shall be paid in a single lump sum on or within 30 days following such Change in Control. In addition, Dr. Guzman will be entitled to (i) receive a bonus equal to thirty percent (30%) of Dr. Guzman's then base salary, and (ii) an immediate vesting of any equity awards issued to Dr. Guzman that are outstanding as of the closing of such Change in Control, provided that they are assumed or continued (in accordance with their terms) by the surviving entity in such Change in Control.

Pursuant to the Guzman Employment Agreement, we may terminate Dr. Guzman's employment at any time for Cause upon a 10 days' advance written notice to Dr. Guzman. In the event Dr. Guzman's employment is terminated at any time for Cause, Dr. Guzman will not receive any severance compensation or benefits, except that, pursuant to our standard payroll policies, we shall pay to Dr. Guzman the Accrued Obligations. Dr. Guzman may resign from his employment with us at any time upon not less than 30 days' advance written notice to us of such resignation. In the event Dr. Guzman resigns from employment with us for any reason (other than a resignation for Good Reason), Dr. Guzman will not receive any severance compensation or benefits, except that we shall pay and provide the Accrued Obligations.

Dr. Guzman's entitlement to receive certain severance benefits is conditioned upon, among other things, his obligation to sign and deliver an effective Release (as that term is defined in the Guzman Employment Agreement) in a form acceptable to us by the 60th day following such termination or such earlier date as set forth in the Release.

Outstanding Equity Awards at Fiscal Year-End 2025

	Option Awards [1]				
Name	**Grant Date**	**Number of securities underlying unexercised options exercisable (#)**	**Number of securities underlying unexercised options unexercisable (#)**	**Option exercise price ($)**	**Option expiration date**
Stephen C. Glover	10/28/2016	483 [2]	-	1,760.50	10/28/2026
Co-Founder, Chief Executive Officer,	4/2/2019	757 [4]	-	4,053.00	4/2/2029
President and Chairman	2/8/2021	361 [4]	-	5,726.00	2/8/2031
	2/3/2022	227 [4]	-	5,726.00	2/3/2032
	5/24/2023	1,085 [4]	542 [4]	152.50	5/24/2033
	7/11/2025		136,900 [4]	0.59	7/11/2035
Peter Wolfe	10/30/2017	29 [3]	-	1,760.50	10/30/2027
Chief Financial Officer and Secretary	4/2/2019	114 [4]	-	4,053.00	4/2/2029
	2/8/2021	63 [4]	-	5,726.00	2/8/2031
	1/28/2022	63 [4]	-	5,726.00	1/28/2032
	5/24/2023	477 [4]	238 [4]	152.50	5/24/2033
	7/11/2025	-	60,100 [4]	0.59	7/11/2035
Pablo A. Guzman, M.D.	4/2/2019	57 [4]	-	4,053.00	4/1/2029
Chief Medical Officer and	10/31/2020	32 [2]	-	5,726.00	10/31/2030
Senior Vice	12/31/2020	9 [2]	-	5,726.00	12/31/2030
President of	3/31/2021	13 [2]	-	5,726.00	3/31/2031
Medical Affairs	6/30/2021	13 [2]	-	5,726.00	6/30/2031
	9/30/2021	13 [2]	-	5,726.00	9/30/2031
	12/31/2021	13 [2]	-	5,726.00	12/31/2031
	3/31/2022	13 [2]	-	5,726.00	3/31/2032
	6/30/2022	13 [2]	-	3,965.50	6/30/2032
	1/25/2023	191 [4]	95 [4]	738.50	1/25/2033
	7/11/2025	-	48,900 [4]	0.59	7/11/2035

(1) All of the outstanding stock option awards issued prior to January 1, 2023 were granted under the ZyVersa 2014 Stock Plan (the "2014 Plan"), and those issued thereafter under the ZyVersa 2022 Omnibus Equity Incentive Plan (the "2022 Plan")
(2) The shares underlying each option immediately vested on the applicable grant date.
(3) Fifty percent of the shares vested immediately and the remaining shares vested one-third annually over three years from the applicable grant date.
(4) The shares underlying each option vested or will vest in equal annual installments over three years from the applicable grant date, subject to continuous service with the Company on each such date.

Non-Employee Director Compensation

The Board sets non-employee director compensation which is designed to provide competitive compensation necessary to attract and retain high quality non-employee directors and to encourage ownership of our common stock to further align their interests with those of our stockholders. In 2025, each non-employee director of the Company was eligible to receive an annual fee of $40,000 as a member of the Board and an additional fee of (a) $7,500 for Compensation Committee members, (b) $15,000 for the Chairman of the Compensation Committee, (c) $4,000 for Corporate Governance Committee members, (d) $8,000 for the Chairman of the Corporate Governance Committee, (e) $8,000 for Audit Committee members, and (f) $18,500 for the Chairman of the Audit Committee.

The following table sets forth the compensation earned by all non-employee directors during the fiscal year ended December 31, 2025:

Name	Fees earned or paid in cash [1] ($)	Option awards [2] ($)	Total ($)
Gregory Freitag	62,500	5,894	68,394
James Sapirstein	63,500	5,894	69,394
Robert Finizio[3]	57,750	5,894	63,644
Min Chul Park	51,500	5,894	57,394

(1) All fees earned or paid in cash are included in accounts payable on the balance sheet of the consolidated financial statements included herein.
(2) The options granted to our non-employee directors vest over three years with 33 1/3% of the options vesting and becoming exercisable on the one-year anniversary of the option grant date, 33 1/3% vest and become exercisable on the two-year anniversary of the option grant date and 33 1/3% vest and become exercisable on the three-year anniversary of the option grant date, subject to the non-employee directors remaining on our Board through the applicable vesting dates.
(3) Mr. Finizio resigned from our Board, effective December 2, 2025.

Actual fees earned or paid in cash, which are prorated for the amount of days on each of the committees in 2024, are as follows:

Mr. Freitag earned $40,000 as a member of the Board, $18,500 as the Chairman of the Audit Committee, and $4,000 as a member of the Nominating and Corporate Governance Committee. Mr. Freitag was also awarded an option grant pursuant to the Company's 2022 Plan.

Mr. Sapirstein earned $40,000 as a member of the Board, $7,500 as a member of the Compensation Committee, $8,000 as the Chairman of the Nominating and Corporate Governance Committee, and $8,000 as a member of the Audit Committee. Mr. Sapirstein was also awarded an option grant pursuant to the Company's 2022 Plan.

Mr. Finizio earned $36,667 as a member of the Board, $13,750 as the Chairman of the Compensation Committee, and $7,338 as a member of the Audit Committee. Mr. Finizio was also awarded an option grant pursuant to the Company's 2022 Plan.

Dr. Park earned $40,000 as a member of the Board, $7,500 as a member of the Compensation Committee, and $4,000 as a member of the Nominating and Corporate Governance Committee. Dr. Park was also awarded an option grant pursuant to the Company's 2022 Plan.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Equity Compensation Plans

2014 Equity Incentive Plan

On December 12, 2022, in connection with the consummation of the Business Combination, the Company approved the amendment to the 2014 Plan (the "2014 Plan Amendment"). The 2014 Plan Amendment provides, among other things, that upon consummation of the Business Combination, no further increases in the shares of common stock reserved and available for issuance under the 2014 Plan shall occur and no new awards shall be made under the 2014 Plan.

2022 Omnibus Equity Incentive Plan

The ZyVersa Therapeutics, Inc. 2022 Omnibus Equity Incentive Plan (the "2022 Plan") became effective upon the consummation of the Business Combination on December 12, 2022. The purpose of the 2022 Plan is to provide a means whereby eligible employees, officers, non-employee directors and other individual service providers develop a sense of proprietorship and personal involvement in the development and financial success of the Company and to encourage them to devote their best efforts to our business, thereby advancing our interests and the interests of our stockholders. By means of the 2022 Plan, we seek to retain the services of such eligible persons and to provide incentives for such persons to exert maximum efforts for our success and the success of our subsidiaries. On June 11, 2025, our board of directors and stockholders approved an amendment and restatement of the 2022 Plan to increase the number of shares of common stock reserved for issuance thereunder to 382,122 shares.

The following table provides information as of December 31, 2025 with respect to our compensation plans under which equity compensation is authorized for issuance.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders [1]	387,033 [2]	$ 54.80	1
Equity compensation plans not approved by security holders	-	$ -	-
Total	387,033	$ 54.80	1

(1) Includes the 2014 Plan, which we assumed in the 2022 Business Combination, and the 2022 Plan.

(2) Includes 4,912 and 382,121 shares of common stock issuable upon exercise of outstanding options pursuant to the 2014 Equity Incentive Plan and 2022 Omnibus Equity Incentive Plan, respectively, as of December 31, 2025.

(3) The 2022 Plan contains an "evergreen" provision, pursuant to which the number of shares of common stock available for issuance under the 2022 Plan will automatically increase on the first day of January each calendar year during the term of the 2022 Plan by an amount equal to 4% of the number of shares outstanding on December 31, 2025.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth beneficial ownership of our Common Stock as of March 25, 2026 by:

- each person known to be the beneficial owner of more than 5% of the outstanding Common Stock of the Company;
- each of the Company's executive officers and directors; and
- all of the Company's current executive officers and directors as a group.

Beneficial ownership is determined according to the rules of the SEC, which generally provide that a person has beneficial ownership of a security if he, she or it possesses sole or shared voting or investment power over that security. Under those rules, beneficial ownership includes securities that the individual or entity has the right to acquire, such as through the exercise of warrants or stock options or the vesting of restricted stock units, within 60 days of March 25, 2026. Shares subject to warrants or options that are currently exercisable or exercisable within 60 days of March 25, 2026 or subject to restricted stock units that vest within 60 days of March 25, 2026 are considered outstanding and beneficially owned by the person holding such warrants, options or restricted stock units for the purpose of computing the percentage ownership of that person but are not treated as outstanding for the purpose of computing the percentage ownership of any other person.

Except as noted by footnote, and subject to community property laws where applicable, based on the information provided to the Company, the persons and entities named in the table below have sole voting and investment power with respect to all shares shown as beneficially owned by them. Unless otherwise indicated, the business address of each beneficial owner listed in the table below is c/o ZyVersa Therapeutics, Inc., 2346 N. Federal Highway, Suite 466, Lighthouse Point, Florida 33064.

The beneficial ownership of our Common Stock is based on 8,095,921 shares of Common Stock issued and outstanding as of March 25, 2026.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Directors and executive officers		
Stephen C. Glover[(1)]	5,508	*
Min Chul Park, Ph.D.[(2)]	247	*
Peter Wolfe[(3)]	1,163	*
Karen Cashmere[(4)]	841	*
James Sapirstein[(5)]	132	*
Gregory Freitag[(6)]	132	*
All directors and executive officers as a group (6 individuals)	8,023	*
Other 5% beneficial owners		
Armistice Capital Master Fund Ltd.[(7)]	898,547	9.99%
Anson Investments Master Fund LP[(8)]	664,000	7.58%

* Indicates beneficial ownership of less than 1%.

