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, 2024
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.)
2200 N. Commerce Parkway, Suite 208 Weston, FL 33326	**33326**
(Address of registrant's 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	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ZVSA	The Nasdaq Capital Market

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 whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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). ☐

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

As of June 30, 2024, 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 $3.76 for such shares on the Nasdaq Capital Market on June 28, 2024) was approximately $3.1 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 20, 2025, the number of shares outstanding of the registrant's common stock, $0.0001 par value per share, was 2,568,191.

DOCUMENTS INCORPORATED BY REFERENCE

None.

ZYVERSA THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2024
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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 realize the anticipated benefits of going public through our business combination with Larkspur Health Acquisition Corp., a special purpose acquisition company;
- 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 listing of our securities on The Nasdaq Capital 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"). On January 21, 2020, we filed an Investigational New Drug application ("IND") for VAR 200, and the United States Food and Drug Administration ("FDA") has allowed our development plans to proceed to a Phase 2a trial in patients with FSGS based on the risk/benefit profile of the active ingredient (2HPβCD). Prior to initiating a Phase 2a trial in patients with FSGS, we are planning to initiate a small open-label Phase 2a trial in patients with diabetic kidney disease in H1-2025, in which we expect to obtain patient proof-of-concept data more quickly than in an FSGS trial. This will enable assessment of drug effects as patients proceed through treatment and will provide insights for developing a lager Phase 2a/b protocol in patients with FSGS. VAR 200 has pharmacologic proof-of-concept data in animal models representative of FSGS, Alport Syndrome, and diabetic kidney disease providing opportunity for indication expansion.

Our Inflammasome ASC Inhibitor IC 100 focuses on chronic inflammatory diseases. Our lead indication for IC 100 is obesity with metabolic complications. IC 100's preclinical development is nearing completion. Our focus is on advancing IC 100 toward a currently planned IND submission in H2-2025, followed by initiation of a Phase 1 trial in healthy overweight patients with a BMU between 27 – 30. IC 100 has preclinical data in animal models representing six different indications, each demonstrating that IC 100 attenuates pathogenic inflammasome signaling pathways leading to reduced inflammation and improved histopathological and/or functional outcomes. Those indications are stroke-related cardiovascular injury, retinopathy of prematurity ("ROP"), multiple sclerosis ("MS"), acute respiratory distress syndrome ("ARDS"), spinal cord injury, and traumatic brain injury (TBI). Likewise, preclinical studies are underway in Alzheimer's and Parkinson's diseases, and we are preparing to initiate IND-enabling preclinical studies in animal models of diet-induced obesity.

About Chronic Kidney Disease (CKD)

Chronic kidney disease ("CKD") is an increasing public health problem which affects over 75 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.

CKD is associated with poor prognosis and in 2017, according to the National Vital Statistics Report, CKD was the ninth-leading cause of death in the United States. To address this significant health problem, on July 10, 2019, the White House and Department of Health and Human Services launched the Advancing American Kidney Health ("AAKH") initiative to advance kidney disease prevention and care in the United States, which has three goals: (1) to reduce the number of patients developing renal failure through better diagnosis, treatment, and preventative care; (2) to maximize provision of home dialysis care; and (3) to expand the pool of kidneys available for transplant. We believe that by mediating removal of excess renal intracellular cholesterol that contributes to kidney damage and dysfunction, VAR 200 has the potential to help address the AAKH initiative's first goal to reduce the number of patients developing renal failure.

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, NLRP1, NLRP3, NLRC4, and NLRP6, and Parkinson's disease is associated with activation of AIM2, NLRP1 and NLRP3. 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 this is more advantageous than targeting a specific sensor protein such as NLRP3, a component of only one type of inflammasome, which is the focus of several potential competitors. 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™ VAR 200.*** We intend to advance development of VAR 200 by initiating a small Phase 2a trial in patients with diabetic kidney disease in H1-2025, in which we expect to obtain patient proof-of-concept data more quickly than in an FSGS trial. This will enable assessment of drug effects as patients proceed through treatment and will provide insights for developing a larger Phase 2a/b protocol in patients with FSGS.

- ***Advance development of Inflammasome ASC Inhibitor IC 100.*** We intend to advance our IC 100 preclinical program toward a planned IND submission in H2-2025 followed by initiation of a Phase 1 trial in healthy patients with a BMI between 27 – 30. This approach has potential to provide an early signal of IC 100's weight loss potential. In preparation for IND submission, we are preparing to initiate two IND-enabling preclinical studies in diet-induced obesity animal models, one to compare the effects of IC 100 with semaglutide, and the other to evaluate the effects of IC 100 in combination with semaglutide.

- ***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™ VAR 200 Platform, FSGS (lead indication), Alport Syndrome, and diabetic kidney disease and four potential indications for our Inflammasome ASC inhibitor IC 100 platform, obesity with certain metabolic complications (lead indication), Parkinson's and Alzheimer's diseases, and multiple sclerosis. 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

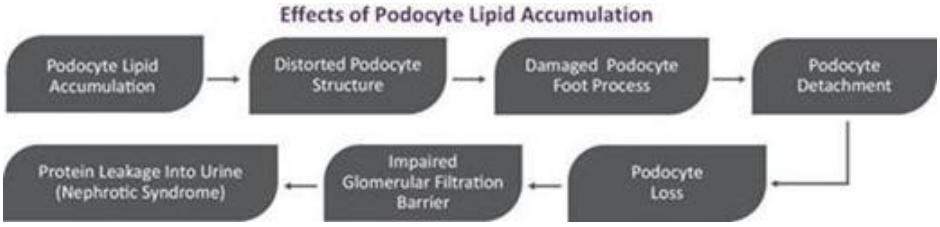
Cholesterol Efflux Mediator ™ VAR 200 (2-hydroxypropyl-beta-cyclodextrin, 2HPβCD)

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. Prior to initiating a Phase 2a trial in patients with FSGS, we are planning to conduct a small Phase 2a trial in patients with diabetic kidney disease, which we expect will provide patient proof-of-concept more quickly than an FSGS study. 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. Although our lead renal indication is FSGS (VAR 200-01), we are planning to initiate a small Phase 2a trial in patients with diabetic kidney disease in H1-2025, in which we expect to obtain patient proof-of-concept data more quickly than in an FSGS trial. This will enable assessment of drug effects as patients proceed through treatment and will provide insights for developing a larger Phase 2a/b protocol in patients with FSGS. Based on the anticipated data and key learnings from these trials, we may progress development of VAR 200 for Alport Syndrome (VAR 200-02) and for diabetic kidney disease (VAR 200-03) based on our indication expansion strategy.

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

In chronic glomerular diseases, cholesterol 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 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 demonstrate that VAR 200 promotes cholesterol 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.

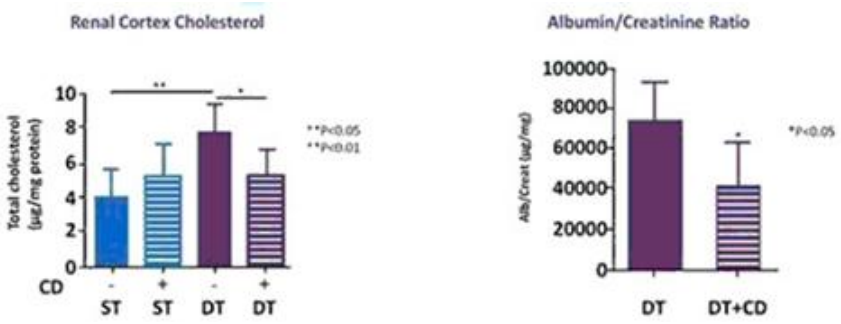
VAR 200 and FSGS

VAR 200 was evaluated in two FSGS mouse models, an experimental nuclear factor of activated T-cells ("NFAT") FSGS model and an Adriamycin ("ADR")-induced FSGS model which is characterized by a milder, less progressive form of nephropathy than the NFAT model.

Nuclear Factor of Activated T-Cells (NFAT) Model

To determine the role of altered podocyte cholesterol homeostasis in NFAT-mediated podocyte injury and the effects of treatment with VAR 200, researchers administered VAR 200 subcutaneously at 4,000 mg/kg to 6-week-old NFATc1^{nuc} mice 24 hours prior to induction with doxycycline, and then every other day for 4 days. Single transgenic ("ST") mice served as a control.

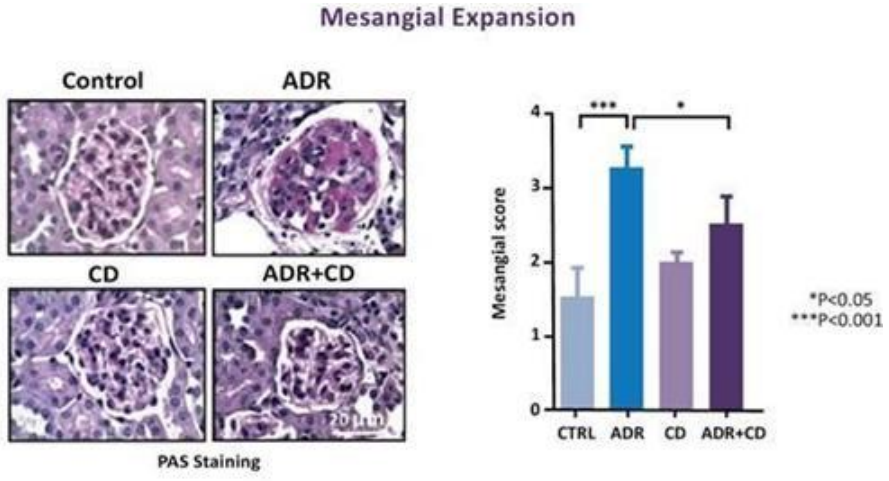
VAR 200 (indicated by "CD" in the graphs below) significantly reduced cholesterol in the renal cortex of FSGS mice compared to untreated double transgenic mice (indicated by "DT" in the graphs below). This was associated with a significant reduction in proteinuria (albumin/creatine ratio) as shown below.



Adriamycin (ADR)-induced Model

In the second FSGS model, researchers injected 5-week-old BALB/c mice with one dose of Adriamycin at 11 mg/kg. Subsequently, VAR 200 was administered 24 hours later at 40 mg/kg via subcutaneous osmotic pump for 10 weeks. Non-induced mice served as a control.

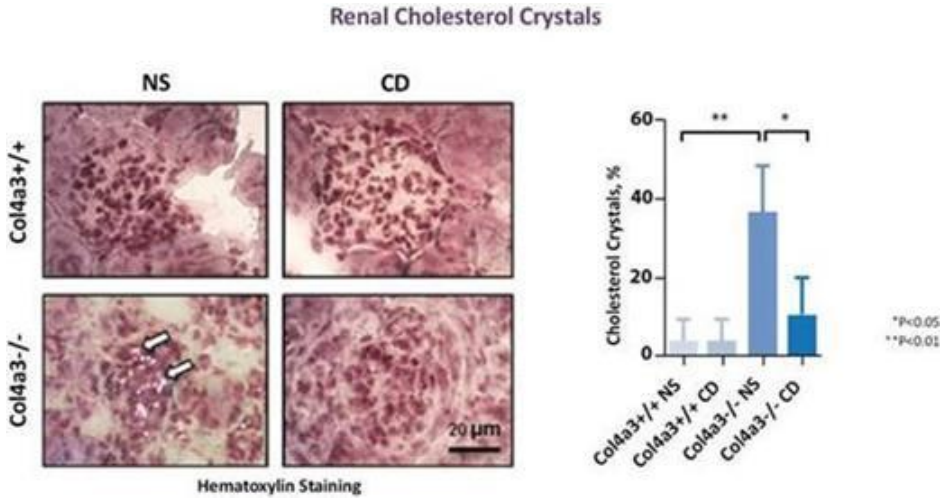
VAR 200 (indicated by "CD" in the graphs below) significantly reduced mesangial expansion, which is commonly associated with lipid deposition, compared to untreated ADR-induced mice as shown below. This was associated with a significant reduction in proteinuria (albumin/creatine) and blood urea nitrogen ("BUN") in VAR 200-treated) ADR-induced mice compared to untreated ADR-induced mice as shown below.