(1) Includes 1,821 shares of Common Stock held by Stephen C. Glover and affiliates, consisting of (i) 1,308 shares of Common Stock held of record by Stephen C. Glover; (ii) 126 shares of Common Stock held of record by MedicaRx Inc.; (iii) 245 shares of common stock held of record by Asclepius Life Sciences Fund, LP; and (iv) 142 shares of Common Stock held of record by Asclepius Master Fund, LTD. The amount also includes options and warrants that are exercisable as of or within 60 days of March 25, 2026 for 3,455 and 232, respectively, shares of Common Stock. Mr. Glover is the managing director of MedicaRx Inc., the managing director of Asclepius Master Fund, LTD, and the managing member of Asclepius Life Sciences Fund, LP.

(2) Represents options that are exercisable as of or within 60 days of March 25, 2026 for 247 shares of Common Stock.

(3) Represents: (i) 127 shares of Common Stock; and (ii) options and warrants that are exercisable as of or within 60 days of March 25, 2026 for 984 and 52, respectively, shares of common stock.

(4) Represents options that are exercisable as of or within 60 days of March 25, 2026 for 841 shares of Common Stock.

(5) Represents options that are exercisable as of or within 60 days of March 25, 2026 for 132 shares of common stock

(6) Represents options that are exercisable as of or within 60 days of March 25, 2026 for 132 shares of common stock

(7) Represents 898,547 shares of Common Stock issuable upon exercise of warrants, but excludes 5,226,383 shares of Common Stock underlying such warrants that are not currently exercisable as a result of a 9.99% beneficial ownership limitation blocker contained in such warrants. 6,124,930 shares of Common Stock underlying warrants that are not currently exercisable and will not become exercisable until stockholder approval is obtained. The securities are held of record by Armistice Capital Master Fund Ltd. Steve Boyd is the CIO of Armistice Capital, LLC and has sole voting and dispositive power over the securities held by Armistice Capital Master Fund Ltd. The business address for Armistice Capital Master Fund Ltd.is 510 Madison Avenue, 7th Floor, New York NY 10022.

(8) Represents 664,000 shares of Common Stock, issuable upon exercise of warrants. The securities are held of record by Anson Investments Master Fund LP. Amin Nathoo and Moez Kassam are directors of Anson Advisors, Inc., and Tony Moore is principal of Anson Fund Management LP, each has voting and dispositive power over the securities held by Anson Investments Master Fund LP. The business address for Anson Investments Master Fund LP is 181 Bay Street, Suite 4200, Toronto, ON, M5J 2T3.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Executive Officer and Director Compensation Arrangements

See "*Executive Compensation*" for information regarding compensation arrangements with the executive officers and directors of the Company, which include, among other things, employment, termination of employment and change in control arrangements, stock awards and certain other benefits.

Director and Officer Indemnification

Our Second Amended and Restated Certificate of Incorporation ("Charter") and Second Amended and Restated Bylaws ("Bylaws") provide for indemnification for our directors and officers to the fullest extent permitted by the DGCL. We have entered into indemnification agreements with each of our directors and executive officers.

Related Party Transaction Policy

Our board of directors has adopted a written related person transaction policy that sets forth the following policies and procedures for the review and approval or ratification of related person transactions.

A "Related Person Transaction" is a transaction, arrangement or relationship in which the company or any of its subsidiaries was, is or will be a participant, the amount of which involved exceeds $120,000, and in which any related person had, has or will have a direct or indirect material interest.

A "Related Person" means:

- any person who is, or at any time during the applicable period was, one of the Company's officers or one of the Company's directors;
- any person who is known by the Company to be the beneficial owner of more than five percent (5%) of its voting stock;
- any immediate family member of any of the foregoing persons, which means any child, stepchild, parent, stepparent, spouse, sibling, mother-in-law, father-in-law, daughter-in-law, brother-in-law or sister-in-law of a director, officer or a beneficial owner of more than five percent (5%) of its voting stock, and any person (other than a tenant or employee) sharing the household of such director, officer or beneficial owner of more than five percent (5%) of its voting stock; and
- any firm, corporation or other entity in which any of the foregoing persons is a partner or principal or in a similar position or in which such person has a ten percent (10%) or greater beneficial ownership interest.

The Company has policies and procedures designed to minimize potential conflicts of interest arising from any dealings it may have with its affiliates and to provide appropriate procedures for the disclosure of any real or potential conflicts of interest that may exist from time to time. Specifically, pursuant to its charter, the audit committee has the responsibility to review related party transactions.

Director Independence

Our board of directors undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that Robert G. Finizio, Min Chul Park, Ph.D., James Sapirstein, and Gregory Freitag, representing four (4) of our five (5) directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, and that each of these directors is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of the Nasdaq. In addition, all members of the audit committee, compensation committee, and nominating and corporate governance committee of our board of directors satisfy the independence standards for such committees established by the SEC and Nasdaq.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Type of Fees	2025	2024
Audit Fees [1][2]	$ 339,065	$ 588,430
Audit-Related Fees [3]	-	-
Tax Fees [4]	-	-
All Other Fees	-	-
Total	**$ 339,065**	**$ 588,430**

(1) Audit fees are fees for professional services rendered in connection with the audit of our consolidated financial statements, statutory filings and registration statements, review of interim financial statements, the review of documents filed with the SEC, comfort letters, consents and certain accounting and consultations in connection with the audits.
(2) Audit fees for the years ended December 31, 2025 and 2024 include professional fees incurred by Ernst and Young of $0 and $20,900, respectively, and Marcum of $339,065 and $567,530, respectively.
(3) Audit-related fees are fees for services related to accounting consultation and compliance with regulatory requirements and are not reported under "Audit Fees".
(4) Tax fees are for services related to tax compliance, tax planning and tax advice. These services included annual U.S. federal and state compliance and preparation of related tax returns and reports.

Pre-Approval Policies and Procedures

The audit committee has the authority and responsibility to pre-approve all audit, review, and non-audit services (including any internal control-related services) to be provided to us or our subsidiaries by the independent auditor. The audit committee may also establish pre-approval policies and procedures in compliance with applicable SEC rules. The pre-approval of services may be delegated to subcommittees of the audit committee consisting of one or more of the audit committee's members, but the decision must be reported to the full audit committee at its next scheduled meeting.

All services rendered by EY and Marcum for the year ended December 31, 2024, and by Marcum for the year ended December 31, 2025, were pre-approved in accordance with the procedures set forth above.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) List of Documents filed as part of this Report

(1) Consolidated Financial Statements

The financial statements and related notes, together with the reports of CBIZ CPAs P.C., our independent registered public accounting firms, appear at pages F-1 through F-22 following the Exhibit List as required by "Part II—Item 8—Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

(3) Exhibits

The following exhibits are filed as part of, or incorporated by reference into, this Annual Report on Form 10-K.

Exhibit Number	Description
2.1+	Business Combination Agreement, dated as of July 20, 2022, by and among Larkspur Health Acquisition Corp., Larkspur Merger Sub Inc., Stephen Glover and ZyVersa Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on July 22, 2022).
3.1	Second Amended and Restated Certificate of Incorporation of ZyVersa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
3.2	Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of ZyVersa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on November 30, 2023).
3.3	Second Certificate of Amendment to the Second Amended and Restated Certificate of Incorporation of ZyVersa Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on April 25, 2024).
3.4	Second Amended and Restated Bylaws of ZyVersa Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
3.5	Certificate of Designation relating to the Series A Convertible Preferred Stock (incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
3.6	Certificate of Designation relating to the Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.4 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
4.1	Specimen Class A Common Stock Certificate of ZyVersa Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
4.2	Form of Warrant issued by the Company in connection with the Public Warrants (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
4.3	Form of Warrant issued by the Company in connection with the Private Placement Warrants (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
4.4	Form of Warrant issued by the Company to each PIPE Investor (incorporated by reference to Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
4.5	Form of Bridge Warrant issued by the Company (incorporated by reference to Exhibit 4.5 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
4.6	Form of Warrant pursuant to License Agreement, dated April 18, 2019, by and between InflamaCORE, LLC and Variant Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.3 to the Company's Form S-4 filed with the SEC on October 21, 2022).
4.7	Form of Warrant pursuant to License Agreement, dated December 15, 2015, by and between L&F Research LLC and Variant Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.4 to the Company's Form S-4 filed with the SEC on October 21, 2022).
4.8	Form of Warrant (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement filed with the SEC on April 24, 2023).
4.9	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement filed with the SEC on April 24, 2023).
4.10	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.11 to the Company's Amendment No. 2 to Form S-1 Registration Statement filed with the SEC on July 7, 2023).
4.11	Form of Common Warrant (incorporated by reference to Exhibit 4.10 to the Company's Amendment No. 2 to Form S-1 Registration Statement, filed with the SEC on July 7, 2023).
4.12	Warrant Amendment (incorporated by reference to Exhibit 4.8.1 to the Company's Post-Effective Amendment No. 1 to Form S-1 Registration Statement, filed with the SEC on July 26, 2023).

4.13	Form of Inducement Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report to Form 8-K filed with the SEC on September 14, 2023).
4.14	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed with the SEC on December 11, 2023).
4.15	Form of Series A Warrant (incorporated by reference to Exhibit 4.2 to the Company's Form 8-K filed with the SEC on December 11, 2023).
4.16	Form of Series B Warrant (incorporated by reference to Exhibit 4.3 to the Company's Form 8-K filed with the SEC on December 11, 2023).
4.17	Form of Series A-1 Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2024).
4.18	Form of Series B-1 Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2024).
4.19	Form of Series A-2 Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 6, 2024).
4.20	Description of the Company's Securities (incorporated by reference to Exhibit 4.8 to the Company's Annual Report on Form 10-K filed with the SEC on March 25, 2024).
4.21	Form of Series A-4 Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2025).
10.1+†	License Agreement, dated April 18, 2019, by and between InflamaCORE, LLC and Variant Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.14 to the Company's Form S-4 filed with the SEC on October 21, 2022).
10.2+†	License Agreement, dated December 15, 2015, by and between L&F Research LLC and Variant Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.15 to the Company's Form S-4 filed with the SEC on October 21, 2022).
10.3+†	First Amendment to License Agreement, dated January 9, 2020, by and between L&F Research LLC and Variant Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.16 to the Company's Form S-4 filed with the SEC on October 21, 2022).
10.4	Second Amendment to Waiver of Certain Rights under License Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 23, 2022).
10.5	Amendment and Restatement Agreement, by and between L&F Research LLC and ZyVersa Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on March 3, 2023).
10.6#	ZyVersa Therapeutics, Inc. 2022 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.7#	Amended and Restated ZyVersa Therapeutics, Inc. 2022 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 30, 2024).
10.8#	Form of Incentive Stock Option Grant Agreement under the Combined Entity 2022 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.6.1 to the Company's Form S-4 filed with the SEC on September 27, 2022).
10.9#	Form of Restricted Stock Unit Award Agreement under the Combined Entity 2022 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.6.2 to the Company's Form S-4 filed with the SEC on September 27, 2022).
10.10#	Form of Non-Qualified Stock Option Grant Agreement under the Combined Entity 2022 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.6.3 to the Company's Form S-4 filed with the SEC on September 27, 2022).
10.11#	Variant Pharmaceuticals, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Company's Form S-4 filed with the SEC on September 27, 2022).
10.12#	Amendment to Variant Pharmaceuticals, Inc. 2014 Equity Incentive Plan (incorporated by reference to Exhibit 10.20 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).