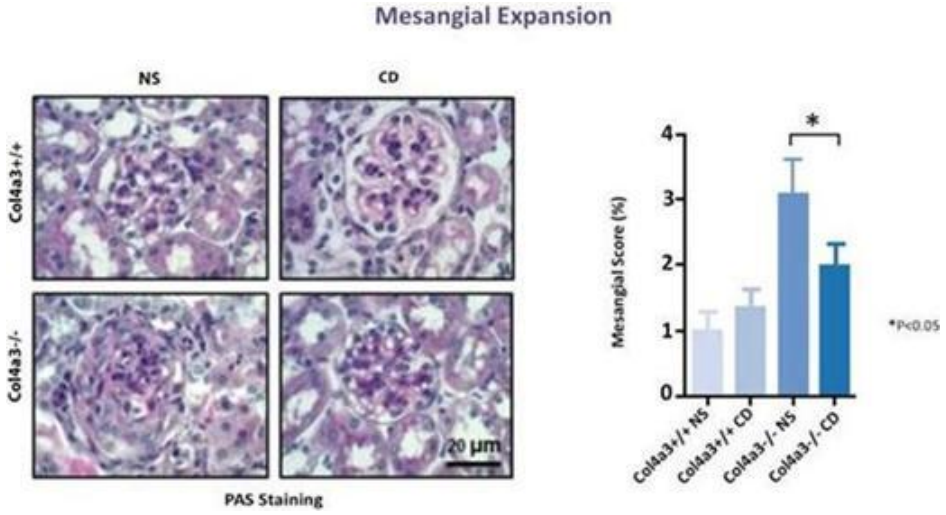
VAR 200 and Alport Syndrome

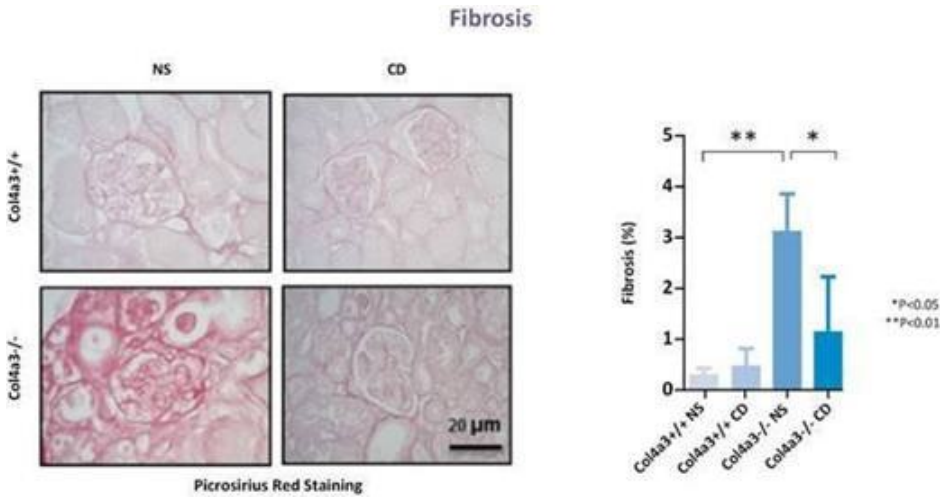
To evaluate whether VAR 200 has a protective effect in Alport Syndrome, a genetic disease, researchers injected four-week-old female Col4a3 knockout (Col4a3−/−) mice with VAR 200 at 4000 mg/kg subcutaneously 3 times per week for 4 weeks. Wild type Col4a3 ("Col43+/+") mice served as controls.

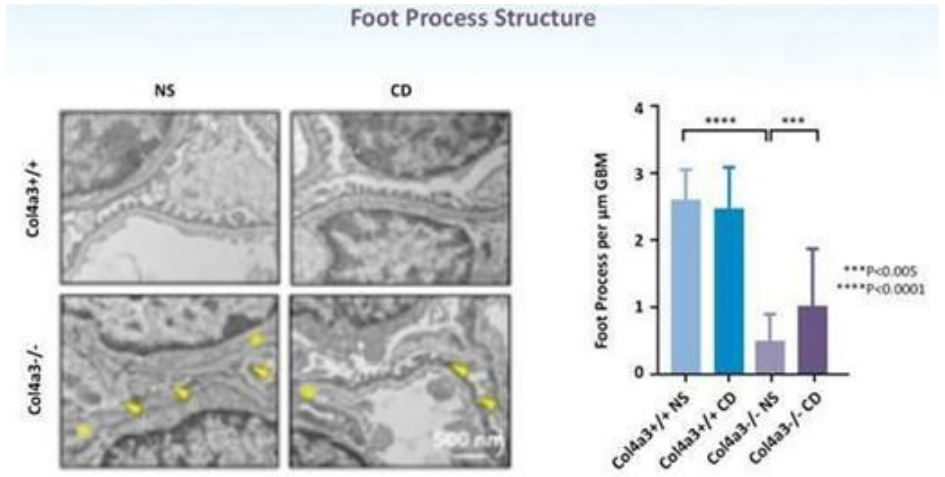
VAR 200 (indicated by “CD” in the graphs below) significantly reduced renal neutral lipid, cholesterol ester, and cholesterol crystal accumulation in Alport Syndrome mice when compared to untreated Alport Syndrome mice as shown below.

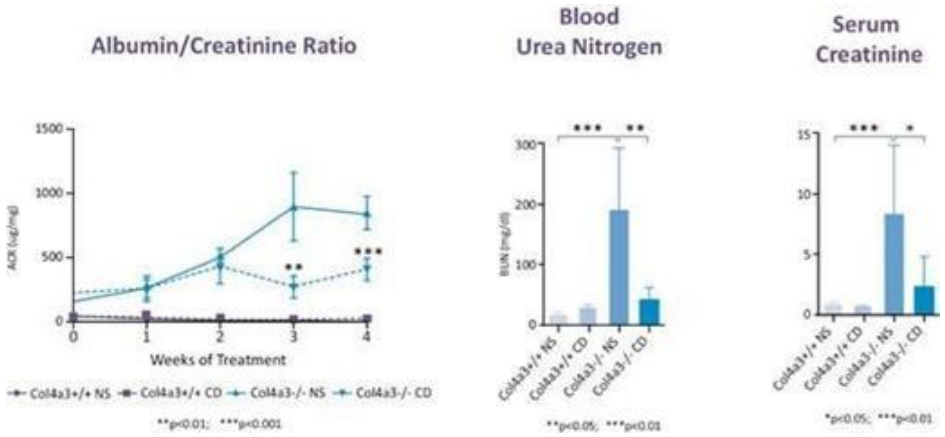


The decreased intracellular lipids in VAR 200-treated Alport Syndrome mice were associated with a significant reduction in renal damage (reduced mesangial expansion, fibrosis, and foot process effacement), and renal function was maintained when compared to untreated Alport Syndrome mice, as evidenced by reduced proteinuria (albumin/creatinine), blood urea nitrogen, and serum creatinine when compared to untreated Alport Syndrome mice as shown below.




Fibrosis
NS
CD
Col4a3+/+
Col4a3-/-
20 µm
Picrosirius Red Staining
Fibrosis (%)
**
*
*P<0.05
**P<0.01
Col4a3+/+ NS
Col4a3+/+ CD
Col4a3-/- NS
Col4a3-/- CD

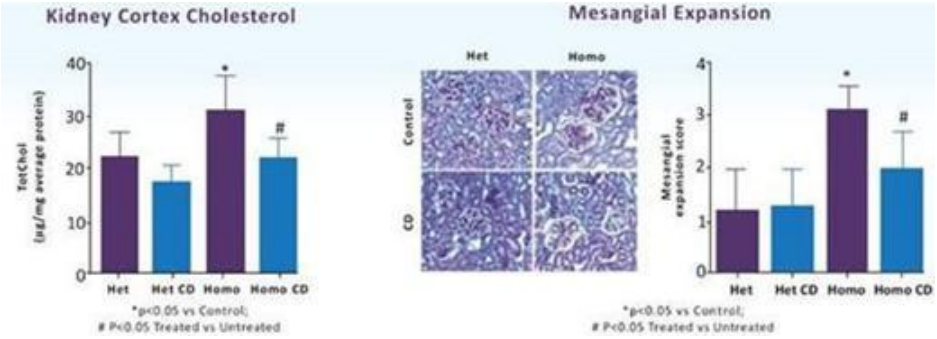

Foot Process Structure
NS
CD
Col4a3+/+
Col4a3-/-
500 nm
Foot Process per µm GBM
****
***
***P<0.005
****P<0.0001
Col4a3+/+ NS
Col4a3+/+ CD
Col4a3-/- NS
Col4a3-/- CD

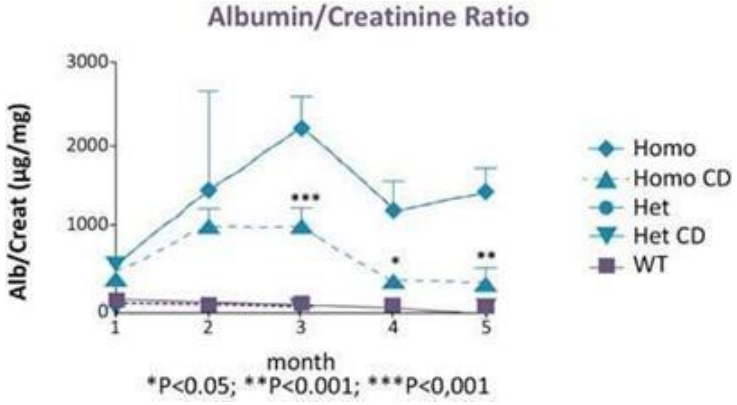

Albumin/Creatinine Ratio
Weeks of Treatment
Col4a3+/+ NS
Col4a3+/+ CD
Col4a3-/- NS
Col4a3-/- CD
**p<0.01; ***p<0.001
Blood Urea Nitrogen
***p<0.05; ***p<0.01
Serum Creatinine
*p<0.05; ***p<0.01

VAR 200 and Diabetic Kidney Disease

To determine if VAR 200 can sequester intracellular cholesterol and protect podocytes from cholesterol-dependent damage in diabetic kidney disease, researchers treated 4-week old BTBR ob/ob homozygous mice, a diabetic model of progressive kidney disease, with 3 weekly subcutaneous injections of VAR 200 at 4,000 mg/kg for 5 months. Heterozygous mice served as controls.

VAR 200 (indicated by "CD" in the graphs below) significantly reduced total cholesterol in the kidney cortex compared with untreated diabetic mice. This was associated with a significant reduction in renal damage (mesangial expansion) and reduced proteinuria (albumin/creatinine) compared to untreated diabetic mice starting at 2 months following treatment, with statistically significant reduced levels from 3 months to end of study as shown below.





Based on the results in animal models of 3 different renal diseases summarized above, we believe that VAR 200 has potential to induce and maintain partial or complete remission of proteinuria in renal patients with nephrotic syndrome, thereby reducing the rate of renal disease progression.

Inflammasome ASC Inhibitor IC 100

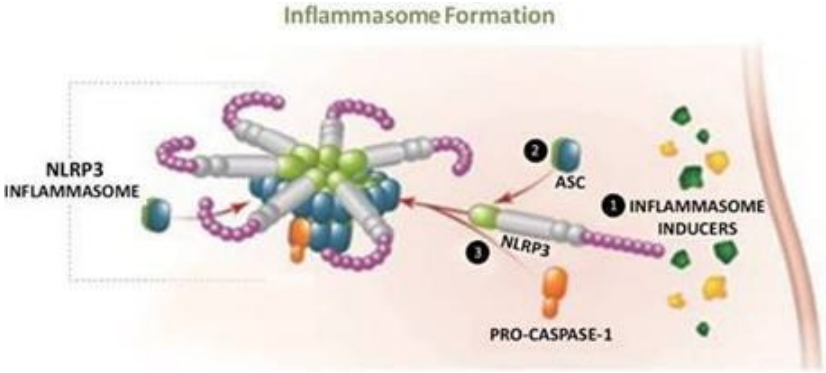
IC 100 is a humanized monoclonal antibody inflammasome ASC inhibitor in preclinical development for the treatment of numerous inflammatory diseases, with obesity with certain metabolic complications as the lead. IC 100 was developed with the intent of attenuating chronic aberrant inflammation that is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

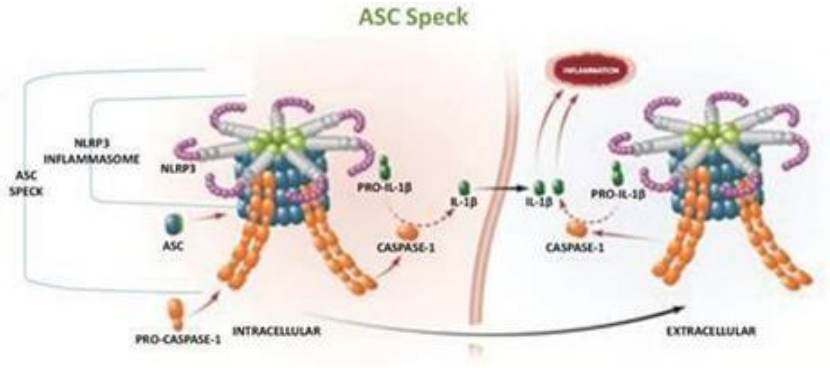
Our focus is on advancing IC 100 toward a planned submission of an IND application in H2-2025, following which we intend to initiate a Phase 1 trial in healthy subjects who are overweight (BMI 27 -30). Non-GLP toxicology data with IC 100 in mice and non-human primates ("NHP") demonstrate no adverse effects nor anti-drug antibodies at doses as high as 300 mg/kg. IC 100 has preclinical data in animal models representing six different indications, each demonstrating that IC 100 attenuates pathogenic inflammasome signaling pathways leading to reduced inflammation and improved histopathological and/or functional outcomes. Those indications are stroke-related cardiovascular injury, retinopathy of prematurity ("ROP"), multiple sclerosis ("MS"), acute respiratory distress syndrome ("ARDS"), spinal cord injury, and traumatic brain injury (TBI). Likewise, preclinical studies are underway in Alzheimer's and Parkinson's diseases, and we are preparing to initiate two IND-enabling preclinical studies with IC 100 in DIO obesity models. One study will compare the effects of IC 100 to semaglutide, and the other will compare the effects of IC 100 administered concurrently with semaglutide.