10.13#	Form of Indemnification Agreement by and between the Company and each of its officers and directors (incorporated by reference to Exhibit 10.15 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.14#	Executive Employment Agreement, by and between the Company and Stephen Glover (incorporated by reference to Exhibit 10.16 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.15#	Executive Employment Agreement, by and between the Company and Karen A. Cashmere (incorporated by reference to Exhibit 10.18 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.16#	Executive Employment Agreement, by and between the Company and Peter Wolfe (incorporated by reference to Exhibit 10.19 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.17#	Executive Employment Agreement by and between the Company and Pablo Guzman, M.D. (incorporated by reference to Exhibit 10.21 to the Company's Registration Statement on Form S-1 filed with the SEC on January 27, 2023).
10.18	Amended and Restated ZyVersa Therapeutics, Inc. 2022 Omnibus Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 12, 2025).
10.19	Form of Securities Purchase Agreement, dated March 5, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the SEC on March 7, 2025).
10.20	Placement Agency Agreement, dated March 5, 2025, between the Company and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the SEC on March 7, 2025).
10.21	Form of Equity Purchase Agreement (incorporated by reference to Exhibit 10.35 to the Company's Registration Statement on Form S-1, filed with the SEC on July 2, 2025).
10.22	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.36 to the Company's Registration Statement on Form S-1, filed with the SEC on July 2, 2025).
10.23	Inducement Letter, dated July 8, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 9, 2025).
19.1	Insider Trading Policies and Procedures (incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K filed with the SEC on March 27, 2025).
21.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
23.1*	Consent of CBIZ CPAs P.C.
23.2*	Consent of Marcum LLP
24.1*	Power of Attorney (included on the signature page).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350.
97.1	Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K/A filed with the SEC on May 15, 2024).
101.INS	XBRL Inline Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibits 101).

\# Management contract or compensatory plan or arrangement.

\+ Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon its request.

† Certain portions of this Exhibit have been omitted in accordance with Regulation S-K Item 601(b)(10). The Registrant agrees to furnish supplementally an unredacted copy of this Exhibit to the SEC upon its request.

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Annual Report on Form 10-K and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the registrant specifically incorporates it by reference.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

ZYVERSA THERAPEUTICS, INC.

Date: March 31, 2026

/s/ Stephen C. Glover
Stephen C. Glover
Chief Executive Officer
(Principal Executive Officer)

Date: March 31, 2026

/s/ Peter Wolfe
Peter Wolfe
Chief Financial Officer
(Principal Financial and Accounting Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Stephen C. Glover and Peter Wolfe, jointly and severally, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her, and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Stephen C. Glover Stephen C. Glover	Chief Executive Officer, President and Chairman *(Principal Executive Officer)*	March 31, 2026
/s/ Peter Wolfe Peter Wolfe	Chief Financial Officer and Secretary *(Principal Financial Officer and Principal Accounting Officer)*	March 31, 2026
/s/ Robert G. Finizio Robert G. Finizio	Director	March 31, 2026
/s/ Min Chul Park, Ph.D. Min Chul Park, Ph.D.	Director	March 31, 2026
/s/ James Sapirstein James Sapirstein	Director	March 31, 2026
/s/ Gregory Frietag Gregory Frietag	Director	March 31, 2026

ZYVERSA THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
ZyVersa Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of ZyVersa Therapeutics, Inc. (the "Company") as of December 31, 2025 the related consolidated statements of operations, changes in stockholders' deficit, and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2 the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ CBIZ CPAs P.C.

We have served as the Company's auditor since 2023 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

New York, NY
March 31, 2026

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
ZyVersa Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of ZyVersa Therapeutics, Inc. (the "Company") as of December 31, 2024 the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

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Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

We have served as the Company's auditor from 2023 to 2025

New York, NY
March 27, 2025

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
Assets		
Current Assets:		
Cash	$ 101,778	$ 1,530,924
Prepaid expenses and other current assets	231,639	184,873
Vendor deposits	14,484	-
Total Current Assets	347,901	1,715,797
In-process research and development	-	18,647,903
Vendor deposit	-	178,476
Deferred offering costs	-	57,238
Total Assets	$ 347,901	$ 20,599,414
Liabilities and Stockholders' (Deficit) Equity		
Current Liabilities:		
Accounts payable	$ 10,123,391	$ 9,337,267
Accrued expenses and other current liabilities	2,611,296	1,894,041
Total Current Liabilities	12,734,687	11,231,308
Deferred tax liability	-	851,659
Total Liabilities	12,734,687	12,082,967
Commitments and contingencies (Note 6)		
Stockholders' (Deficit) 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 December 31, 2025 and 2024	-	-
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of December 31, 2025 and 2024	1	1
Common stock, $0.0001 par value, 250,000,000 shares authorized;		
8,095,928 and 2,508,198 shares issued as of December 31, 2025 and 2024, respectively, and 8,095,921 and 2,508,191 shares outstanding as of December 31, 2025 and 2024, respectively	809	251
Additional paid-in-capital	125,204,509	121,155,922
Accumulated deficit	(137,584,937)	(112,632,559)
Treasury stock, at cost, 7 shares at December 31, 2025 and 2024	(7,168)	(7,168)
Total Stockholders' (Deficit) Equity	(12,386,786)	8,516,447
Total Liabilities and Stockholders' (Deficit) Equity	$ 347,901	$ 20,599,414

The accompanying notes are an integral part of these consolidated financial statements.

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,	
	2025	**2024**
Operating Expenses:		
Research and development	$ 1,113,105	$ 1,779,275
General and administrative	5,731,682	7,357,559
Impairment of in-process research and development	18,647,903	-
Total Operating Expenses	25,492,690	9,136,834
Loss From Operations	(25,492,690)	(9,136,834)
Other (Income) Expense:		
Interest expense	513,209	269,856
Change in fair value of equity payable	(201,862)	-
Pre-Tax Net Loss	(25,804,037)	(9,406,690)
Income tax benefit (provision)	851,659	(6,745)
Net Loss	$ (24,952,378)	$ (9,413,435)
Net Loss Per Share		
- Basic and Diluted	$ (4.18)	$ (8.48)
Weighted Average Number of Common Shares Outstanding		
- Basic and Diluted	5,963,943	1,110,033

The accompanying notes are an integral part of these consolidated financial statements.

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

	For the Years Ended December 31, 2025 and 2024										
	Series A Preferred Stock		Series B Preferred Stock		Common Stock		Treasury Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance - December 31, 2023	50	$ -	5,062	$ 1	405,212	$ 40	(7)	$ (7,168)	$ 114,300,849	$ (103,219,124)	$ 11,074,598
Exercise of warrants	-	-	-	-	213,800	21	-	-	2,672,479	-	2,672,500
Exercise of pre-funded warrants	-	-	-	-	131,481	13	-	-	(13)	-	-
Issuance of common stock pursuant to vendor agreements	-	-	-	-	60,000	6	-	-	196,764	-	196,770
Round up share adjustment due to reverse split	-	-	-	-	75,410	8	-	-	(8)	-	-
Stock-based compensation	-	-	-	-	-	-	-	-	705,567	-	705,567
Warrant inducement offer - exercise proceeds [1]	-	-	-	-	1,057,800	106	-	-	(894,631)	-	(894,525)
Warrant modification	-	-	-	-	-	-	-	-	3,033,284	-	3,033,284
At the market stock issuance [2]	-	-	-	-	564,495	57	-	-	1,142,245	-	1,142,302
Shelf registration equity issuance costs	-	-	-	-	-	-	-	-	(614)	-	(614)
Net loss	-	-	-	-	-	-	-	-	-	(9,413,435)	(9,413,435)
Balance - December 31, 2024	50	$ -	5,062	$ 1	2,508,198	$ 251	(7)	$ (7,168)	$ 121,155,922	$ (112,632,559)	$ 8,516,447
Issuance of common stock pursuant to vendor agreements	-	-	-	-	420,000	42	-	-	239,958	-	240,000
Private placement of warrants [3]	-	-	-	-	-	-	-	-	1,655,584	-	1,655,584
Warrant modifications	-	-	-	-	-	-	-	-	1,816,646	-	1,816,646
Exercise of pre-funded warrants	-	-	-	-	2,105,265	210	-	-	-	-	210
Warrant inducement offer - exercise proceeds [4]	-	-	-	-	3,062,465	306	-	-	113,568	-	113,874
Stock-based compensation	-	-	-	-	-	-	-	-	222,831	-	222,831
Net loss	-	-	-	-	-	-	-	-	-	(24,952,378)	(24,952,378)
Balance - December 31, 2025	50	$ -	5,062	$ 1	8,095,928	$ 809	(7)	$ (7,168)	$ 125,204,509	$ (137,584,937)	$ (12,386,786)

[1] Includes gross proceeds of $2,514,088 less issuance costs of $3,408,613

[2] Includes gross proceeds of $1,354,404 less issuance costs of $212,102

[3] Includes gross proceeds of $1,999,791 less cash issuance costs of $290,317 and a non-cash warrant modification charge of $53,890

[4] Includes gross proceeds of $2,051,852 less cash issuance costs of $175,222 and a non-cash warrant modification charge of $1,762,756

The accompanying notes are an integral part of these consolidated financial statements.

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,	
	2025	**2024**
Cash Flows From Operating Activities:		
Net loss	$ (24,952,378)	$ (9,413,435)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of in-process research and development	18,647,903	-
Stock-based compensation	222,831	705,567
Issuance of common stock pursuant to vendor agreements	240,000	196,770
Write-off of deferred offering costs	57,238	-
Depreciation of fixed assets	-	6,933
Non-cash rent expense	-	7,839
Deferred tax (benefit) provision	(851,659)	6,745
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(46,766)	30,586
Accounts payable	689,268	888,609
Vendor deposits	161,927	(80,000)
Operating lease liability	-	(8,656)
Accrued expenses and other current liabilities	717,255	139,508
Net Cash Used In Operating Activities	(5,114,381)	(7,519,534)
Cash Flows From Financing Activities:		
Exercise of warrants	-	2,672,500
Private placement of warrants	1,999,791	-
Warrant inducement offer - exercise proceeds	2,051,852	2,514,088
Exercise of pre-funded warrants	210	-
Payment of offering costs	-	(40,163)
At the market issuance of stock proceeds	-	1,354,404
Registration and issuance costs associated with warrant issuance	(366,618)	(588,045)
Net Cash Provided By Financing Activities	3,685,235	5,912,784
Net Decrease in Cash	(1,429,146)	(1,606,750)
Cash - Beginning of Period	1,530,924	3,137,674
Cash - End of Period	$ 101,778	$ 1,530,924
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash investing and financing activities:		
Warrant modifications - incremental value	$ 1,816,646	$ 3,033,284
Accounts payable and accrued expenses for offering costs	$ 98,921	$ 17,075

The accompanying notes are an integral part of these consolidated financial statements.