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.

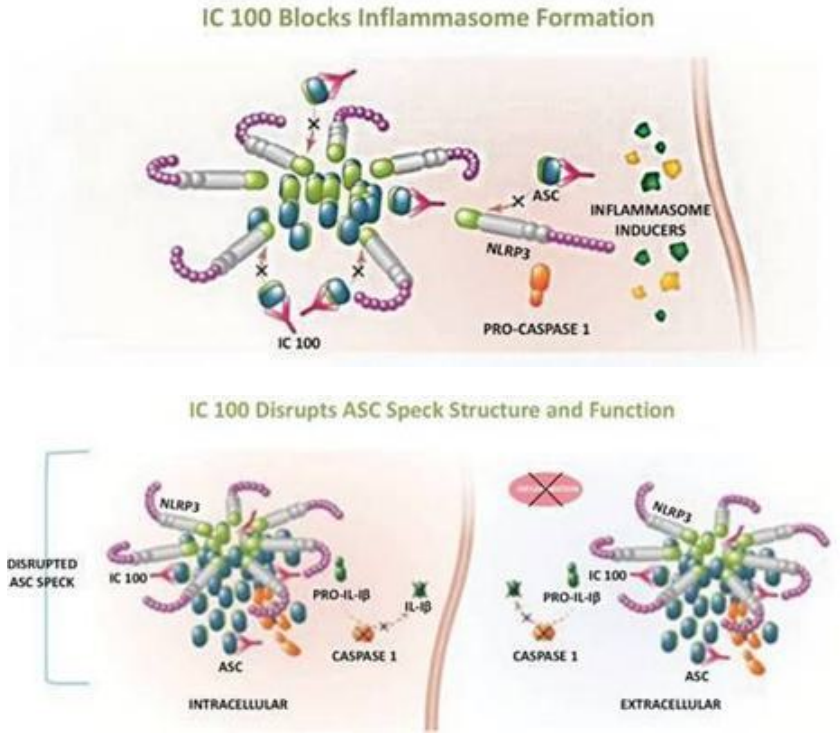




Inflammasome ASC Inhibitor IC 100 Mechanism of Action

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 recent 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 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

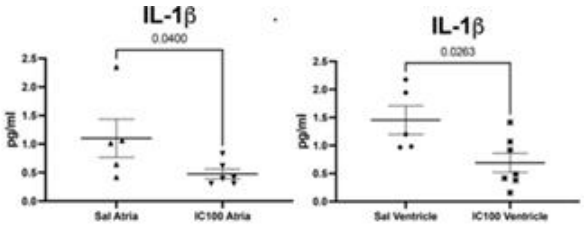
Non-GLP toxicology studies in mice and non-human primates demonstrate that IC 100 has a good safety profile. There were no drug-related adverse events at doses up to 300 mg/kg in either species. Likewise, epigenetic screening demonstrates a lower immunogenicity potential than many biologics. Based on our preclinical study in an animal model representing MS, inflammation was attenuated without immunosuppression. IC 100 has preclinical data in animal models representing six different indications, each demonstrating that IC 100 attenuates pathogenic inflammasome signaling pathways leading to reduced inflammation and improved histopathological and/or functional outcomes. Those indications are stroke-related cardiovascular injury, retinopathy of prematurity ("ROP"), multiple sclerosis ("MS"), acute respiratory distress syndrome ("ARDS"), spinal cord injury, and traumatic brain injury (TBI). Following is a summary of preclinical data in stroke-related cardiovascular injury, ROP, and MS. For an overview of preclinical data collected to date, refer to the IC 100 White Paper at https://investors.zyversa.com/static-files/64964310-ab95-4a06-bc47-dd44c63dc5c7.

IC 100 and Stroke-related Cardiovascular Injury

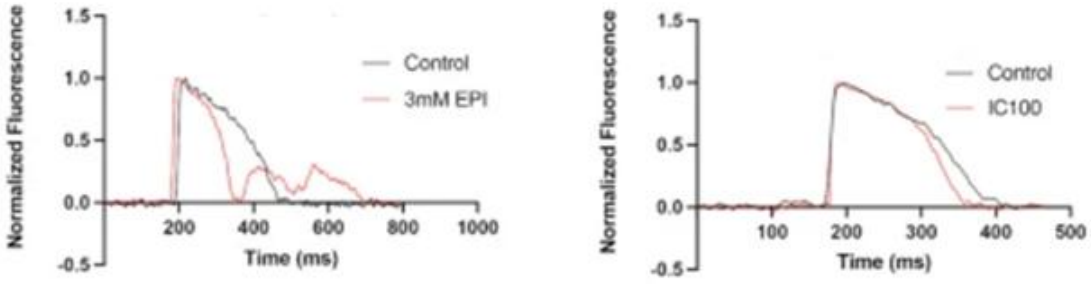
Cardiac dysfunction occurs in 70% of patients following a stroke which is associated with a surge of catecholamines and inflammasome-induced systemic and cardiac inflammation. To determine if IC 100 can attenuate post-stroke cardiac inflammation, IC 100 was administered IV at 30 mg/kg in a mouse model of photothrombotic stroke (PTS) thirty minutes post-PTS. Additionally, catecholamine-treated zebrafish hearts were used to determine if IC 100 can protect against post-stroke cardiac dysfunction. Action potential duration was evaluated in excised zebrafish hearts with and without IC 100 (10 μg/ml) 20 seconds after catecholamine treatment.

IC 100 attenuated cardiac inflammation post-stroke based on significant reductions in IL-1β, and it improved cardiac function as evidenced by attenuation of the shortened action potential duration depicted in the images below.

IL-1β Levels in Mouse Atria and Ventricles



Ventricular Action Potential Traces from Excised Zebra Fish Hearts Exposed to Epinephrine



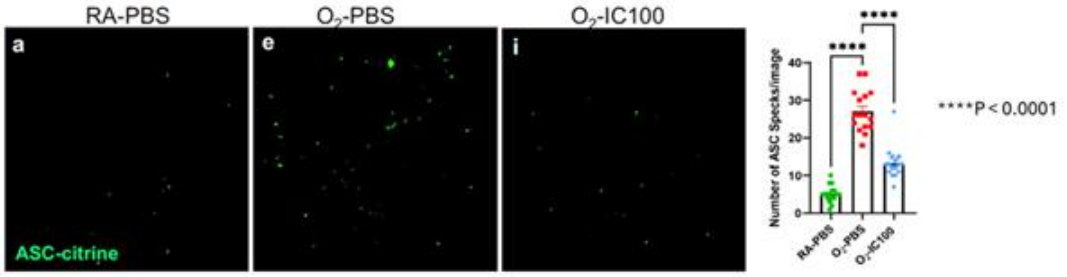
These data suggest that IC 100 has potential to attenuate stroke-related cardiovascular disease.

IC 100 and ROP

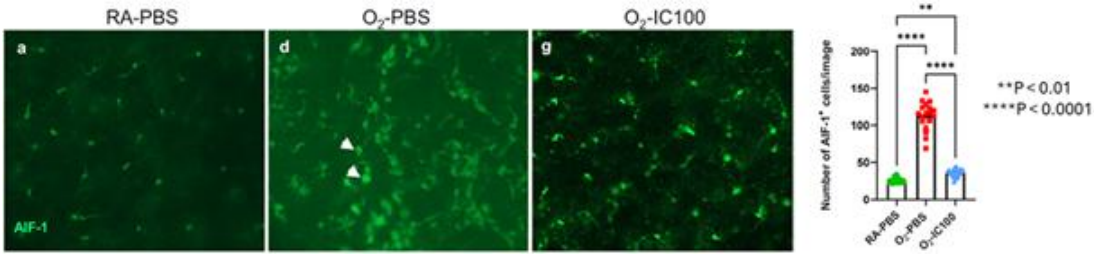
To determine if IC 100 has potential to attenuate retinal microglial activation and inflammation leading to retinopathy and impaired vision, IC 100 was administered immediately after 5 days of 75% O2 exposure by multiple IP injections of 10 or 20 µg/g or by single IVT injection of 2.5 µg/0.5 µL per eye in an oxygen-induced mouse model of retinopathy (OIR models).

IC 100 attenuated retinal inflammation as evidenced by a 55% reduction in retinal ASC speck formation, and it reduced microglial density and activation compared to the placebo-treated oxygen-exposed retina (02-PBS), as depicted below.

Retinal ASC Speck Formation

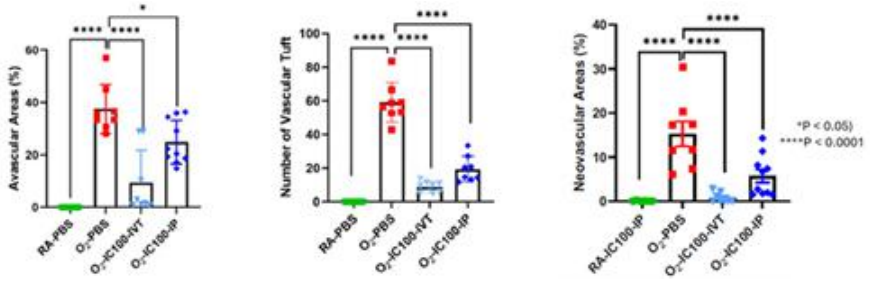


Retinal Microglial Density and Activation



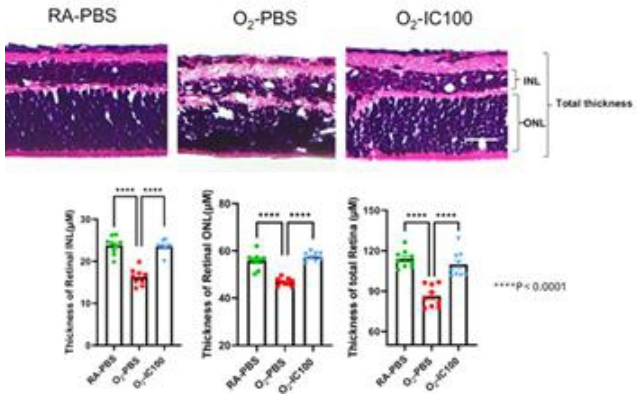
IC 100 alleviated vaso-obliteration. Compared to the placebo-treated oxygen-exposed retina (0_2-PBS), IC 100 reduced the percentage of avascular areas, the number of vascular tufts, and the percentage of intravitreal neovascularization, as depicted below.

Quantification of Avascular Areas, Vascular Tufts, and Neovascular Areas

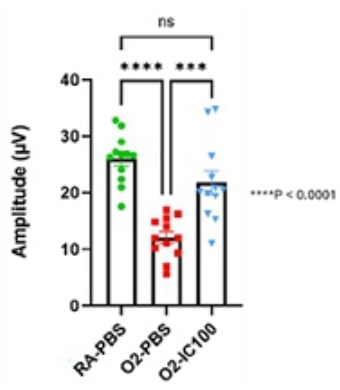


IC 100 restored retinal structure. With IC 100 the thickness of the inner nuclear layer (INL), outer nuclear layer (ONL), and total retinal layer was comparable to the placebo control (RA-PBS). IC 100 also restored retinal function. With IC 100 there was a 70% increase in amplitude compared to the placebo-treated oxygen-exposed retina (02-PBS). Results are depicted below.