Note 1 – Business Organization and Nature of Operations

Organization and Operations

ZyVersa Therapeutics, Inc. ("ZyVersa" and the "Company") is a clinical stage biopharmaceutical company leveraging proprietary technologies to develop first-in-class drugs for patients with chronic renal or inflammatory diseases with high unmet medical needs. The Company's mission is to develop drugs that optimize health outcomes and improve patients' quality of life.

Note 2 - Going Concern and Management's Plans

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of asset amounts or the classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

As of December 31, 2025, the Company had cash of approximately $0.1 million and a working capital deficit of approximately $12.4 million. During the year ended December 31, 2025, the Company incurred a net loss of approximately $25.0 million and used cash in operations of approximately $5.1 million. The Company has an accumulated deficit of approximately $137.6 million as of December 31, 2025.

The Company has not yet achieved profitability and expects to continue to incur cash outflows from operations. It is expected that its research and development and general and administrative expenses will continue to increase and, as a result, the Company will eventually need to generate significant product revenues to achieve profitability.

Consequently, the Company will be required to raise additional funds through equity or debt financing. On February 27, 2026, the Company entered into a Securities Purchase agreement and received approximately $1.0 million. See Note 10 – Subsequent Events – Securities Purchase Agreement for additional details. Management believes that the Company has access to capital resources and continues to evaluate additional financing opportunities; however, there can be no assurance that it will be successful in securing additional capital or that the Company will be able to obtain funds on commercially acceptable terms, if at all. There is also no assurance that the amount of funds the Company might raise will enable the Company to complete its development initiatives or attain profitable operations. The aforementioned conditions raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the issuance date of these financial statements.

Note 3 – Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been derived from the accounting records of the Company and its consolidated subsidiaries. All significant intercompany balances have been eliminated in the consolidated financial statements. The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the accounting rules and regulations of the United States Securities and Exchange Commission ("SEC").

On April 25, 2024, the Company effected a reverse stock split of its common stock at a ratio of 1-for-10 (the "2024 Reverse Split"). Upon the effectiveness of the 2024 Reverse Split, every 10 issued shares of common stock were reclassified and combined into one share of common stock. In addition, the number of shares of common stock issuable upon the exercise of the Company's equity awards, convertible securities and warrants were proportionally decreased, and the corresponding conversion price or exercise price was proportionally increased. No fractional shares were issued as a result of the 2024 Reverse Split.

Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the 2024 Reverse Split and adjustment of the conversion price or exercise price of each outstanding equity award, convertible security and warrants as if the transaction had occurred as of the beginning of the earliest period presented.

Use of Estimates

Preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the financial statements and the amounts disclosed in the related notes to the financial statements. The Company bases its estimates and judgments on historical experience and on various other assumptions that it believes are reasonable under the circumstances. The amounts of assets and liabilities reported in the Company's balance sheets and the amounts of expenses reported for each of the periods presented are affected by estimates and assumptions, which are used for, but not limited to, fair value calculations for equity securities, share based compensation, impairment of in-process research and development, as well as establishment of valuation allowances for deferred tax assets. Certain of the Company's estimates could be affected by external conditions, including those unique to the Company and general economic conditions. It is reasonably possible that actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents in the financial statements. As of December 31, 2025 and 2024, the Company had no cash equivalents.

The Company has cash deposits which, at times, may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits. The Company has not experienced losses in such accounts and periodically evaluates the creditworthiness of its financial institutions.

Business Combination

In applying the acquisition method of accounting for business combinations, amounts assigned to identifiable assets and liabilities acquired are based on estimated fair values as of the date of acquisition, with the remainder recorded as goodwill. Intangible assets are initially valued at fair value using generally accepted valuation methods appropriate for the type of intangible asset. In-process research and development (IPR&D) acquired in a business combination is capitalized as an indefinite-lived intangible asset until regulatory approval is obtained, at which time it is accounted for as a definite-lived asset and amortized over its estimated useful life, or discontinuation, at which point the intangible asset will be written off.

Long-Lived Assets

The Company accounts for long-lived assets in accordance with the provisions of ASC 360-10-35, *Property, Plant and Equipment, Impairment or Disposal of Long-lived Assets*. This accounting standard requires that definite-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Goodwill and Intangible Assets

The Company accounts for goodwill and intangible assets in accordance with ASC 350, *Intangibles – Goodwill and Other*. Goodwill represents the excess of the purchase price of an entity over the estimated fair value of the assets acquired and liabilities assumed. ASC 350 requires that goodwill and other intangibles with indefinite lives be tested for impairment annually or on an interim basis if events or circumstances indicate that the fair value of an asset has decreased below its carrying value. The Company intends to perform its annual impairment testing during the fourth quarter of each year.

In determining whether a quantitative assessment is required, the Company evaluates relevant events or circumstances to determine whether it is more likely than not that the fair value of a reporting unit or an indefinite-lived intangible asset is less than its carrying amount. If, after performing the qualitative assessment, an entity concludes that it is more likely than not that the fair value of a reporting unit or an indefinite-lived intangible asset is less than its carrying amount, the entity would perform the quantitative impairment test described in ASC 350. However, if, after applying the qualitative assessment, the entity concludes that it is not more than likely that the fair value is less than the carrying amount, the quantitative impairment test is not required. The Company bases these assumptions on its historical data and experience, industry projections, micro and macro general economic condition projections, and its expectations.

Equipment, Net

Equipment is stated at cost, net of accumulated depreciation, which is recorded commencing at the in-service date and depreciated using the straight- line method at rates sufficient to charge the cost of depreciable assets to operations over their estimated useful lives, which is 5 years. As of December 31, 2025 and 2024, equipment consisted of $52,000 medical equipment, placed in service on September 1, 2019, less accumulated depreciation of $52,000 and $52,000 as of December 31, 2025 and 2024, respectively. During the years ended December 31, 2025 and 2024, the Company recognized depreciation expense of $0 and $6,933, respectively. Depreciation expense was included in general and administrative expenses in the statements of operations for the year ended December 31, 2024.

Deferred Offering Costs

Deferred offering costs, which primarily consist of direct, incremental professional fees incurred in connection with a debt or equity financing, are capitalized as deferred offering costs (a non-current asset) on the balance sheet. Once the financing closes, the Company reclassifies such costs as either discounts to notes payable or as a reduction of proceeds received from equity transactions so that such costs are recorded as a reduction of additional paid-in capital. If the completion of a contemplated financing was deemed to be no longer probable, the related deferred offering costs would be charged to general and administrative expense in the consolidated financial statements.

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on ASC 820 “Fair Value Measurements and Disclosures” (“ASC 820”), which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 — quoted prices in active markets for identical assets or liabilities;
Level 2 — quoted prices for similar assets and liabilities in active markets or inputs that are observable; and
Level 3 — inputs that are unobservable (for example, cash flow modeling inputs based on assumptions).

The carrying amounts of the Company’s financial instruments, such as cash, accounts payable, and deposits approximate fair values due to the short-term nature of these instruments.

Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of items that have been included or excluded in the financial statements or tax returns. Deferred tax assets and liabilities are determined on the basis of the difference between the tax basis of assets and liabilities and their respective financial reporting amounts (“temporary differences”) at enacted tax rates in effect for the years in which the temporary differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the assets will not be realized. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the statements of operations in the period that includes the enactment date.

The Company utilizes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Research and Development

Research and development expenses are charged to operations as incurred.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date. The fair value amount is then recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period.

Warrant Classification

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in ASC 480, Distinguishing Liabilities from Equity, and ASC 815, Derivatives and Hedging. The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's common stock, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

Fair Value of Stock Options and Warrants

The Company has computed the fair value of stock options and warrants granted using the Black-Scholes option pricing model. Option forfeitures are accounted for at the time of occurrence. Common stock is being valued using the market approach using the trading prices of the common stock on the OTCQB® Venture Market. The expected term used for options is the estimated period of time that options granted are expected to be outstanding. The expected term used for warrants is the contractual life. The Company utilizes the "simplified" method to develop an estimate of the expected term of "plain vanilla" option grants. The Company did not have a public trading history for the common shares to support its historical volatility calculations until December 13, 2022. Accordingly, the Company used a blended volatility whereby it uses its historical volatility for the period from December 13, 2022 through the valuation date and uses the average of peer-group data of four comparable entities to supplement its own historical data for the preceding years in computing its expected volatility. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common and dilutive common-equivalent shares outstanding during each period.

The following table sets forth the outstanding potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to do so would be anti-dilutive:

	For the Years Ended December 31,	
	2025	**2024**
Warrants [1]	6,911,773	1,747,093
Options	387,357	9,612
Series A Convertible Preferred Stock	72	72
Series B Convertible Preferred Stock	2,067	2,067
Total potentially dilutive shares	7,301,269	1,758,844

[1] As part of the InflamaCORE, LLC license agreement, warrants to purchase 342 shares of common stock are to be issued upon the satisfaction of certain milestones and, accordingly, are not included in the amount currently reported. See Note 8 - Commitments and Contingencies - License Agreements for details.

Vendor Concentration

As of December 31, 2025 and 2024, accounts payable to one vendor accounted for 56% of the accounts payable related to research and development. The Company relies on this vendor to perform critical research and development.

Segment Reporting

Reportable segments are components of an enterprise about which separate financial information is available for evaluation by the chief operating decision maker ("CODM") in making decisions about how to allocate resources and assess performance. The Company has one operating and reporting segment (clinical stage biopharmaceutical), namely, the development of drugs for patients with chronic renal or inflammatory diseases with high unmet medical needs. The CODM, who is the Company's chief executive officer, utilizes the Company's financial information on an aggregate, consolidated basis for purposes of making operating decisions, allocating resources and assessing financial performance, as well as for making strategic operations decisions and managing the organization. The CODM is not regularly provided with disaggregated actual expense information, other than the actual expense information included in the consolidated statements of operations. The measure of segment assets is reported on the balance sheet as total assets. The Company has not yet generated any revenue from product sales.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220 – 04). This update requires an entity to disclose more detailed information regarding expenses for the entity. The amendments require that at each interim and the annual reporting period, the entity must disclose amounts related to purchases of inventory, employee compensation, depreciation, and intangible asset amortization. Including the amounts, the entity is required to disclose and qualitative description of the amounts remaining in relevant expense captions, and to disclose the total amount of selling expenses and the definition of selling expenses. The amendments in this update should be applied prospectively to financial statements issued for reporting periods, and retrospectively to any prior periods presented in the financials. Although early adoption is permitted, the new guidance becomes effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Since this new ASU addresses only disclosures, the Company does not expect the adoption of this ASU to have any material effects on its financial condition, results of operations or cash flows.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The amendments in this update address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This update also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in ASU 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments in ASU 2023-09 were adopted by the Company on a prospective basis during the year ended December 31, 2025. There was no material impact to the Company's financial statements as a result of adopting ASU 2023-09. Refer to Note 6 – Income Taxes for the inclusion of new disclosures required.

Note 4 – In-Process Research and Development

In December of 2022, in connection with a business combination, the Company recorded an indefinite-lived intangible asset related to in-process research and development ("IPR&D"). ASC 350 requires that intangible assets with indefinite lives be tested for impairment annually or on an interim basis if events or circumstances indicate that the fair value of an asset has decreased below its carrying value. During the year ended December 31, 2025, management determined that it was more likely than not that the Company's single reporting unit's fair value was below its carrying amount, due to a significant and sustained decline in the Company's market capitalization, therefore an impairment test was performed on the Company's IPR&D intangible asset.

Current limitations on accessing significant capital in what is currently a risk averse environment for biotech (as evidenced by decreased investor appetite for risk, market volatility, regulatory uncertainty from a changing Food and Drug Administration and a challenging economic environment), resulted in a sustained decline in the Company's market capitalization, and the Company's ability to further finance the development of its drug candidates to the next milestone could be adversely impacted. Accordingly, the Company determined that the carrying value of its IPR&D intangible asset was not recoverable and it was fully impaired. Therefore, the Company recorded an $18.6 million impairment charge, reflected within operating expenses in the consolidated statements of operations for the year ended December 31, 2025.

Note 5 – Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following as of December 31, 2025 and December 31, 2024:

	For the Years Ended December 31,	
	2025	**2024**
Payroll accrual	$ 1,343,382	$ 1,039,338
Interest accrual	666,958	268,972
Bonus accrual	536,500	536,500
Accrued issuable equity	57,195	-
Other accrued expenses	-	41,970
Registration delay liability	7,261	7,261
Total accrued expenses and other current liabilities	$ 2,611,296	$ 1,894,041

Note 6 – Income Taxes

The Company is subject to United States federal and state income taxes.

Our income (loss) before provision for income taxes for the years ended December 31, 2025 and 2024 was as follows:

	12/31/2025	12/31/2024
Domestic	$ (25,804,037)	$ (9,406,690)
Foreign	-	-
Income before income taxes	$ (25,804,037)	$ (9,406,690)

The components of income (loss) before provision for income taxes are as follows for the years ended December 31, 2025 and 2024:

	For the Years Ended December 31,	
	2025	2024
Current tax benefit:		
Federal	$ -	$ -
State	-	23,240
	-	23,240
Deferred tax benefit:		
Federal	(5,062,687)	(1,688,265)
State	(1,127,073)	(164,376)
	(6,189,760)	(1,852,641)
Change in valuation allowance	5,338,101	1,859,386
Provision for income taxes	$ (851,659)	$ 6,745

The reconciliation of taxes at the federal statutory rate to our provision for (benefit from) income taxes for the year ended December 31, 2025 in accordance with the guidance upon adoption of ASU 2023-09 was as follows:

	For the Year Ended December 31, 2025	
Description	**Amount**	**Percent**
U.S. Federal Statutory Tax Rate	(5,418,848)	21.0%
State Income Taxes, Net of Federal Income Tax Effect [1]	99,730	-0.4%
Valuation Allowance	4,297,670	-16.7%
Nontaxable or Nondeductible items	126,650	-0.4%
Other	43,139	-0.2%
Effective Tax Rate	(851,659)	3.3%

[1] State taxes in Florida made up the majority (greater than 50 percent) of the tax effect in this category.

The reconciliation of taxes at the federal statutory rate to our provision for (benefit from) income taxes for the year ended December 31, 2024 in accordance with the guidance prior to the adoption of ASU 2023-09 was as follows:

	For the Year Ended December 31, 2024
Federal statutory rate	21.0%
State tax rate, net of federal benefit	3.0%
Permanent items	(0.0)%
Stock Based Comp	(3.2)%
Effect of change in state rate	0.2%
Prior period adjustments and other	(1.3)%
Change in valuation allowance	(19.8)%
Other	0.0%
Effective income tax rate	(0.1)%

The cumulative tax effect of significant items comprising our net deferred tax asset (liability) is as follows for December 31, 2025 and 2024:

	As of December 31,	
Deferred tax asset attributable to:	**2025**	**2024**
Net operating loss carryforwards	$ 14,419,237	$ 12,544,318
Stock-based compensation	3,099,252	3,155,058
Capitalized research and development costs	1,360,579	1,753,207
Capitalized start-up costs	650,957	781,342
Capitalized licensing costs	563,812	609,669
Capitalized patents	443,841	392,691
Warrants	135,527	135,319
Accrued Payroll	618,058	394,406
Contributions carryforward	125	2,878
Deferred tax asset	21,291,388	19,768,888
Valuation Allowance	(21,291,388)	(15,953,288)
	-	3,815,600
IPR&D	-	(4,667,259)
Deferred tax liability	-	(4,667,259)
Net deferred tax liability	$ -	$ (851,659)

As of December 31, 2025, the Company has federal net operating loss carryforwards totaling $59,859,961. All federal NOLs were generated in tax years beginning after December 31, 2017, and may be carried forward indefinitely. Utilization of these NOLs is limited to offsetting up to 80% of taxable income in any given year, in accordance with the Tax Cuts and Jobs Act. The NOL carryforwards are subject to limitations under Section 382 of the Internal Revenue Code in the event of a change in ownership.

The Company has state net operating loss carryforwards totaling $42,546,493 as of December 31, 2025. All NOLs were generated in tax years beginning after December 31, 2017, and may be carried forward indefinitely, subject to annual deduction limitations under state tax law.

A valuation allowance of $21,291,388 has been recorded against deferred tax assets, including carryforwards, where it is not more likely than not that such assets will be realized. The Company evaluates the realizability of carryforwards based on projections of future taxable income and other relevant factors.

Valuation Allowance	**2025**
Valuation Allowance - beginning of period	$ (15,953,288)
Additions charged to income tax benefit	-
Allowances taken or written off	(5,338,100)
Other adjustments	-
Valuation allowance - end of period	$ (21,291,388)

Management has evaluated and concluded that there were no material uncertain tax positions requiring recognition in the Company’s financial statements as of December 31, 2025 and 2024.

No tax audits were commenced or were in process during the years ended December 31, 2025 and 2024 and no tax-related interest or penalties were incurred during those years. The Company's tax returns beginning with the year ended December 31, 2021 remain subject to examination.

Upon adoption of ASU 2023-09, Improvements to Income Tax Disclosures, as described in Note 2, Summary of Significant Accounting Policies, cash paid for income taxes, net of refunds, during the year ended December 31, 2025 was as follows:

Income Tax Paid	**2025**
Federal	$ -
State and Local	-
Total Income Taxes Paid, Net	$ -

Tax Law Change

On July 4th, 2025, the President signed into law significant federal tax legislation, H.R.1 (the "Tax Reform Act of 2025"). The legislation includes numerous changes to U.S. corporate income tax law, including but not limited to: permanent 100% bonus depreciation for qualified property, immediate expensing of domestic research and experimental expenditures, modifications to the limitation on business interest expense, increased Section 179 expensing limits, changes to the international tax regime, and expanded limitations on the deductibility of executive compensation under IRC Section 162(m). Most provisions are effective for tax years beginning after December 31, 2024, with certain transition rules and exceptions.

The Company has evaluated the impact of the Tax Reform Act of 2025 on its consolidated financial statements. There was no material impact given the Company's tax loss profile and valuation allowance position.

Note 7 – Commitments and Contingencies

Litigations, Claims and Assessments

The Company may be involved in legal proceedings, claims and assessments arising in the ordinary course of business. The Company records contingent liabilities resulting from such claims, if any, when a loss is assessed to be probable and the amount of the loss is reasonably estimable.

Disputed Vendor Invoices

On June 30, 2024 and July 1, 2024, the Company received two invoices from a vendor in the amounts of $923,880 and $144,300, respectively. The June 30, 2024 invoice represents retroactive interest on invoices going back to September 30, 2022. The July 1, 2024 invoice included miscellaneous unsupported charges related to services performed over the past several years. On August 1, 2024, ZyVersa management sent the vendor a letter disputing the interest and unsupported charges and has requested the vendor to rescind each of them. Although the Company has requested the vendor to rescind the retroactive interest on invoices, the Company believes that, in accordance with the agreement, the vendor can legally charge the Company interest from the point they were notified of the vendor's intent to charge interest. As such, the Company began accruing interest starting on July 1, 2024, and accordingly, has recorded $780,539 and $268,972 within accrued expenses and other current liabilities on the consolidated balance sheets as of December 31, 2025 and 2024, respectively. The Company has accounted for the unaccrued interest and unsupported charges of $1,066,978 as a loss contingency and because the liability is not deemed probable, it has not been recorded as a liability in the consolidated balance sheet as of December 31, 2025 or 2024.

Operating Leases

On January 18, 2019, the Company entered into a lease agreement for approximately 3,500 square feet of office space in Weston, Florida for a term of five years. Under the lease agreement, the annual base rent, which excludes the Company's share of taxes and operating costs, was approximately $89,000 for the first year and has increased approximately 3% every year thereafter for a total base rent lease commitment of approximately $497,000. On January 15, 2024, the Company extended the lease for an additional year for a total base rent lease commitment of $112,064. On January 9, 2025, the Company extended the lease for an additional year for a total base rent lease commitment of approximately $120,819. The Company used the short-term lease practical expedient which permits the Company to not capitalize leases with a term equal to or less than 12 months. The lease agreement ended on January 31, 2026 and it was not extended.

The Company recognized rent expense in connection with its operating lease for the years ended December 31, 2025 and 2024 of $175,660 and $170,022, respectively.

Note 8 – Stockholders' Equity (Deficit)

Equity Incentive Plans

Predecessor 2014 Equity Incentive Plan

On December 12, 2022, in connection with the consummation of the Business Combination, the Predecessor approved the amendment to the 2014 Plan (the "2014 Plan Amendment"). The 2014 Plan Amendment provides, among other things, that upon consummation of the Business Combination, no further increases in the shares of common stock reserved and available for issuance under the 2014 Plan shall occur and no new awards shall be made under the 2014 Plan.

2022 Omnibus Equity Incentive Plan

The Company is authorized to issue awards under the 2022 Omnibus Equity Incentive Plan (the "2022 Plan"), as amended on October 31, 2023 and October 29, 2024. Under the 2022 Plan, 382,122 shares of common stock are authorized for issuance as of December 31, 2025. The number of shares of common stock available for issuance under the 2022 Plan shall automatically increase on the first trading day of January each calendar year during the term of the 2022 Plan, beginning with calendar year 2023, by an amount equal to four percent (4%) of the total number of shares of common stock outstanding on the last trading day in December of the immediately preceding calendar year. The 2022 Plan provides for the issuance of incentive stock options, non-statutory stock options, rights to purchase common stock, stock appreciation rights, restricted stock and restricted stock units to employees, directors and consultants of the Company and its affiliates. The 2022 Plan requires the exercise price of stock options to be not less than the fair value of the Company's common stock on the date of grant. As of December 31, 2025, there were 377,965 shares available for future issuance under the 2022 Plan.