Retinal Layer Thickness



Amplitude

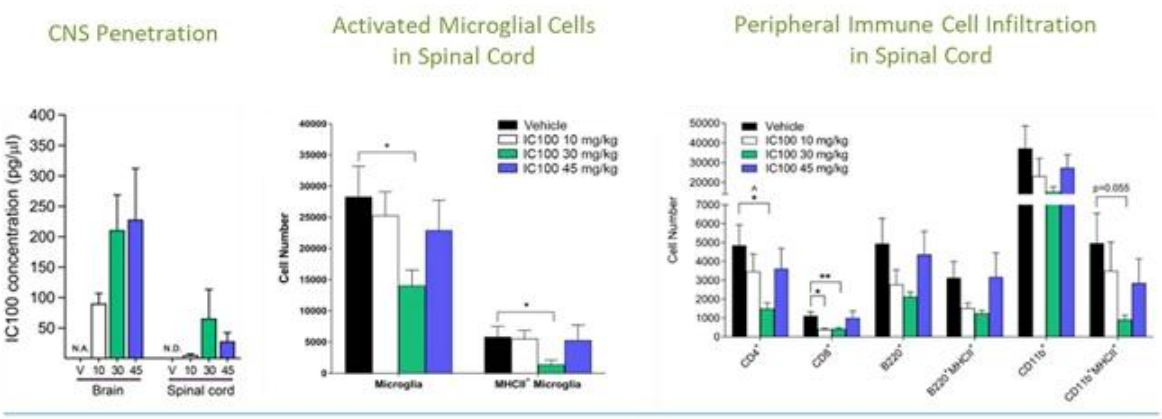


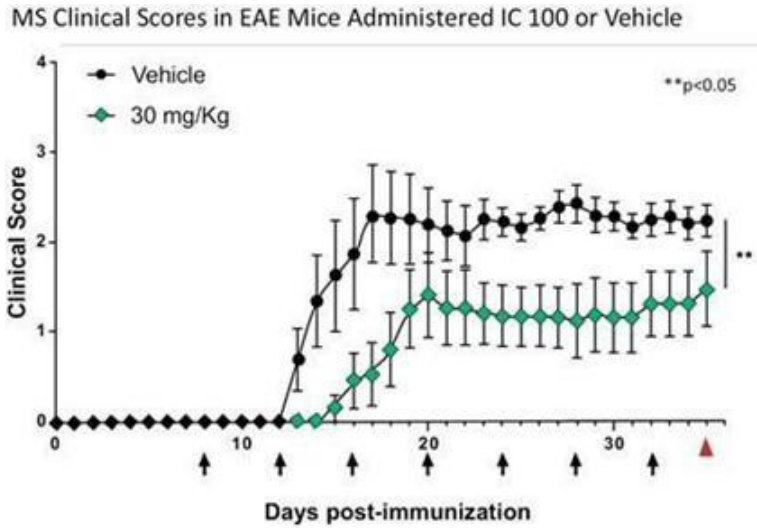
These data demonstrate that inhibition of ASC speck formation by IC 100 in an animal model of retinopathy of prematurity reduced retinal inflammation and its resulting structural damage and dysfunction.

IC 100 and MS

To determine if IC 100 protects against MS progression, researchers induced active experimental autoimmune encephalomyelitis ("EAE") in C57BL/6 mice through immunization with myelin oligodendrocyte glycoprotein peptide 35 – 55 ("MOG35 – 55"). IC 100 was administered via intraperitoneal ("IP") injection at 10, 30, or 45 mg/kg on day 8 before appearance of clinical symptoms, followed by treatment every 4 days for 32 days. Vehicle served as a control.

IC 100 penetrated the spinal cord and decreased the number of spinal cords activated microglial CD4+, CD8+, and myeloid cells. This was associated with delayed onset and significantly improved functionality based on MS clinical scores as shown below.



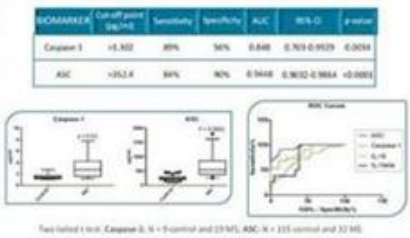


ASC as a Biomarker

Biomarkers are valuable tools to predict, diagnose, and monitor disease progression. They can also be used to target patients who are likely to respond to specific treatments, and to monitor ongoing efficacy of those treatments over time.

Researchers at the University of Miami evaluated serum inflammasome proteins as potential biomarkers for inflammatory disorders and identified ASC as a potential candidate. Serum ASC levels were elevated in patients with various inflammatory disorders when compared to healthy people. Additionally, when compared to caspase-1 as a biomarker in patients with multiple sclerosis, ASC had a similar sensitivity to caspase-1, but a significantly higher specificity than caspase-1.

Disease/Condition	ASC (pg/ml)
Multiple Sclerosis	> 352.4
Depression	> 273.7
Stroke	> 404.8
TBI	> 275
Mild Cognitive Impairment (MCI)	> 264.9
Healthy	< 195.3



ASC levels have been demonstrated to correlate with disease outcomes and disease severity, for example:

- In brain injured patients, levels of ASC proteins within the first 5 days after injury were predictive of outcomes 5 months after trauma.
- In patients with MS segmented into those with mild or moderate disease severity, serum ASC levels were higher in patients with moderate versus mild disease.

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 Parkinson's and Alzheimer's diseases, and multiple sclerosis in addition to its lead indication, obesity with certain metabolic complications.

Cholesterol Efflux Mediator™ VAR 200 Opportunity

According to a report from Precedence Research, the global renal drug market was $17.71 billion in 2024 and projected to reach $30.3 billion by 2034. There are two key drivers of this growth. The first is the significant increase in obesity and diabetes which leads 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, such as creation of a kidney-on-a chip, which accurately mimics human kidney filtration, and availability of genomic and multiomic data. Both of these technologies have facilitated a better understanding of the molecular mechanisms underlying kidney disease. A more recent growth driver for the renal drug market is an expected regulatory change that that will shorten the regulatory path for drugs in development for FSGS based on recommendations from the Parasol project. 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. It is believed that the FDA will adopt this recommendation based on Dr. Thompson's statement that data supporting the recommendation came from over 25 studies conducted all over the globe and involved more than 1,600 patients, providing a robust foundation for informed regulatory decisions.

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.

Condition	Overview	U.S. Prevalence	Unmet Needs
Multiple Sclerosis	Inflammatory disease that attacks myelinated axons in CNS leading to loss of muscle control, incontinence, paralysis of lower extremities, and mental dysfunction	1 Million[1]	Current drugs don't effectively delay/halt disease progression, and none are neuroprotective
Parkinson's Disease	Complex, multifaceted, neurodegenerative disorder involving aging, genetics, and environmental factors	~1 Million[2]	No neuroprotective or disease-modifying therapies
Alzheimer's Disease	Decline in mental function that progresses to dementia	6.7 Million[3]	No drugs delay prevention of impairment
Obesity/Overweight	Abnormal or excessive fat accumulation that presents a risk to health (body mass index over 30)	208.5 Million[4]	Current drugs don't preserve muscle mass nor protect against inflammatory comorbidities

References:

1. National Multiple Sclerosis Society
2. Parkinson's Foundation
3. Alzheimer's Association
4. GBD 2021 US Obesity Forecasting Collaborators. Lancet. 2024 Dec 7;404(10469):2278-2298

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 $1.8 million for the year ended December 31 2024 and $3.2 million for the year ended December 31, 2023.

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, fibrosis, and vasoconstriction. 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 addresses lipid accumulation in the glomerulus. 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 included heart disease, Parkinson’s disease, melanoma, type 2 diabetes, cancer-related oral mucositis, Hidradenitis Suppurativa, and obesity at risk of cardiovascular disease. One company has a phase 3 trial underway in small cell lung cancer. 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, 2024, we had seven (7) 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

An investment in our common stock is speculative and involves a high degree of risk including the risk of a loss of your entire investment. You should carefully consider the risks and uncertainties described below and the other information contained in this report and our other reports filed with the Securities and Exchange Commission. The risks set forth below are not the only ones facing us. Additional risks and uncertainties may exist that could also adversely affect our business, operations and financial condition. If any of the following risks actually materialize our business, financial condition and/or operations could suffer. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock.

Summary

Our business is subject to numerous risks and uncertainties. The following summarizes key risks and uncertainties that could materially adversely affect us. You should read this summary together with the more detailed risk factors contained below.

- Our current or future product candidates may never be approved or achieve commercial market acceptance;
- We are a development stage company with a limited operating history and no revenues and there are a number of factors that may affect our business prospects;

- 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;
- We will need additional capital to develop and commercialize our product candidates. If we are unable to raise sufficient capital, we would be forced to delay, reduce or eliminate our product development programs;
- Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates, in particular VAR 200 and IC 100;
- Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration;
- We may not realize the anticipated benefits of our business, and any acquisition, strategic relationship, joint venture or investment could disrupt our business and harm our operating results and financial condition;
- If we are unable to manage our growth and expand our operations successfully, our reputation, brands, business and results of operations may be harmed;
- We are subject to risks related to our dependency on our key management members and other key personnel, as well as attracting, retaining and developing qualified personnel in a highly competitive talent market;
- We may be subject to litigation risks and may face liabilities and damage to our professional reputation as a result;
- Our business is subject to extensive domestic and foreign regulations that may subject us to significant costs and compliance requirements;
- We may be subject to risks related to our status as an emerging growth company within the meaning of the Securities Act;
- Failure to achieve and maintain effective internal control over financial reporting could result in our failure to accurately or timely report our financial condition or results of operations which could have a material adverse effect on our business and stock price;
- We may be unable to continue as a going concern.
- If our estimates or judgments relating to our critical accounting policies prove to be incorrect, our operating results could be adversely affected;
- The requirements of being a public company may strain our resources, result in litigation and divert management's attention;
- An active trading market for our Common Stock may never develop or be sustained;
- The price of our Common Stock may be volatile, which could result in substantial losses for investors;
- Claims by third parties that we infringe or misuse their proprietary technology could subject us to significant liability and could force us to redesign our services and products or to incur significant costs; and
- If we are unable to protect our intellectual property effectively, our business would be harmed.

Risks Related to Our Business, Financial Position and Need for Capital

Our current and future product candidates may never be approved or achieve commercial market acceptance.

Our success depends on the market's confidence that we can develop product candidates for patients with high unmet medical needs, optimize health outcomes and improve patients' quality of life. Failure of our current and future product candidates, or those jointly developed with our collaborators, to develop or perform as expected could significantly impair our business. We and our collaborators may not succeed in achieving commercial market acceptance for our current or future product candidates due to a number of factors, including:

- the impact of our investments in product innovation and commercial growth;
- our ability to demonstrate the utility of our platform and their potential advantages over existing technologies to academic institutions, biopharmaceutical companies and the medical community;
- our ability, and that of our collaborators, to comply with FDA and other regulatory requirements; and
- the rate of development of our product candidates and reputation among academic institutions, key opinion leaders and advocacy groups.

Additionally, our business could be negatively impacted due to changes in our research and development plans, financial constraints, the regulatory environment, negative publicity about our product candidates or competing products both of which are circumstances outside of our control. We may not be successful in addressing these or other factors that might affect the market acceptance of our product candidates and technologies. Failure to develop, obtain approval or achieve commercial market acceptance of our product candidates could materially harm our business, financial condition and results of operations.

We are a development stage company with a limited operating history and no revenues, and there are a number of factors that may affect our prospects.

We are a development stage pharmaceutical company with a limited operating history and no revenues. The likelihood of success of our business plan must be considered in light of the problems, substantial expenses, difficulties, complications and delays frequently encountered in connection with developing and expanding early-stage businesses and the regulatory and competitive environment in which we operate. Pharmaceutical and biopharmaceutical product development is a highly speculative undertaking, involves a substantial degree of risk and is a capital-intensive business. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by development stage pharmaceutical companies such as our Company, and note that we cannot assure you that we will be able to successfully address these risks.

Our operations to date have been primarily limited to our organizational and capital-raising activities, negotiating our license agreements, and conducting development activities for VAR 200 and IC 100. We have not demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, conduct sales and marketing activities necessary for successful product commercialization or manage an operational public company. Because of our limited operating history, we have limited insight into trends that may emerge and affect our business, and errors may be made in developing an approach to address those trends and the other challenges faced by development stage pharmaceutical companies such as our Company. Failure to adequately respond to such trends and challenges could cause our business, results of operations and financial condition to suffer or fail. Further, our limited operating history may make it difficult for our stockholders to make any predictions about our likelihood of future success or viability.

Factors relating to our business that may affect our prospects may include other such as:

- our ability to obtain additional funding to develop and commercialize our product candidates;
- any delays in regulatory review and approval for implementation of our development plans;

- delays in the commencement, enrollment and timing of clinical trials;
- the success of our preclinical and clinical trials through all phases of preclinical and clinical development;
- any delays in regulatory review and approval of our product candidates;
- our ability to obtain and maintain regulatory approval for our product candidates that we seek to develop in the United States and foreign jurisdictions;
- potential side effects of our product candidates that could delay or prevent commercialization, limit the indications for our product candidates, if approved, require the establishment of Risk Evaluation and Mitigation Strategies ("REMS"), cause an approved drug to be taken off the market or subject us to fines and penalties and third-party claims;
- market acceptance of our product candidates, if approved for marketing;
- our dependence on third parties to manufacture and supply our product candidates;
- our dependence on clinical research organizations ("CROs") to conduct our clinical trials;
- our dependence on contract manufacturing organizations ("CMOs") to produce our products for clinical purposes and commercialization;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability to identify, acquire and incorporate other businesses, products and/or technologies;
- our ability to establish and maintain an effective sales and marketing infrastructure, either through the creation of a commercial infrastructure or through strategic collaborations;
- competition from existing products or new products that may emerge;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business;
- our ability to leverage our partners' proprietary technology platform to discover and develop additional product candidates;
- our ability to attract and retain key personnel to manage our business effectively;
- our ability to manage an operational public company and continue to comply with the rules and requirements of the SEC, and the regulations promulgated thereunder, and Nasdaq's listing requirement;
- our ability to build our finance infrastructure and improve our accounting systems and controls;
- potential product liability claims;
- potential liabilities associated with hazardous materials; and
- our ability to obtain and maintain adequate insurance policies.

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, 2024, our accumulated net loss was approximately $179 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. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We may be unable to continue as a going concern.

We are a development stage pharmaceutical company with no commercial products. Our primary product candidates are in the process of being developed and will require significant additional preclinical and clinical development and investment before they could potentially be commercialized. As a result, we have not generated any revenue from operations since inception, and we have incurred substantial net losses to date. Moreover, our cash position is vastly inadequate to support our business plans and substantial additional funding will be needed in order to pursue those plans, which include research and development of our primary product candidates, seeking regulatory approval for those product candidates, and pursuing their commercialization in the United States and other markets. Our independent registered public accounting firm's report for the year ended December 31, 2024, contains an explanatory paragraph that expresses doubt about our ability to continue as a going concern. Those circumstances raise substantial doubt about our ability to continue as a going concern. In particular, we believe that our current cash on hand will only be sufficient to meet our anticipated cash requirements on a month-to-month basis. If we are unable to continue as a going concern, we might have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. In addition, our lack of cash resources and our potential inability to continue as a going concern may materially adversely affect the value of our capital stock and our ability to raise new capital or to enter into critical contractual relations with third parties.

If the Company is not able to maintain an effective system of internal control over financial reporting, the reliability of its financial reporting, investor confidence in the Company and the value of its common stock could be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act ("Section 404"), requires that we evaluate and determine the effectiveness of internal controls over financial reporting and provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

We will need additional capital to develop and commercialize our product candidates. If we are unable to raise sufficient capital, we would be forced to delay, reduce or eliminate our product development programs.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we start clinical trials for VAR 200 and conduct preclinical development of IC 100. We have no commitments or arrangements for any additional financing to fund our development and commercialization efforts for VAR 200, IC 100, or any other product candidate that we may seek to develop. We will need to raise substantial additional capital to develop and commercialize VAR 200, IC 100, and any other product candidate that we may seek to develop. Because successful development of VAR 200 or IC 100 is uncertain, we are unable to estimate the actual funds required to complete their development and commercialization.

Until we can generate a sufficient amount of revenue from VAR 200, IC 100, or any other product candidate that we may seek to develop, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaborations and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or curtail, our operations. To the extent that we raise additional funds by issuing equity securities, or securities convertible into equity securities, the ownership of our then existing stockholders may be diluted, which dilution could be significant depending on the price at which we may be able to sell our securities. Also, if we raise additional capital through the incurrence of indebtedness, we may become subject to additional covenants restricting our business activities, the holders of debt instruments may have rights and privileges senior to those of our equity investors, and servicing the interest and principal repayment obligations under such debt instruments could divert funds that would otherwise be available to support research and development, clinical or commercialization activities. Corresponding, we may not be able to enter into collaborations that we seek to establish. To the extent that we raise additional funds through collaborations and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical and clinical trials for our product candidates;
- whether the FDA requires that we perform additional studies for our product candidates that we seek to develop beyond those that we anticipate;
- the terms and timing of any future collaboration, licensing or other arrangements that we may establish;
- the outcome, timing and cost of regulatory approvals;
- the effect of competing technological and market developments;
- the cost and timing of establishing commercial-scale outsourced manufacturing capabilities;
- market acceptance of our product candidates, if we receive regulatory approval;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates, if we receive regulatory approval; and
- the extent to which we acquire, license or invest in businesses, products or technologies.

We are subject to various U.S. anti-corruption laws and other anti-bribery and anti-kickback laws and regulations.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and other anticorruption, anti-bribery, and anti-money laundering laws in the jurisdictions in which it does business. These laws generally prohibit us and our employees from improperly influencing government officials or commercial parties in order to obtain or retain business, direct business to any person or gain any improper advantage. The FCPA and other applicable anti-bribery and anti-corruption laws also may hold us liable for acts of corruption and bribery committed by our third-party business partners, representatives and agents who are acting on our behalf. We and our third-party business partners, representatives and agents may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities and it may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries and its employees, representatives, contractors and agents, even if it does not explicitly authorize such activities. These laws also require that we keep accurate books and records and maintain internal controls and compliance procedures designed to prevent any such actions. While we have policies and procedures to address compliance with such laws, it cannot assure that its employees and agents will not take actions in violation of its policies or applicable law, for which it may be ultimately held responsible and its exposure for violating these laws increases as its international presence expands and as it increases sales and operations in foreign jurisdictions. Any violation of the FCPA or other applicable anti-bribery, anti-corruption and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, imposition of significant legal fees, loss of export privileges, severe criminal or civil sanctions or suspension or debarment from U.S. government contracts, substantial diversion of management's attention, a drop in our stock price or overall adverse consequences to our business, all of which may have an adverse effect on our reputation, business, financial condition and operating results.

Risks Related to Development, Regulatory Approval and Commercialization

Our operations or those of our third-party providers might be affected by the occurrence of a catastrophic event, such as war or other armed conflicts, geopolitical tensions or trade wars, pandemic or natural disasters.

We rely on consultants, clinical research organizations, and third parties to perform pre-clinical and clinical studies, and manufacturing and regulatory functions. A disruption on our operations, or those of our third-party service providers, due to a major earthquake, other natural disasters, including climate-related events (such as drought, water security, heat waves, cold waves, wildfires, and poor air quality), epidemic, pandemic, war, or other catastrophic event, could cause interruptions to our business operations and our research and development efforts. Climate-related catastrophic events that may harm our business, or that of our third-party service providers, are also increasing in frequency and severity. A catastrophic event affecting us, or our third-party service providers, could have a material adverse effect on our operations and financial condition.

The occurrence of an epidemic or a pandemic, such as the COVID-19 pandemic, has had, and may in the future, have an adverse effect on our operating results. The extent to which epidemics and pandemics impact our financial condition or results of operations will depend on many factors outside of our control and whether there is a material impact on the businesses or productivity of our employees and other partners. A global pandemic may also intensify the other risks described in this Part I, Item 1A of this report.

If we encounter difficulties enrolling patients in our future clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Identifying and qualifying patients to participate in clinical trials will be critical to our success. The timing of current and future clinical trials will depend on the speed at which we can recruit patients to participate in future testing of our product candidates. We may in the future experience difficulties or delays enrolling patients in our clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials, clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating and patient's safety concerns over participating in a clinical trial. We will be required to identify and enroll a sufficient number of patients for any clinical trial for our product candidates. Potential patients may not be adequately diagnosed or identified with the diseases which we are targeting or may not meet the entry criteria for our trials. Additionally, some patients may have neutralizing antibodies at titer levels that would prevent them from being enrolled in a clinical trial for any of our product candidates. As a consequence, enrollment in our clinical trials may be limited or slowed. We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for such future clinical trials. We may not be able to identify, recruit, and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a trial. If we have difficulty enrolling a sufficient number of patients to conduct clinical trials on our product candidates, we may need to delay, limit, or terminate future clinical trials, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our business is dependent on the successful development, regulatory approval and commercialization of our product candidates, in particular VAR 200 and IC 100.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization or partnering of our product candidates. In the future, we may also become dependent on just one of our product candidates or any future product candidates that we may in-license, acquire or develop. The preclinical and clinical and commercial success of our product candidates will depend on a number of factors, including the following:

- the ability to raise additional capital on acceptable terms, or at all;
- timely completion of our clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the FDA, or similar foreign regulatory agencies to conduct additional preclinical or clinical trials beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities, the safety and efficacy of our product candidates or any future product candidates;
- our ability to identify an active compound within the drug product that can be detected in a pharmacokinetics study;
- the prevalence, duration and severity of potential side effects experienced in connection with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;
- the ability of third parties with whom we contract to manufacture clinical trial and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMP, or good agricultural and collection practices, or GACP;
- a continued acceptable safety profile during preclinical and clinical development and following approval of our product candidates or any future product candidates;
- our ability to successfully commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- acceptance by physicians, patients and payors of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;

- our ability to comply with numerous post-approval regulatory requirements;
- our and our partners' ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates;
- our and our partners' ability to avoid third-party patent interference or intellectual property infringement claims; and
- our ability to in-license or acquire additional product candidates or commercial-stage products that we believe we can successfully develop and commercialize.

VAR 200 may not obtain an FDA designation as an Orphan Drug for FSGS. The FDA received our submission for Orphan Drug Designation on September 17, 2018. Orphan Drug Designation was unable to be granted because (1) the FSGS preclinical model used to support the request reflected prevention rather than treatment of FSGS, which was the proposed indication for VAR 200, and (2) the FDA felt that the prevalence estimate provided was underestimated based on the assumptions and calculations used. We plan to reapply for Orphan Drug Designation when clinical data are available for VAR 200, using additional information to support the prevalence rate of FSGS.

If we are unable to achieve one or more of the above factors, many of which are beyond our control, in a timely manner or at all, we could experience significant delays and increased costs or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot assure you that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue operations.

Preclinical drug development for our product candidate IC 100 is very expensive, time-consuming and uncertain. Our preclinical trials may fail to adequately demonstrate pharmacologic activity in therapeutic areas of interest; cause unintended short- or long-term effects in other bodily systems; or produce unexpected toxicity that may alter or risk benefit assessment. The class of compounds reflective of IC 100 has not entered into clinical trials, and the effects of the pharmacologic class are unknown. These and other factors could prevent or delay further development.

The scientific discoveries that form the basis for our efforts to generate and develop its product candidates are relatively recent. The scientific evidence to support the feasibility of developing agents based on our approach is both preliminary and limited. IC 100 represents a novel therapeutic modality and the successful development may require additional studies and efforts to optimize its therapeutic potential. IC 100 may not demonstrate in patients the therapeutic properties ascribed to it in the laboratory or preclinical studies, and may interact with human biological systems in unforeseen, ineffective or even harmful ways. If we are unable to successfully develop and commercialize IC 100 it may never become profitable and the value of its capital stock may decline.

IC 100 is a relatively novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.

We have concentrated its research and development efforts on a limited number of initial targeted disease indications. There can be no assurance that we will not experience problems or delays in developing its current or future indications and that such problems or delays will not cause unanticipated costs, or that any such development problems can be solved. Preclinical data generated on IC 100 along with a proposed clinical development plan requires review and allowance by the FDA under an Investigational New Drug Application. We have not generated the data to support such an application, and the results of preclinical studies will require FDA review prior to the initiation of clinical studies which may not be granted.

We may not be successful in our efforts to use and expand our development platform to build a pipeline of product candidates.

A key element of our strategy for IC 100 is to use its experienced management and scientific team to evaluate IC 100 in broad range of human disease in order to build a pipeline of product candidates. Although our research and development efforts to date have resulted in potential product candidates, we may not be able to continue to identify and develop additional product candidates. Even if we are successful in continuing to build its pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, these potential product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to its financial position. There is no assurance that we will be successful in its preclinical and clinical development, and the process of obtaining regulatory approvals will, in any event, require the expenditure of substantial time and financial resources.

Clinical drug development for our product candidates is very expensive, time-consuming and uncertain. Our clinical trials may fail to adequately demonstrate the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization.

Clinical drug development for our product candidates is very expensive, time-consuming, difficult to design and implement and its outcome is inherently uncertain. Before obtaining regulatory approval for the commercial sale of a product candidate, we must demonstrate through clinical trials that a product candidate is both safe and effective for use in the target indication, which is impossible to predict. Most product candidates that commence clinical trials are never approved by regulatory authorities for commercialization. Our product candidates are in various stages of development and a failure of one more clinical trial can occur at any stage of testing or at any time during the trial process. We expect that clinical trials for these product candidates will continue for several years, but may take significantly longer than expected to complete. Not all of our product candidates have been tested in humans and the first use in humans may reveal unexpected effects. We have not completed all clinical trials for the approval of any of our product candidates.