On January 1, 2026, the total number of shares under the 2022 Omnibus Equity Incentive Plan automatically increased to 705,958.

Common Stock

On February 3, 2025, the Company entered into a marketing agreement with a vendor in which the Company agreed to issue 60,000 shares of common stock in exchange for marketing services. The fair value of the common stock of $81,600 was recognized as expense on a straight-line basis over the two-month term of the contract. The shares were issued on February 3, 2025.

On March 20, 2025, the Company entered into a marketing agreement with a vendor in which the Company agreed to issue 100,000 shares of common stock in exchange for digital marketing services. The fair value of the common stock of $70,100 was recognized as expense on a straight-line basis over the three-month term of the contract. On April 11, 2025, the Company issued the 100,000 shares of common stock to the vendor using the market value of $77,000 on that date. The difference between the original expense amount and the value when the shares were issued was reflected in the change in fair value of equity payable in other (income) expense on the condensed consolidated statements of operations.

On May 1, 2025, the Company entered into a marketing agreement with a vendor in which the Company agreed to issue 100,000 shares of common stock in exchange for marketing services. The fair value of the common stock of $51,800 was recognized as expense on a straight-line basis of the expense over the two-month term of the contract. On May 13, 2025, the Company issued the 100,000 shares of common stock to the vendor using the market value of $51,800 on that date.

On August 1, 2025, the Company entered into a marketing agreement with a vendor in which the Company agreed to issue 160,000 shares of common stock in exchange for marketing services. The fair value of the common stock of $29,600 was recognized as expense on a straight-line basis over the two-month term of the contract.

Equity Purchase Agreement

On June 24, 2025, the Company entered into an Equity Purchase Agreement (the "Purchase Agreement") with Williamsburg Venture Holdings, LLC (the "Purchaser"), whereby the Company has the right, but not the obligation, to sell to the Purchaser, and the Purchaser is obligated to purchase, up to an aggregate of $10.0 million of shares (the "ELOC Shares") of the Company's common stock. The term of the Purchase Agreement is the earlier of June 24, 2027, or the date on which the Purchaser has purchased ELOC Shares for an aggregate purchase price of $10.0 million. The Company has also agreed to issue to the Purchaser 426,829 shares common stock ("Commitment Shares"), which will be issued on a pro rata basis as the Company draws down ELOC shares, with any remaining shares to be issued upon termination. The fair value of the Commitment Shares on the date of the Purchase Agreement of $265,957 was established as accrued issuable equity and was expensed, along with approximately $74,000 of additional issuance costs. No shares have been purchased as of December 31, 2025.

Stock-Based Compensation

For the year ended December 31, 2025, the Company recorded stock-based compensation expense of $222,831 (of which, $10,345 was included in research and development and $212,486 was included in general and administrative expense) related to options issued to employees and consultants. As of December 31, 2025, there was $208,316 of unrecognized stock-based compensation expense, which the Company expects to recognize over a weighted average period of 1.9 years.

For the year ended December 31, 2024, the Company recorded stock-based compensation expense of $705,567 (of which, $61,789 was included in research and development and $643,778 was included in general and administrative expense) related to options issued to employees and consultants. As of December 31, 2024, there was $321,893 of unrecognized stock-based compensation expense, which the Company expects to recognize over a weighted average period of 1.3 years.

Stock Options

On July 11, 2025, the Company granted ten-year stock options to purchase 377,964 shares of common stock to employees and directors of the Company under the 2022 Plan. The stock options had an aggregate grant date value of $201,296, vest annually over three years and have an exercise price of $0.59 per share.

The grant date fair value of stock options granted during the years ended December 31, 2025 and 2024 was determined using the Black Scholes method, with the following assumptions used:

	For the Years Ended December 31,	
	2025	**2024**
Fair value of common stock on date of grant or modification	$0.13 - $0.59	N/A
Risk free interest rate	3.55% - 4.09%	N/A
Expected term (years)	0.24 - 9.75	N/A
Expected volatility	78.7% - 161.5%	N/A
Expected dividends	0.00%	N/A

A summary of the option activity for the year ended December 31, 2025 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2025	9,612	$ 2,248.58		
Granted	377,964	0.59		
Exercised	-	-		
Expired	(219)	1,760.50		
Outstanding, December 31, 2025	387,357	$ 55.67	9.4	$ -
Exercisable, December 31, 2025	8,045	$ 2,605.21	5.1	$ -

The following table presents information related to stock options as of December 31, 2025:

Options Outstanding			Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options	
$ 0.59	377,964	-	-	
$ 152.50	4,157	7.4	2,916	
$ 738.50	286	7.1	191	
$ 791.00	38	7.2	26	
$ 1,760.50	1,060	1.2	1,060	
$ 3,965.50	37	6.5	37	
$ 4,053.00	2,095	3.3	2,095	
$ 5,726.00	1,720	5.5	1,720	
	387,357	5.1	8,045	

Stock Warrants

On March 7, 2025, the Company closed on a private placement (the "Private Placement") with an institutional investor, pursuant to which the Company sold pre-funded warrants (the "March 2025 Pre-Funded Warrants") to purchase 2,105,265 shares of common stock and Series A-3 common warrants (the "March 2025 Common Warrants") to purchase 2,105,265 shares of common stock at a combined purchase price of $0.9499 which resulted in gross proceeds of approximately $2.0 million. In addition, the Company and the investor executed an amendment to certain November 5, 2024 common share purchase warrants to reduce the exercise price of certain outstanding warrants to purchase 957,200 shares of common stock from $2.06 per share to $1.00 per share. The $53,890 incremental fair value of the modified warrants as compared to the original warrants was recognized as an additional issuance cost of the Private Placement. The March 2025 Pre-Funded Warrants are exercisable immediately, may be exercised at any time until all March 2025 Pre-Funded Warrants are exercised in full, and have an exercise price of $0.0001 per share. As of December 31, 2025, all March 2025 Pre-Funded Warrants were exercised. The March 2025 Common Warrants became exercisable upon Stockholder Approval on June 11, 2025 for a term of five years and have an exercise price of $1.00 per share. Total cash issuance costs were $290,317 including $199,863 of placement fees, $64,312 of legal fees, and $26,142 of other costs.

Warrant Inducement Offer

On July 8, 2025, the Company entered into a warrant exercise inducement offer letter agreement (the "Inducement Letter") with a holder (the "Holder") of (i) outstanding Series A-2 common stock purchase warrants, as amended (the "Series A-2 Warrants"), exercisable for up to an aggregate of 957,200 shares of the Company's common stock, and (ii) Series A-3 common stock purchase warrants (the "Series A-3 Warrants" and together with the Series A-2 Warrants, the "Existing Warrants") exercisable for up to an aggregate of 2,105,265 shares of common stock, which warrants were originally issued by the Company on November 5, 2024 and March 5, 2025, respectively. The Existing Warrants had an exercise price of $1.00 per share.

The Holder agreed to exercise the Existing Warrants for cash at a reduced exercise price of $0.67 per share in consideration of the Company's agreement to issue the Holder new warrants to purchase up to a number of shares of common stock equal to 200% of the number of shares of common stock issued pursuant to the Holder's exercise of Existing Warrants, comprised of new Series A-4 warrants to purchase up to 6,124,930 shares of common stock (the "Inducement Warrants") at an exercise price of $0.67 per share with an exercise term of 5 years from the initial exercise date. The Company received $2,051,852 in cash proceeds and incurred $175,222 in transaction costs consisting of $133,370 cash fee paid to its financial advisor and $41,852 in other fees. As a result of the reduction in exercise price of the Existing Warrants, the Company recognized a non-cash warrant modification charge of $1,762,756. Because the modification represented a short-term inducement, modification accounting was only performed on the warrants that were actually exercised under the program. The Company recognized the $1,762,756 modification-date incremental value of the modified Existing Warrants and Inducement Warrants issued as compared to the original Existing Warrants, as an issuance cost of the warrant exercise, which was classified as equity with no impact on the consolidated statements of operations. The initial exercise date of the Inducement Warrants is the date that the Company's stockholders approve the issuance of shares of common stock underlying the warrants (the "Inducement Warrants Shares") pursuant to the applicable rules and regulations of The Nasdaq Stock Market LLC ("Nasdaq"). On October 6, 2025, Nasdaq filed with the SEC a Form 25, removing and delisting the Company's securities from Nasdaq. Based on the foregoing and because applicable rules and regulations of the OTC Markets Group Inc. do not require stockholder approval for the issuance of the Inducement Warrant Shares, the Company noted that stockholder approval is no longer required.

The modification date fair value of stock warrants modified during the years ended December 31, 2025 and 2024 was determined using the Black Scholes method, with the following assumptions used:

	For the Years Ended December 31,	
	2025	**2024**
Fair value of common stock on date of modification	$0.64 - $0.98	$2.54 - $3.46
Risk free interest rate	3.92% - 4.09%	3.62% - 4.62%
Expected term (years)	4.9 - 5.3 years	0.6 - 5.3 years
Expected volatility	125%	87% - 111%
Expected dividends	n/a	n/a

A summary of the warrant activity for the year ended December 31, 2025 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2025	1,747,093	$ 59.59		
Issued [1]	8,230,195	0.75		
Repriced - Old [2]	(957,200)	2.06		
Repriced - New [2]	957,200	1.00		
Repriced - Old [3]	(957,200)	1.00		
Repriced - New [3]	957,200	0.67		
Repriced - Old [4]	(2,105,265)	1.00		
Repriced - New [4]	2,105,265	0.67		
Forfeited	(3,050)	12.50		
Exercised [1]	(3,062,465)	0.67		
Outstanding, December 31, 2025	6,911,773	$ 15.34	4.48	$ -
Exercisable, December 31, 2025	6,911,573	$ 15.29	4.48	$ -

[1] Warrants issued and exercised exclude 2,105,265 March 2025 Pre-Funded Warrants with an exercise price of $0.0001.
[2] Warrants represent the reset of the exercise price of certain November 2024 warrants to purchase 957,200 shares of common stock from $2.06 to $1.00 per share.
[3] Warrants represent the reset of the exercise price of certain March 2025 warrants to purchase 957,200 shares of common stock from $1.00 to $0.67 per share.
[4] Warrants represent the reset of the exercise price of certain March 2025 warrants to purchase 2,105,265 shares of common stock from $1.00 to $0.67 per share.

The following table presents information related to stock warrants as of December 31, 2025:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$ 0.67	6,124,930	4.52	6,124,930
$ 2.06	679,800	4.44	679,800
$ 12.50	4,050	2.94	4,050
$ 47.50	20,347	3.20	20,347
$ 57.75	19,965	2.52	19,965
$ 350.00	27,551	2.32	27,551
$ 700.00	13,944	1.95	13,944
$ 1,760.50	200	-	-
$ 2,415.00	3,651	1.95	3,651
$ 4,025.00	17,335	1.95	17,335
	6,911,773	4.48	6,911,573

Note 9 – Segment Reporting

The Company has one operating and reporting segment (clinical stage biopharmaceutical), namely, the development of drugs for patients with chronic renal or inflammatory diseases with high unmet medical needs. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The chief operating decision maker ("CODM"), who is the Company's chief executive officer, utilizes the Company's financial information on an aggregate, consolidated basis for purposes of making operating decisions, allocating resources and assessing financial performance, as well as for making strategic operations decisions and managing the organization. The CODM is not regularly provided with disaggregated actual expense information, other than the actual expense information included in the consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the balance sheet as total assets. The Company has not yet generated any revenue from product sales.