We may experience delays in ongoing and future clinical trials for our product candidates and do not know if future clinical trials, if any, will begin on time, need to be redesigned, enroll adequate number of patients on time or be completed on schedule, if at all. In addition, we, any partner with which we currently or may in the future collaborate, the FDA, an Institutional Review Board (an "IRB") or other regulatory authorities, including state and local agencies and counterpart agencies in foreign countries, may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including:

- discovery of safety or tolerability concerns, such as serious or unexpected toxicities or side effects or exposure to otherwise unacceptable health risks, experienced by study participants or other safety issues;
- lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;
- slower than expected rates of subject recruitment and enrollment rates or inability to enroll a sufficient number of patients in clinical trials resulting from numerous factors, including the prevalence of other companies' clinical trials for their product candidates for the same indication, or clinical trials for indications for which patients do not as commonly seek treatment;
- delays or difficulties in our clinical trials due to quarantines or other restrictions resulting from the COVID-19 pandemic;
- difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- difficulty in obtaining IRB approval for studies to be conducted at each clinical trial site;
- delays in manufacturing or obtaining, or inability to manufacture or obtain, sufficient quantities of materials for use in clinical trials;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- changes in applicable laws, regulations and regulatory policies;

- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective contract research organizations ("CRO"), clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper formulation and dosing;
- failure by us, our employees, our CROs or their employees or other third-party contractors to comply with contractual and applicable regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees or any partner with which we may collaborate or their employees to comply with applicable FDA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for drug and biologic products;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols; or
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data.

We or any partner with which we may collaborate may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. In the event that we or our potential partners abandon or are delayed in the clinical development efforts related to our product candidates, we may not be able to execute on our business plan effectively and our business, financial condition, operating results and prospects would be harmed.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials.

We may be unable to obtain regulatory approval for VAR 200 or IC 100, our early-stage product candidates under applicable regulatory requirements. The FDA and foreign regulatory bodies have substantial discretion in the approval process, including the ability to delay, limit or deny approval of product candidates. The delay, limitation or denial of any regulatory approval would adversely impact commercialization, our potential to generate revenue, our business and our operating results.

We currently have no products approved for sale, and we may never obtain regulatory approval to commercialize any of our current or future product candidates. The research, testing, manufacturing, safety surveillance, efficacy, quality control, recordkeeping, labeling, packaging, storage, approval, sale, marketing, distribution, import, export and reporting of safety and other post-market information related to our drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and in foreign countries, and such regulations differ from country to country. We are not permitted to market any of our current product candidates in the United States until we receive approval of a NDA, BLA or other applicable regulatory filing from the FDA. We are also not permitted to market any of our current product candidates in any foreign countries until we or our partners receive the requisite approval from the applicable regulatory authorities of such countries. To gain approval to market a new drug such as VAR 200 or IC 100, the FDA and/or foreign regulatory authorities must receive, among other things, preclinical and clinical data that adequately demonstrate the safety, purity, potency, efficacy and compliant manufacturing of the drug product for the intended indication applied for in a NDA, BLA or other applicable regulatory filing. The development and approval of new drug products involves a long, expensive and uncertain process, and delay or failure can occur at any stage. A number of companies in the pharmaceutical and biopharmaceutical industry have suffered significant setbacks in nonclinical development, clinical trials, including in Phase 3 clinical development, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Success in clinical trials does not ensure that later clinical trials will be successful, or that nonclinical studies will be successful. The results of clinical trials by other parties may not be indicative of the results in trials we or our partners may conduct.

The FDA and foreign regulatory bodies have substantial discretion in the drug development and approval process, including the ability to delay, limit drug development or limit or deny approval of product candidates for many reasons. The FDA or the applicable foreign regulatory body may:

- disagree with the design or implementation of one or more clinical trials;
- not deem a product candidate safe and effective for its proposed indication, or may deem a product candidate's safety or other perceived risks to outweigh its clinical or other benefits;
- not find the data from preclinical studies and clinical trials sufficient to support approval, or the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or the applicable foreign regulatory body for approval;
- disagree with our interpretation of data from preclinical studies or clinical trials performed by us or third parties, or with the interpretation of any partner with which we may collaborate;
- determine the data collected from preclinical or clinical trials may not be sufficient to support the submission of an IND or NDA, or other applicable regulatory filing;
- require additional preclinical studies or clinical trials;
- identify deficiencies in the formulation, quality control, labeling or specifications of our current or future product candidates;
- require clinical trials in pediatric patients in order to establish pharmacokinetics or safety for this more drug-sensitive population;
- grant approval contingent on the performance of costly additional post-approval clinical trials;
- approve our current or any future product candidates for a more limited indication or a narrower patient population than we originally requested or with strong warnings that may affect marketability;
- not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates;
- not approve of the manufacturing processes, controls or facilities of third-party manufacturers or testing labs with which we contract;
- consider our products a device instead of a drug requiring a different approval process and manufacturing needs;
- consider one of our products a combination product instead of a singular drug requiring additional clinical trials or increased number of patients per study; or
- change its approval policies or adopt new regulations in a manner rendering our clinical data or regulatory filings insufficient for approval.

Any delay, limitation or denial in any applicable regulatory approval for any of our product candidates would delay or adversely impact commercialization of our product candidates and would harm our business, financial condition, operating results and prospects.

Even if our current product candidates or any future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.

The commercial success of any of our current or future product candidates, if approved, will depend significantly on the broad adoption and use of the resulting product by physicians, patients and payors for approved indications, and may not be commercially successful. The degree and rate of adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the effectiveness of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans and other healthcare payors for any of our product candidates that may be approved;
- the cost of treatment with our product candidates in relation to alternative treatments and willingness to pay for the product, if approved, on the part of patients;
- acceptance by physicians, major operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience;
- the revenue and profitability that our product candidate may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our product candidates;
- any FDA requirement to undertake a risk evaluation and mitigation strategy, or REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- our ability to maintain sufficient quantities of supply to meet demand;
- adverse publicity about our product candidates or favorable publicity about competitive products; and
- potential product liability claims.

If any of our current or future product candidates are approved for use but fail to achieve the broad degree of physician and patient adoption necessary for commercial success, our operating results and financial condition will be adversely affected, which may delay, prevent or limit our ability to generate revenue and continue our business.

Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition, and a strong emphasis on developing proprietary therapeutics. Numerous pharmaceutical companies, generic drug companies, biotechnology companies, and academic and research institutions are engaged in the development, patenting, manufacturing, and marketing of health care products competitive with those that we are developing, including Travere, Pfizer, Goldfinch Bio, Boehringer Ingelheim, Astra Zeneca, Sanofi, Novartis, Roche and others. Many of our competitors have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than us. Some of the companies that offer competing products also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. In addition, certain of our product candidates, if approved, may compete with a share of some patients' discretionary budgets and for physicians' attention within their clinical practices.

We anticipate that, if we obtain regulatory approval of our product candidates, we will face significant competition from other approved therapies. If approved, our product candidates may also compete with unregulated, unapproved, off-label, and over the counter treatments. Certain of our product candidates, if approved, will present novel therapeutic approaches for the approved indications and will have to compete with existing therapies, some of which are widely known and accepted by physicians and patients. To compete successfully in this market, we will have to demonstrate that the relative cost, safety and efficacy of our approved products, if any, provide an attractive alternative to existing and other new therapies. Such competition could lead to reduced market share for our product candidates and contribute to downward pressure on the pricing of our product candidates, which could harm our business, financial condition, operating results and prospects.

We expect to face generic or similar type of product competition for our product candidates, which could adversely affect our business, financial condition, operating results and prospects.

Upon the expiration or loss of any patent protection for any of our product candidates that are approved, or upon the "at-risk" launch, despite pending patent infringement litigation against the generic product or its equivalent, by a generic competitor of a generic version of any of our product candidates that are approved, which may be sold at significantly lower prices than our approved product candidates, we could lose a significant portion of sales of that product in a short period of time, which would adversely affect our business, financial condition, operating results and prospects.

Any product candidates that we commercialize, or that any partner with which we may collaborate commercializes, will be subject to ongoing and continued regulatory review.

Even after we or our partners achieve U.S. regulatory approval for a product candidate, if any, we or our partners will be subject to continued regulatory review and compliance obligations. For example, with respect to our product candidates, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. A product candidate's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials or a REMS, to monitor the safety and efficacy of the product. We will also be subject to ongoing FDA obligations and continued regulatory review with respect to, among other things, the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product candidates. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP requirements, with the FDA's good clinical practice, or GCP, or good agricultural and collections practices, or GACP, requirements and good laboratory practice, or GLP, requirements, which are regulations and guidelines enforced by the FDA for all of our product candidates in clinical and preclinical development, and for any clinical trials that we conduct post-approval. To the extent that a product candidate is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

If we, our partners, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our partners to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose other civil or criminal penalties;
- suspend any ongoing clinical trials;
- delay or refuse to approve pending applications or supplements to approved applications filed by us or our potential partners;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us or our partners to initiate a product recall.

The regulations, policies or guidance of the FDA and other applicable government agencies may change, and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We may in the future conduct clinical trials for our product candidates outside the United States and the FDA and applicable foreign regulatory authorities may not accept data from such trials.

We may in the future choose to conduct one or more of our clinical trials outside the United States, including in Canada, Europe and South America. Although the FDA or applicable foreign regulatory authority may accept data from clinical trials conducted outside the United States or the applicable jurisdiction, acceptance of such study data by the FDA or applicable foreign regulatory authority may be subject to certain conditions. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance the FDA or applicable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or applicable foreign regulatory authority does not accept such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

Our product candidates may cause undesirable side effects or have other unexpected properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in post-approval regulatory action.

Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Undesirable side effects caused by product candidates could cause us, any partners with which we may collaborate or regulatory authorities to interrupt, modify, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. Results of clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us, or our potential partners, to cease further development of or deny approval of product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in product liability claims. Any of these occurrences may harm our business, financial condition, operating results and prospects.

Additionally, if we or others identify undesirable side effects, or other previously unknown problems, caused by our product candidates after obtaining U.S. or foreign regulatory approval or other products with the same or related active ingredients, a number of potentially negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require a recall of the product or we or our potential partners may voluntarily recall a product;
- regulatory authorities may require the addition of warnings or contraindications in the product labeling, narrowing of the indication in the product label or field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or institute a REMS;
- we may have limitations on how we promote the product;
- we may be required to change the way the product is administered or modify the product in some other way; the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- the FDA or applicable foreign regulatory authority may require additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product
- sales of the product may decrease significantly;
- we could be sued and held liable for harm caused to patients; and
- our brand and reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us or our potential partners from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing our product candidates.

We may face product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our product candidates could result in injury to a patient or even death. We cannot offer any assurance that we will not face product liability suits in the future, nor can we assure you that our insurance coverage will be sufficient to cover our liability under any such cases.

In addition, a liability claim may be brought against us even if our product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- inability to gain regulatory approval of our product candidates;
- the inability to commercialize our product candidates;
- decreased demand for our product candidates;
- impairment of our business reputation;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions;
- substantial costs of any related litigation or similar disputes;
- distraction of management's attention and other resources from our primary business;
- substantial monetary awards to patients or other claimants against us that may not be covered by insurance; or
- loss of revenue.

We currently maintain product liability insurance coverage, which may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability.

We will need to increase our product liability coverage if any of our product candidates receive regulatory approval, which will be costly, and we may be unable to obtain this increased product liability insurance on commercially reasonable terms, or at all. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and could harm our business, financial condition, operating results and prospects.

If any of our product candidates are approved for marketing and we are found to have improperly promoted off-label uses, or if physicians misuse our products or use our products off-label, we may become subject to prohibitions on the sale or marketing of our products, product liability claims and significant fines, penalties and sanctions, and our brand and reputation could be harmed.

The FDA and other regulatory agencies strictly regulate the marketing and promotional claims that are made about drug and biologic products. In particular, a product may not be promoted for uses or indications that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling and comparative safety or efficacy claims cannot be made without direct comparative clinical data. If we are found to have promoted off-label uses of any of our product candidates, we may receive warning or untitled letters and become subject to significant liability, which would materially harm our business. Both federal and state governments have levied large civil and criminal fines against companies for alleged improper promotion and have enjoined several companies from engaging in off-label promotion. If we become the target of such an investigation or prosecution based on our marketing and promotional practices, we could face similar sanctions, which would materially harm our business. In addition, management's attention could be diverted from our business operations, significant legal expenses could be incurred and our brand and reputation could be damaged. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we are deemed by the FDA to have engaged in the promotion of our products for off-label use, we could be subject to FDA regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment or restructuring of our operations.

We cannot, however, prevent a physician from using our product candidates outside of those indications for use when in the physician's independent professional medical judgment he or she deems appropriate. Physicians may also misuse our product candidates or use improper techniques, potentially leading to adverse results, side effects or injury, which may lead to product liability claims. If our product candidates are misused or used with improper technique, we may become subject to costly litigation by physicians or their patients. Furthermore, the use of our product candidates for indications other than those cleared by the FDA may not effectively treat such conditions, which could harm our reputation among physicians and patients.

We may choose not to continue developing or commercializing any of our product candidates at any time during development or after approval, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates or not to continue commercializing one or more of our approved product candidates for a variety of reasons, including the appearance of new technologies that make our product obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses.

We or our current and prospective partners may be subject to product recalls in the future that could harm our brand and reputation and could negatively affect our business.