Note 10 – Subsequent Events

The Company has evaluated subsequent events through the date the financial statements were issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the financial statements, except as discussed below.

Securities Purchase Agreement

On February 27, 2026, the Company entered into a Securities Purchase Agreement with certain accredited investors, pursuant to which the Company issued convertible promissory notes (the "Notes") in an aggregate principal amount of $1.0 million and Series A-4 Common Stock Purchase Warrants (the "Warrants") to purchase shares of the Company's common stock, par value $0.0001 per share.

The Notes bear interest at a rate of 10% per annum, with interest accruing on the unpaid principal amount and payable on the maturity date. The Notes mature twelve months from the date of issuance and are convertible into shares of Common Stock at a conversion price equal to (i) 80% of the price per share paid in a Qualified Offering, upon its occurrence, or (ii) 80% of the lowest daily volume-weighted average price of the Common Stock during the 10 trading days prior to delivery of a conversion notice that occurs following the earlier of (x) six months after the issuance date or (y) an event of default. This share price is subject to a floor price of $0.02 per share.

The Warrants are exercisable beginning on the six-month anniversary of their issuance (the "Initial Exercise Date"), and expire on the five-year anniversary of the issuance date. The exercise price of the Warrants is equal to (i) 110% of the price per share paid in a Qualified Offering that occurs by the Initial Exercise Date, or (ii) 110% of the volume-weighted average price for the five-trading-day period beginning on the 181st day and ending on the 185th day after the issuance date if a Qualified Offering has not occurred by the Initial Exercise Date. The number of shares of Common Stock issuable upon exercise of each Warrant is calculated by dividing 50% of the applicable Purchaser's subscription amount by the exercise price. The Warrants contain standard anti-dilution adjustments, including adjustments for stock dividends, stock splits, and certain fundamental transactions.

ZYVERSA THERAPEUTICS, INC.

STATEMENT OF COMPANY POLICY ON INSIDER TRADING AND POLICY REGARDING SPECIAL TRADING PROCEDURES

Approved by the Board of Directors on December 12, 2022

Two copies of this Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures (collectively, this "Policy") are being provided to you. You should read this Policy, address questions to Peter Wolfe, the Chief Financial Officer of ZyVersa Therapeutics, Inc. (the "Company") and return one signed copy to:

Peter Wolfe
Chief Financial Officer
ZyVersa Therapeutics, Inc.
pwolfe@zyversa.com

I. POLICY STATEMENT ON INSIDER TRADING

The Company has adopted a policy on insider trading (the "Policy") that applies to each officer, director and employee of the Company*. A statement regarding such policy has been distributed to all officers, directors and employees. It is the policy of the Company that no director, officer or other employee (or any other person designated by this Policy or the Company's Chief Financial Officer) who is aware of material nonpublic information related to the Company may, directly or indirectly, through family members or other persons or entities:

1. engage in transactions in the securities of the Company (except as otherwise expressly provided in this Policy);

2. recommend that any other person engage in transactions in the securities of the Company;

3. disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information or to persons outside of the Company, including, but not limited to, family, friends, business associates, investors and expert consulting firms, unless such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company; or

* The term "Company" refers to ZyVersa Therapeutics, Inc., its subsidiaries and its affiliates, collectively or individually, as the context requires.

4. assist anyone engaged in the above activities.

In addition, it is the policy of the Company that no director, officer or other employee (or any other person designated as subject to this Policy) who, in the course of working for the Company, learns of material nonpublic information about a company with which the Company does business, including a customer or supplier of the Company, may trade in that company's securities until the information becomes public or is no longer material.

This Policy applies to all directors, officers and employees of the Company, its subsidiaries and its affiliates. You must read, sign and retain this Policy statement and, upon request by the Company, re-acknowledge it.

II. DISCUSSION: WHAT IS "INSIDER TRADING"?

Insider trading is, in addition to being a violation of this Policy, a violation of securities laws. The penalties for insider trading are discussed herein.

The term "insider trading" generally is used to refer to the use of material, nonpublic information to trade in securities or to communications of material, nonpublic information to others who may trade on the basis of such information.

While the law concerning insider trading is not static, it is generally understood that the law prohibits insiders of the Company from doing the following:

1. Trading in the Company's securities while in possession of material, nonpublic information concerning the Company.

2. Having others trade on the insider's behalf while he or she is in possession of material, nonpublic information.

3. Communicating nonpublic information concerning the Company or other companies that the Company does business with to others who may then trade in the Company's securities or pass on the information to others who may trade in the Company's securities. Such conduct, also known as "tipping," violates laws that impose strict penalties upon both companies and individuals, including both financial sanctions and prison. Tipping results in civil and criminal liability for the insider of the Company who communicates such information, even if such insider does not actually trade himself, and for the person who received the information if the person has reason to know that it was an improper disclosure and acts on such information or passes it on to others who may act on it.1

The elements of insider trading and the potential penalties for such unlawful conduct are discussed herein.

1 When calculating the civil and criminal liability of a tipper, a tipper may be held responsible for the profits of his "tippees." This means that the tipper may be required to pay back the government all of the profits received by his tippee (and others in the chain of the tip), even if the tipper did not actually profit. Similarly, the profits of a tippee may be used to calculate the prison sentence of the tipper, which may extend the length of any sentence.

A. <u>Who is an Insider?</u>

The concept of "insider" generally includes any person who possesses nonpublic information about the Company and who has a duty to the Company to keep this information confidential. This Policy applies to all directors, officers and employees of the Company and its subsidiaries. In addition, the Company may determine that other persons should be subject to this Policy, such as service providers, contractors or consultants who have access to material nonpublic information in connection with such service. Outsiders who could be subject to this Policy include, among others, the Company's attorneys, accountants, consultants, advisory board members, investment bankers and the employees of such organizations.

This Policy also applies to your family members who reside with you (including a spouse, child, child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws), anyone else who lives in your household, and any family members whose transactions in the Company securities are directed by you or are subject to your influence or control (collectively referred to as "family members"). This Policy further applies to any entities that you influence or control, including any corporations, partnerships or trusts (collectively referred to as "controlled entities").

B. <u>What is Material Information?</u>

"Material Information" generally is defined as information for which there is a substantial likelihood that a reasonable investor would consider such information important in making his or her investment decisions, or information that could be reasonably expected to affect the price of a company's securities, whether it is positive or negative. It is important to remember that materiality will always be judged with the benefit of hindsight.

Although there is no precise definition of materiality, information is likely to be "material" if it relates to:

- earnings or expectations for the quarter or the year;
- forecasts or projections of future earnings or losses, or other earnings guidance;
- changes to previously announced earnings guidance or the decision to suspend earnings guidance;
- clinical development milestones;
- changes in dividends, the declaration of a stock split or an offering of additional securities;
- proposals or agreements involving a merger, acquisition, tender offer, joint venture, divestiture or leveraged buy-out;
- changes in relationships with major customers, or obtaining or losing important contracts;
- development of a significant new product, process or service;
- bank borrowings or other financing transactions out of the ordinary course;
- important product developments;
- major financing developments;
- major personnel changes;
- criminal indictments or material civil litigation or government investigations;
- significant disputes with major suppliers or customers;
- labor disputes including strikes or lockouts;
- substantial change in accounting methods;
- cybersecurity risks and incidents;
- debt service or liquidity problems;
- bankruptcy or insolvency;
- public offerings or private sales of debt or equity securities;
- calls, redemptions or repurchases of the Company's securities; or
- change in auditors or notification that the auditor's reports may no longer be relied upon.

"Inside" information could be material because of its expected effect on the price of the Company's securities, the securities of another company or the securities of several companies. Moreover, the resulting prohibition against the misuse of "inside" information includes not only restrictions on trading in the Company's securities but restrictions on trading in the securities of other companies affected by the inside information.

C. What is Nonpublic Information?

In order for information to qualify as "inside" information it must not only be "material," it must be "nonpublic." "Nonpublic" information is information which has not been made available to investors generally. This includes information received from sources or in circumstances indicating the information has not yet been generally circulated.

At such time as material, nonpublic information has been released to the investing public, it loses its status as "inside" information. However, for "nonpublic" information to become public information it must be disseminated through recognized channels of distribution designed to reach the securities marketplace or public disclosure documents filed with the SEC that are available on EDGAR, and sufficient time must pass for the information to become available in the market.

To show that "material" information is public, it is generally necessary to point to some fact verifying that the information has become generally available, such as disclosure by filing of a Quarterly Report on Form 10-Q, Annual Report on Form 10-K, Current Report on Form 8-K or other report with the Securities and Exchange Commission or disclosure by press release to a national business and financial wire service (such as Dow Jones or Reuters), a national news service or a national newspaper (such as The Wall Street Journal). The circulation of rumors or "talk on the street," even if accurate, widespread and reported in the media, does not constitute the requisite public disclosure.

Material, nonpublic information is not made public by selective dissemination. Material information improperly disclosed only to institutional investors or to a favored analyst or a group of analysts retains its status as "nonpublic" information, the use of which is subject to insider trading laws. Similarly, partial disclosure does not constitute public dissemination. So long as any material component of the "inside" information has yet to be publicly disclosed, the information is deemed "nonpublic" and may not be misused.

It is the policy of the Company to not consider material information public until the second business day after appropriate public dissemination.

D. What Transactions Are Subject to this Policy?

This Policy applies to transactions in the Company's securities, including common stock, options or warrants to purchase common stock, or any other securities that the Company may issue, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company securities.

This Policy does not apply to the following transactions, except as specifically noted:

1. Stock Option Exercises. This Policy does not apply to the exercise of any employee stock option acquired pursuant to the Company's equity plans, or to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

2. Restricted Stock Awards. This Policy does not apply to the vesting of restricted stock, or of a tax withholding right pursuant to which you elect to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock. This Policy, however, does apply to any market sale of restricted stock.

3. Transactions with the Company. This Policy does not apply to the purchase of the Company securities from the Company or the sale of the Company securities to the Company.

E. <u>What Are the Consequences of Violations of This Policy?</u>

Engaging in securities transactions while aware of material, nonpublic information, or the disclosure of material, nonpublic information is illegal.

Penalties for the purchase or sale of securities, while aware of material, nonpublic information, or communicating material, nonpublic information to others who then trade in such securities, are severe, both for the individuals involved in such unlawful conduct and, potentially, for their employers. A person can be subject to some or all of the penalties below even if he or she does not personally benefit from the violation (i.e., if the violation was one for tipping information). Penalties include:

- jail sentences of up to 10 years;
- disgorgement of profits;
- fines for the person who committed the violation of up to three times the profit gained or loss avoided, whether or not the person actually benefited;
- criminal fines (no matter how small the profit) up to $1 million; and
- fines for the employer or other controlling person, such as a supervisor, of up to the greater of $1,000,000 or three times the amount of the profit gained or loss avoided.

In addition, a violation of this Policy can be expected to result in serious sanctions by the Company, which may include dismissal for cause of the person involved, whether or not the employee's failure to comply with this Policy results in a violation of law.

III. POLICY REGARDING SPECIAL TRADING PROCEDURES

The following Special Trading Policies are applicable to all directors, officers and employees of the Company.

A. <u>Trading Windows and Pre-Clearance.</u>

There are times when the Company may be engaged in a material, nonpublic development. Although you may not know the specifics of the development, if you engaged in a trade before such development was disclosed to the public or resolved you might expose yourself and the Company to a charge of insider trading that could be costly and difficult to refute. In addition, a trade by you during such a development could result in significant adverse publicity for the Company.

Therefore, except pursuant to paragraph 3 below, you, your family members and controlled entities may only purchase or sell securities of the Company during the three or four "trading windows" that occur each year and only after pre-clearing your intent to trade with the Company's Chief Financial Officer.

The trading windows consist of the period that begins on the second business day after issuance of a press release or other announcement by the Company disclosing quarterly or annual earnings through the date which is 14 days prior to the quarter or fiscal year end. To the extent a second trading window begins during the duration of an existing trading window, the trading window will continue for the duration of the trading window that expires on the latest date. In accordance with the procedure for waivers described below, in special circumstances a waiver may be given to allow a trade to occur outside of a trading window.

If you intend to engage in a trade during a trading window you must first receive permission to engage in a trade from the Company's Chief Financial Officer*. The Company's Chief Financial Officer may refuse to permit any transaction if he or she determines that it could give rise to a charge of insider trading. The Company's Chief Financial Officer may seek advice of outside counsel as he or she may consider appropriate.

* If the Company's Chief Financial Officer will be absent from the office or unavailable for a significant period of time, he or she will designate another executive officer of the Company to handle trading requests.

After receiving permission to engage in a trade, you should either complete your trade within three business days or make a new trading request.

The exercise of options to purchase for cash and hold common stock of the Company or the purchase from the Company of common stock of the Company is not subject to the Special Trading Procedures outlined above, but the shares so acquired may not be sold except during a trading window, after authorization from the Company's Chief Financial Officer has been received and after all other requirements of this Policy have been satisfied. Accordingly, the exercise of options and immediate sale of some or all of the shares through a broker is covered by these Special Trading Procedures.

B. Event-Specific Black-out Procedures.

From time to time, an event may occur that is material to the Company and is known by only a few directors or officers. So long as the event remains material and nonpublic, the persons who are aware of the event, as well as other persons covered by these Special Trading Procedures, may not trade in the Company's securities. The existence of an event-specific blackout will not be announced, other than it may be announced to those who are aware of the event giving rise to the blackout. If, however, a person whose trades are subject to pre-clearance requests permission to trade in the Company's securities during an event-specific blackout, the Company's Chief Financial Officer will inform the requesting person of the existence of a blackout period, without disclosing the reason for the blackout. Any person made aware of the existence of an event-specific blackout should not disclose the existence of the blackout to any other person. The failure of the Company's Chief Financial Officer to designate a person as being subject to an event-specific blackout will not relieve that person of the obligation not to trade while aware of material, nonpublic information.

C. Rule 10b5-1 Plans.

The Securities and Exchange Commission has established regulations under which individuals may purchase and sell securities in compliance with "insider trading" laws (more specifically, Rule 10b5-1 of the Securities Exchange Act of 1934) if such purchases or sales are made pursuant to (i) a binding contract to purchase or sell the security, (ii) instructions provided to a third person to execute the trade for the instructing person or entity's account or (iii) an adopted written plan for trading securities; provided, that at the time of the decision to enter into such contract or plan or decision to provide such instructions, you were not aware of material, nonpublic information. In addition to other requirements set forth in such regulations, the contract, instructions or plan must (a) specify the amount, price and date of the purchase or sale or (b) provide a written formula or algorithm or computer program for determining the amounts, prices and dates of such purchases or sales.

Under the Company's policy, you, your family members and your controlled entities may only enter into a contract or plan or provide instructions for the purchase or sale of securities of the Company in compliance with these regulations after receiving written pre-clearance from the Company's Chief Financial Officer. A copy of the Rule 10b5-1 Plan should be submitted for approval at least three business days prior to the entry into the Rule 10b5-1 Plan.

D. Post-Trade Reporting.

You are required to report to the Company's Chief Financial Officer any transaction in securities of the Company by you, your family members or controlled entities not later than the business day following the date of your transaction. Each report you make to the Company's Chief Financial Officer should include the date of the transaction, quantity, price and broker through which the transaction was effected. This reporting requirement may be satisfied by sending (or having your broker send) duplicate confirmations of trades to the Company's Chief Financial Officer if such information is received by the required date.

The foregoing reporting requirement is designed to help monitor compliance with the Special Trading Procedures set forth herein and to enable the Company to help those persons who are subject to reporting obligations under Section 16 of the Securities Exchange Act of 1934 to comply with such reporting obligations. Each officer and director, however, and not the Company, is personally responsible for ensuring that his or her transactions do not give rise to "short swing" liability under Section 16 and for filing timely reports of transactions with the Securities and Exchange Commission.

E. Compliance with the Company's Statement of Company Policy on Insider Trading.

Even if you receive pre-clearance and it is during a trading window, you, your family members and your controlled entities may not trade in securities of the Company if you are in possession of material, nonpublic information about the Company. The procedures set forth herein are in addition to the general insider trading policy and are not a substitute therefor.

IV. PROHIBITION AGAINST CERTAIN TRANSACTIONS

1. **Prohibition on Short Sales.** Neither you, your family members nor your controlled entities may sell any securities of the Company that are not owned by such person at the time of the sale (a "short sale") including a "sale against the box" (a sale with delayed delivery).

2. **Trading in Standardized Options**. An "option" is the right either to buy or sell a specified amount or value of a particular underlying interest at a fixed exercise price by exercising the option before its specified expiration date. An option which gives a right to buy is a "call" option, and an option which gives a right to sell is a "put" option. Standardized options (which are so labeled as a result of their standardized terms) offer the opportunity to invest using substantial leverage and therefore lend themselves to significant potential for abusive trading on material inside information. Standardized options also expire soon after issuance and thus necessarily involve short-term speculation, even where the date of expiration of the option makes the option exempt from certain Securities and Exchange Commission restrictions.

The writing of a call or the acquisition of a put also involves a "bet against the company" and therefore presents a clear conflict of interest for you. As a result, neither you, your family members nor controlled entities may trade in standardized options relating to the Company securities at any time.

3. **Hedging Transactions**. Certain forms of hedging or monetization transactions, such as zero-cost collars and forward sale contracts, allow "insiders" to lock in much of the value of his or her stock holdings, often in exchange for all or part of the potential for upside appreciation in the stock. These transactions allow "insiders" to continue to own the covered securities, but without the full risks and rewards of ownership. When that occurs, the "insiders" may no longer have the same objectives as the Company's other shareholders. Therefore, neither you, your family members nor your controlled entities may engage in any such transactions.

4. **Margin Accounts and Pledges.** Securities held in a margin account may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged or hypothecated as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when you are aware of material, nonpublic information or otherwise are not permitted to trade in the Company securities, neither you, your family members nor your controlled entities may hold the Company securities in a margin account or pledge the Company securities as collateral for a loan unless such transaction has been pre-approved by the Company's Chief Financial Officer.

V. POST-TERMINATION TRANSACTIONS

This Policy continues to apply to any and all transactions in the Company's securities following termination of your employment or other services to the Company. If you are in possession of material nonpublic information when you are terminated, you may not trade in the Company's securities until that information has become public or is no longer material. The pre-clearance procedures specified above, however, will cease to apply to transactions in the Company's securities upon the expiration of any blackout period applicable at the time of the termination of service.

VI. REPORTING OF VIOLATIONS

If you know or have reason to believe that this Policy or the Special Trading Procedures described above have been or may be violated, you should bring the actual or potential violation to the attention of the Company's Chief Financial Officer or report it through the Company's secure Corporate Compliance Hotline at (833) 636-3075 or at https://www.whistleblowerservices.com/ZyVersa .

VII. TRAININGS REGARDING INSIDER TRADING

All directors and employees of the Company are required to annually attend trainings hosted or recommended by the Company regarding the laws governing insider trading.

VIII. MODIFICATIONS; WAIVERS

The Company reserves the right to amend or modify the procedures set forth herein at any time. Waiver of any provision of this Policy or the Special Trading Procedures in a specific instance may be authorized in writing by the Company's Chief Financial Officer (or his or her designee).

IX. QUESTIONS

If you have any questions regarding this Policy or the Special Trading Procedures described above, you should contact the Company's Chief Financial Officer.

ACKNOWLEDGMENT

I have read and understand ZyVersa Therapeutics, Inc.'s Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures. I understand that, if I am an employee of the Company or one of its subsidiaries, my failure to comply in all respects with the Company's policies, including the Statement of Company Policy on Insider Trading and Policy Regarding Special Trading Procedures set forth herein, is a basis for termination for cause of my employment from the Company and any subsidiary thereof to which my employment now relates or may in the future relate. I will comply with the Policy for as long as I am subject to the Policy.

Signature: _____

Printed Name: _____ Date: _____

This document states a policy of ZyVersa Therapeutics, Inc. and is not intended to be regarded as the rendering of legal advice. This policy statement is intended to promote compliance with existing law and is not intended to create or impose liability that would not exist in the absence of the policy statement.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Forms S-1 (File No. 333-288470) and Form S-8 (File No. 333-272106, File No. 333-277062, File No. 333-284475), of our report dated March 31, 2026, with respect to the consolidated financial statements of ZyVersa Therapeutics, Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

New York, NY
March 31, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-288470) and Form S-8 (File No. 333-272106, File No. 333-277062, File No. 333-284475) of our report dated March 27, 2025, with respect to the consolidated financial statements of ZyVersa Therapeutics, Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

New York, NY
March 31, 2026

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen C. Glover certify that:

1. I have reviewed this annual report on Form 10-K of ZyVersa Therapeutics, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 31, 2026

/s/ Stephen C. Glover
Stephen C. Glover
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter Wolfe certify that:

1. I have reviewed this annual report on Form 10-K of ZyVersa Therapeutics, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

   a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared;

   b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):

   a. all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

   b. any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 31, 2026

/s/ Peter Wolfe
Peter Wolfe
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF
THE PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of ZyVersa Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Stephen C. Glover, President and Chief Executive Officer of the Company, and Peter Wolfe, Chief Financial Officer of the Company, certify, to the knowledge of the undersigned, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 31, 2026

/s/ Stephen C. Glover
Stephen C. Glover
President and Chief Executive Officer
(*Principal Executive Officer)*

Date: March 31, 2026

/s/ Peter Wolfe
Peter Wolfe
Chief Financial Officer
(*Principal Financial and Accounting Officer)*

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.