We or our current and prospective partners may be subject to product recalls, withdrawals or seizures if any of our product candidates, if approved for marketing, fail to meet specifications or are believed to cause injury or illness or if we are alleged to have violated governmental regulations including those related to the manufacture, labeling, promotion, sale or distribution. Any recall, withdrawal or seizure in the future could materially and adversely affect consumer confidence in our brands and lead to decreased demand for our approved products. In addition, a recall, withdrawal or seizure of any of our approved products would require significant management attention, would likely result in substantial and unexpected expenditures and would harm our business, financial condition and operating results.

If we or any partners with which we may collaborate are unable to achieve and maintain coverage and adequate levels of reimbursement for any of our product candidates for which we receive regulatory approval, or any future products we may seek to commercialize, their commercial success may be severely hindered.

For any of our product candidates that become available only by prescription, successful sales by us or by any partners with which we may collaborate depend on the availability of coverage and adequate reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. The availability of coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and private third-party payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates do not demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. 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.

In addition, the market for our product candidates will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available.

Further, third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, although private third-party payors tend to follow Medicare, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could harm our business, financial condition, operating results and prospects.

Healthcare legislative or regulatory reform measures, including government restrictions on pricing and reimbursement, could have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been legislative and regulatory changes related to the healthcare system that could affect our ability to profitably sell or commercialize any product candidates for which we obtain marketing approval in the future. The potential pricing and reimbursement environment for our product candidates may change in the future and become more challenging due to, among other reasons, policies advanced by the current or any new presidential administration, federal agencies, healthcare legislation passed by Congress, or fiscal challenges faced by all levels of government health administration authorities, or by similar changes in foreign countries. The implementation of any such changes could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects, including our share price and ability to raise capital.

We may also be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could adversely affect our business, operations and financial condition.

Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We are subject to regulation by both the federal government and the states in which we or our partners conduct our business. The laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce either the referral of an individual or in return for the purchase, lease, or order of any good, facility item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, including, for example, the federal civil False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Affordable Care Act, which require manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be provided to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws governing 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.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Achieving and sustaining compliance with these laws may prove costly. In addition, any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental laws or regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the exclusion from participation in federal and state healthcare programs, individual imprisonment or the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Disruptions at the FDA and other government agencies caused by funding shortages, staffing limitations or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the government agency's ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and or modifications to approved drugs or to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. With the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates.

Our business involves the use of hazardous materials and we and our third-party suppliers and manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

The manufacturing activities of our third-party suppliers and manufacturers involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our suppliers' or manufacturers' facilities pending use and disposal. We and our suppliers and manufacturers cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our service providers and others and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party suppliers and manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage.

Our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants, vendors, CROs and any partners with which we may collaborate may engage in fraudulent or other illegal activity. Misconduct by these persons could include intentional, reckless or negligent conduct or unauthorized activity that violates: laws or regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA or foreign regulatory authorities; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations, and serious harm to our reputation. In addition, federal procurement laws impose substantial penalties for misconduct in connection with government contracts and require certain contractors to maintain a code of business ethics and conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our operating results.

Actual or alleged non-compliance with applicable employment laws and regulation may require operational changes and undermine our competitive positioning or have other material adverse effects on our business.

Our business is subject to a variety of employment laws and regulations and may become subject to additional such requirements in the future. Although we believe we are in in material compliance with applicable employment laws and regulations, in the event of a change in requirements, we may be required to modify our operations or to utilize resources to maintain compliance with such laws and regulations. Moreover, we may be subject to various employment-related claims including individual actions, class actions, and government enforcement actions relating to alleged employment discrimination, employee classification and related withholding, wage-hour disputes, labor standards or healthcare and benefit issues in the future. Such claims, regardless of validity, may have a material adverse effect on our business, financial condition, cash flows or other results of operations.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize VAR 200 or IC 100 or our other product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain market access and appropriate reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

In most foreign countries, particularly in the European Union and Japan, prescription drug pricing and/or reimbursement is subject to governmental control. In those countries that impose price controls, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies.

Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay the commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues that are generated from the sale of the product in that country. If reimbursement of any of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, or if there is competition from lower priced cross-border sales, our results of operations will be negatively affected.

As a result of the Business Combination with a special purpose acquisition company, regulatory obligations may impact us differently than other publicly traded companies.

We became a publicly traded company by completing the Business Combination with Larkspur, a special purpose acquisition company (a "SPAC"). As a result of the Business Combination, and the transactions contemplated thereby, our regulatory obligations have, and may continue to impact us differently than other publicly traded companies. For instance, the SEC and other regulatory agencies may issue additional guidance or apply further regulatory scrutiny to companies like us that have completed a business combination with a SPAC. Managing this regulatory environment, which has and may continue to evolve, could divert management's attention from the operation of our business, negatively impact our ability to raise additional capital when needed or have an adverse effect on the price of our common stock.

Risks Related to Our Dependence on Third Parties

We have in the past relied and expect to continue to rely on third-party CROs and other third parties to conduct and oversee our clinical trials and other aspects of product development. If these third parties do not meet our requirements or otherwise conduct the trials as required, we may not be able to satisfy our contractual obligations or obtain regulatory approval for, or commercialize, our product candidates when expected or at all.

We have in the past relied and expect to continue to rely on third-party CROs to conduct and oversee our clinical trials and other aspects of product development. We also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA's regulations and GCPs, which are an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors, and state regulations governing the handling, storage, security and recordkeeping for drug and biologic products. These CROs and other third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical trials and preclinical studies, and control only certain aspects of their activities. We and our CROs and other third-party contractors are required to comply with GCP, GLP, and GACP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCP, GLP and GACP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP, GLP and GACP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other regulatory authority may require us to perform additional clinical trials before approving our or our partners' marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical or preclinical trials complies with applicable GCP and GLP requirements. In addition, our clinical trials must generally be conducted with product produced under cGMP regulations. Our failure to comply with these regulations and policies may require us to repeat clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we do not control whether or not they devote sufficient time and resources to our clinical trials. Our CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities, which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If any of our CROs or clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may not be able to enter into arrangements with alternative CROs or clinical trial sites, or do so on commercially reasonable terms. In addition, if our relationship with clinical trial sites is terminated, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and could receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

We rely completely on third-party contractors to supply, manufacture and distribute clinical drug supplies for our product candidates, including certain sole-source suppliers and manufacturers, we intend to rely on third parties for commercial supply, manufacturing and distribution if any of our product candidates receive regulatory approval and we expect to rely on third parties for supply, manufacturing and distribution of preclinical, clinical and commercial supplies of any future product candidates.

We do not currently have, nor do we plan to acquire, the infrastructure or capability to supply, manufacture or distribute preclinical, clinical or commercial quantities of drug substances or products. Our ability to develop our product candidates depends and our ability to commercially supply our products will depend, in part, on our ability to successfully obtain the raw materials and APIs and other substances and materials used in our product candidates from third parties and to have finished products manufactured by third parties in accordance with regulatory requirements and in sufficient quantities for preclinical and clinical testing and commercialization. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to develop or commercialize our product candidates.

We rely and will continue to rely on certain third parties as the sole source of the materials they supply or the finished products they manufacture. Any of our existing suppliers or manufacturers may:

- fail to supply us with product on a timely basis or in the requested amount due to unexpected damage to or destruction of facilities or equipment or otherwise;
- fail to increase manufacturing capacity and produce drug product and components in larger quantities and at higher yields in a timely or cost-effective manner, or at all, to sufficiently meet our commercial needs;
- be unable to meet our production demands due to issues related to their reliance on sole-source suppliers and manufacturers;
- supply us with product that fails to meet regulatory requirements;
- become unavailable through business interruption or financial insolvency;
- lose regulatory status as an approved source;
- be unable or unwilling to renew current supply agreements when such agreements expire on a timely basis, on acceptable terms or at all; or
- discontinue production or manufacturing of necessary drug substances or products.

In the event of any of the foregoing, if we do not have an alternative supplier or manufacturer in place, we would be required to expend substantial management time and expense to identify, qualify and transfer processes to alternative suppliers or manufacturers. Transferring technology to other sites may require additional processes, technologies and validation studies, which are costly, may take considerable amounts of time, may not be successful and, in most cases, require review and approval by the FDA. Any need to find and qualify new suppliers or manufacturers could significantly delay production of our product candidates, adversely impact our ability to market our product candidates and adversely affect our business. Replacements may not be available to us on a timely basis, on acceptable terms or at all. Additionally, we and our manufacturers do not currently maintain significant inventory of drug substances and other materials. Any interruption in the supply of a drug substance or other material or in the manufacture of our product candidates could have a material adverse effect on our business, financial condition, operating results and prospects.

We do not have direct control over the ability of our contract suppliers and manufacturers to maintain adequate capacity and capabilities to serve our needs, including quality control, quality assurance and qualified personnel. Although we are ultimately responsible for ensuring compliance with regulatory requirements such as cGMPs and GACP, we are dependent on our contract suppliers and manufacturers for day-to-day compliance with cGMPs or GACP for production of raw materials, APIs and finished products. Facilities used by our contract suppliers and manufacturers to produce the APIs and other substances and materials or finished products for commercial sale must pass inspection and be approved by the FDA and other relevant regulatory authorities. Our contract suppliers and manufacturers must comply with cGMP and GACP requirements enforced by the FDA through its facilities inspection program and review of submitted technical information. If the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for injuries sustained as a result. Any of these factors could cause a delay or termination of preclinical studies, clinical trials or regulatory submissions or approvals of our product candidates, and could entail higher costs or result in our being unable to effectively commercialize our approved products on a timely basis, or at all.

In addition, these contract manufacturers are engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the supply or manufacture of our product candidates, or if it withdraws its approval in the future, we may need to find alternative supply or manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval of or market our product candidates, if approved.

Our reliance on contract manufacturers and suppliers further exposes us to the possibility that they, or third parties with access to their facilities, will have access to and may misappropriate our trade secrets or other proprietary information.

If we are not able to establish and maintain collaborations, we may have to alter our development and commercialization plans.

The development and potential commercialization of our product candidates will require substantial additional cash to fund expenses. In order to fund further development of our product candidates, we may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the partner's resources and experience, the terms and conditions of the proposed collaboration and the proposed partner's evaluation of a number of factors. Those factors may include the design or results of clinical trials; the likelihood of approval by the FDA or other regulatory authorities; the potential market for the subject product candidate; the costs and complexities of manufacturing and delivering such product candidate to patients; the potential of competing products; any uncertainty with respect to our ownership of our intellectual property; and industry and market conditions generally. The partner may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under future license agreements from entering into agreements on certain terms with potential partners. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future partners.

Future collaborations we may enter into may involve the following risks:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, may divert resources or create competing priorities;
- collaborators may delay discovery and preclinical development, provide insufficient funding for product development of targets selected by us, stop or abandon discovery and preclinical development for a product candidate, repeat or conduct new discovery and preclinical development for a product candidate;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed than ours;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development of our product candidates;

- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the discovery, preclinical development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- collaborators may not properly maintain or defend our intellectual property rights or intellectual property rights licensed to us or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaborations typically impose detailed obligations on each party. If we were to breach our obligations, we may face substantial consequences, including potential termination of the collaboration, and our rights to our partners' product candidates, in which we have invested substantial time and money, would be lost.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

Risks Related to Managing Our Growth, Our Employees and Our Operations

We will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in executing our growth strategy and managing any growth.

Our management, personnel, systems and facilities currently in place are not adequate to support our business plan and near-term future growth. We will need to further expand our chemistry and manufacturing team, clinical team, managerial, operational, financial, and other resources to support our planned research, development and commercialization activities.

To manage our operations, growth and various projects effectively requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;

- attract and retain sufficient numbers of talented employees;

- develop a marketing, sales and distribution capability;

- manage our commercialization activities for our product candidates effectively and in a cost-effective manner;

- establish and maintain relationships with development and commercialization partners;
- manage our preclinical and clinical trials effectively;
- manage our third-party supply and manufacturing operations effectively and in a cost-effective manner, while increasing production capabilities for our current product candidates to commercial levels; and
- manage our development efforts effectively while carrying out our contractual obligations to partners and other third parties.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to preclinical and clinical testing. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. We rely on consultants for certain functions of our business and will need to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively manage our growth and expand our organization by hiring new employees and expanding our use of consultants, we might be unable to successfully implement the tasks necessary to execute effectively on our planned research, development and commercialization activities and, accordingly, might not achieve our research, development and commercialization goals.

If we fail to attract and retain management and other key personnel, we may be unable to continue to successfully develop or commercialize our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive pharmaceuticals industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical, sales and marketing and other personnel. We are highly dependent on our management, including: Stephen C. Glover, Peter Wolfe and Karen A. Cashmere. The loss of the services of any of these individuals could impede, delay or prevent the successful development of our product pipeline, completion of our planned clinical trials, commercialization of our product candidates or in-licensing or acquisition of new assets and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we might not be able to find suitable replacements on a timely basis or at all, and our business could be harmed as a result. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract offers from other companies.

We might not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Weston, FL area where we are headquartered. We could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will harm our ability to implement our business strategy and achieve our business objectives.

In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

The competitive job market creates a challenge and potential risk as we grow and strive to attract and retain a highly skilled workforce.

Competition for our employees, including highly skilled technology and product professionals, is extremely intense reflecting a tight labor market. This can present a risk as we compete for experienced candidates, especially if the competition is able to offer more attractive financial terms of employment. This risk extends to our current employee population. We may also invest significant time and expense in engaging and developing our employees as we grow our business, which also increases their value to other companies that may seek to recruit them. Turnover can result in significant replacement costs and lost productivity. Additionally, U.S. immigration policy may make it more difficult for qualified foreign nationals to obtain or maintain work visas under the H-1B classification. These H-1B visa limitations may make it more difficult and/or more expensive for us to hire the skilled professionals we need to execute our growth strategy and may adversely impact our business.

Our failure to successfully in-license, acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

We intend to in-license, acquire, develop and market additional products and product candidates and we may in-license or acquire commercial-stage products or engage in other strategic transactions. Because our internal research and development capabilities are limited, we may be dependent upon pharmaceutical companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including preclinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions entail numerous potential operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management’s time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- substantial acquisition and integration costs;
- write-downs of assets or impairment charges;

- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers, partners or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain our key employees or those of any acquired businesses.

Accordingly, there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, and any transaction that we do complete could harm our business, financial condition, operating results and prospects.

Manufacturing and supply of the APIs and other substances and materials used in our product candidates is a complex and technically challenging undertaking, and there is potential for failure at many points in the manufacturing, testing, quality assurance and distribution supply chain, as well as the potential for latent defects after products have been manufactured and distributed.

Manufacturing and supply of APIs, other substances and materials and finished drug products is technically challenging. Changes beyond our direct control can impact the quality, volume, price and successful delivery of our product candidates and can impede, delay, limit or prevent the successful development and commercialization of our product candidates. Mistakes and mishandling are not uncommon and can affect successful production and supply. Some of these risks include:

- failure of our manufacturers to follow cGMP or GACP requirements or mishandling of product while in production or in preparation for transit;
- inability of our contract suppliers and manufacturers to efficiently and cost-effectively increase and maintain high yields and batch quality, consistency and stability;
- our inability to develop an FDA approved bioassay for release of any future product;
- difficulty in establishing optimal drug delivery substances and techniques, production and storage methods and packaging and shipment processes;
- transportation and import/export risk, particularly given the global nature of our supply chain;
- delays in analytical results or failure of analytical techniques that we depend on for quality control and release of any future product;
- natural disasters, pandemics, labor disputes, financial distress, lack of raw material supply, issues with facilities and equipment or other forms of disruption to business operations of our contract manufacturers and suppliers; and
- latent defects that may become apparent after the product has been released and which may result in recall and destruction of product.

Any of these factors could result in delays or higher costs in connection with our clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, which could harm our business, financial condition, operating results and prospects.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our operations to date have been primarily limited to researching and developing our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- delays in the commencement, enrollment and the timing of clinical testing for our product candidates;
- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review and approval of product candidates in clinical development;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on FDA guidelines and requirements, and the quantity of production;
- our ability to obtain additional funding to develop our product candidates;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies;
- the level of demand for our product candidates, should they receive approval, which may vary significantly;
- potential side effects of our product candidates that could delay or prevent commercialization or cause an approved drug to be taken off the market;
- the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our product candidates, if approved;
- our dependency on third-party manufacturers to supply or manufacture our product candidates;
- our ability to establish an effective sales, marketing and distribution infrastructure in a timely manner;
- market acceptance of our product candidates, if approved, and our ability to forecast demand for those product candidates;
- our ability to receive approval and commercialize our product candidates outside of the United States;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential litigation or other disputes;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies; and
- future accounting pronouncements or changes in our accounting policies.

Our operating results and liquidity needs could be negatively affected by market fluctuations and economic downturn.

Our operating results and liquidity could be negatively affected by economic conditions generally, both in the United States and elsewhere around the world. The market for discretionary medical products and procedures may be particularly vulnerable to unfavorable economic conditions. Some patients may consider certain of our product candidates to be discretionary, and if full reimbursement for such products is not available, demand for these products may be tied to the discretionary spending levels of our targeted patient populations. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our operating results and liquidity could be adversely affected by those factors in many ways, including weakening demand for certain of our products and making it more difficult for us to raise funds if necessary, and our stock price may decline. Additionally, although we plan to market our products primarily in the United States, we could in the future have partners with extensive global operations, indirectly exposing us to risk.

Our business and operations would suffer in the event of failures in our internal computer systems.

Despite the implementation of security measures, our computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our manufacturing activities, development programs and our business operations. For example, the loss of manufacturing records or clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization and development of our products and product candidates could be delayed.

We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks.

Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. The size and complexity of our information technology systems, and those of our third-party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. Further, any such interruption, security breach, loss or disclosure of confidential information, could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations or cash flow.

Due to our primarily remote workforce, we may face increased cyber risks that could significantly harm our business and operations.

We have adopted a primarily remote workforce since the COVID-19 pandemic and may be exposed to increased cybersecurity risks as a result such business practices. Although to date we have not experienced any material losses relating to cyberattacks, there can be no assurance that we will not suffer such losses in the future. Cyberattacks are increasing in their frequency, sophistication, and intensity. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance its protective measures or to investigate and remediate any information security vulnerabilities. If we are unable to effectively manage the cybersecurity and other risks of remote work, our business could be harmed or otherwise negatively impacted.

Risks Related to Our Intellectual Property

Failure to adequately protect our intellectual property could adversely affect our business, financial condition, and operating results.

Our business depends on its intellectual property and proprietary technology, the protection of which is crucial to the success of its business. We rely on a combination of trademark, copyright, and trade secret laws, license agreements, intellectual property assignment agreements, and confidentiality procedures to protect its intellectual property. Additionally, we rely on proprietary information (such as trade secrets, know-how and confidential information) to protect intellectual property that may not be patentable, or that we believe is best protected by means that do not require public disclosure. We generally attempt to protect our intellectual property, technology, and confidential information by requiring our employees and consultants who develop intellectual property on our behalf to enter into confidentiality and invention assignment agreements and third parties we share information with to enter into nondisclosure agreements. These agreements may not effectively prevent unauthorized use or disclosure of our confidential information, intellectual property, or technology and may not provide an adequate remedy in the event of unauthorized use or disclosure of our confidential information or technology, or infringement of our intellectual property. For example, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be willfully breached or may otherwise fail to prevent disclosure, third-party infringement or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information. In addition, our proprietary information may otherwise become known or be independently developed by our competitors or other third parties. To the extent that our employees, consultants, contractors, and other third parties use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our intellectual property rights and other proprietary rights, and failure to obtain or maintain protection for our proprietary information could adversely affect our competitive business position.

Despite our efforts to protect our proprietary rights, other parties may unintentionally or willfully disclose, obtain or use our technologies or systems, which may allow unauthorized parties to copy aspects of our platform or other software, technology, and functionality or obtain and use information that we consider proprietary. In addition, unauthorized parties may also attempt, or successfully endeavor, to obtain our intellectual property, confidential information and trade secrets through various methods, including through scraping of public data or other content from our website or mobile applications, cybersecurity attacks, and legal or other methods of protecting this data may be inadequate. Monitoring unauthorized use and disclosures of our intellectual property, proprietary technology, or confidential information can be difficult and expensive and we cannot be sure that the steps we have taken will prevent misappropriation or infringement of our intellectual property or proprietary rights.

We have registered domain names for websites that we use in our business, such as *www.zyversa.com* and other variations. The inclusion of the website address in this document does not include or incorporate by reference the information on our website into this document.

Competitors have and may continue to adopt service names similar to ours, thereby harming our ability to build brand identity and possibly leading to user confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks that are similar to our trademarks. Further, litigation or proceedings before the U.S. Patent and Trademark Office or other governmental authorities and administrative bodies in the United States and abroad may be necessary in the future to enforce our intellectual property rights and to determine the validity and scope of the proprietary rights of others. Any litigation we initiate concerning the violation by third parties of our intellectual property rights is likely to be expensive and time-consuming and could lead to the invalidation of, or render unenforceable, its intellectual property, or could otherwise have negative consequences for us. Even if we sue other parties for such infringement, such suits may have adverse consequences for our business. In addition, we may not timely or successfully apply for a patent or register its trademarks or otherwise secure its intellectual property, which could result in negative effects to our market share, financial condition and results of operations. Our efforts to protect, maintain, or enforce our proprietary rights may not be respected in the future or may be invalidated, circumvented or challenged, and could result in substantial costs and diversion of resources, which could adversely affect our business, financial condition, and operating results.

We may be unable to continue to use the domain names that we use in our business or prevent third parties from acquiring and using domain names that infringe on, are similar to, or otherwise decrease the value of our brand, trademarks, or service marks.

We have registered domain names that we use in, or are related to, its business. If we lose the ability to use a domain name, whether due to trademark claims, failure to renew the applicable registration, or any other cause, we may be forced to market our offerings under a new domain name, which could cause us substantial harm, or to incur significant expense in order to purchase rights to the domain name in question. We may not be able to obtain preferred domain names outside the United States due to a variety of reasons, including because they are already held by others. In addition, our competitors and others could attempt to capitalize on our brand recognition by using domain names similar to our domain names. We may be unable to prevent third parties from acquiring and using domain names that infringe on, are similar to, or otherwise decrease the value of our brand or our trademarks or service marks. Protecting, maintaining, and enforcing our rights in our domain names may require litigation, which could result in substantial costs and diversion of resources, which could in turn adversely affect our business, financial condition, and operating results.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific, and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office (the "USPTO") has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. It is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Further, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims, or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

If we fail to comply with our obligations under our intellectual property license agreements, we could lose license rights that are important to our business.

We are a party to certain license agreements that impose various diligence, milestone, royalty, insurance and other obligations on us. If we fail to comply with these obligations, the respective licensors may have the right to terminate the license, in which event we may not be able to develop or market the affected product candidate. The loss of such rights could materially adversely affect our business, financial condition, operating results and prospects. For more information about these license arrangements, see "*Part I – Business – Strategic Alliances and Arrangements*."

If we are sued for infringing intellectual property rights of third parties, it will be costly and time-consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We cannot guarantee that marketing and selling such candidates and using such technologies will not infringe existing or future patents. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields relating to our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our product candidates, technologies or methods of delivery or use infringe their patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various drugs, biologics, drug delivery systems or their methods of use, and which of these patents may be valid and enforceable. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

In addition, there may be issued patents of third parties that are infringed or are alleged to be infringed by our product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates or proprietary technologies infringe such third parties' intellectual property rights, including litigation resulting from filing under Paragraph IV of the Hatch-Waxman Act. These lawsuits could claim that there are existing patent rights for such drug and this type of litigation can be costly and could adversely affect our operating results and divert the attention of managerial and technical personnel, even if we do not infringe such patents or the patents asserted against us are ultimately established as invalid. There is a risk that a court would decide that we are infringing the third party's patents and would order us to stop the activities covered by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having violated the other party's patents.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek licenses from third parties. These licenses may not be available on commercially acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property, or such rights might be restrictive and limit our present and future activities. Ultimately, we or a licensee could be prevented from commercializing a product, or forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

In addition to possible infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference, derivation, re-examination or other post-grant proceedings declared or granted by the USPTO, and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or of our other products.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. To date, no litigation asserting infringement claims has ever been brought against us. If a third-party claims that we infringe its intellectual property rights, we may face a number of issues, including:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting us from selling or licensing the product or using the technology unless the third party licenses its intellectual property rights to us, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products or technologies; and

- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could harm our ability to raise additional funds or otherwise adversely affect our business, financial condition, operating results and prospects.

Because we rely on certain third-party licensors and partners, and will continue to do so in the future, if one of our licensors or partners is sued for infringing a third party's intellectual property rights, our business, financial condition, operating results and prospects could suffer in the same manner as if we were sued directly. In addition to facing litigation risks, we have agreed to indemnify certain third-party licensors and partners against claims of infringement caused by our proprietary technologies, and we have entered or may enter into cost-sharing agreements with some our licensors and partners that could require us to pay some of the costs of patent litigation brought against those third parties whether or not the alleged infringement is caused by our proprietary technologies. In certain instances, these cost-sharing agreements could also require us to assume greater responsibility for infringement damages than would be assumed just on the basis of our technology.

The occurrence of any of the foregoing could adversely affect our business, financial condition or operating results.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time-consuming.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive and time-consuming, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted narrowly or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products.

Interference, derivation or other proceedings brought at the USPTO may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential partners. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential partners, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock or warrants could be significantly harmed.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that our trade secrets will be misappropriated or disclosed, and confidentiality agreements with employees and third parties may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, collaborators, contractors and advisors to enter into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with us prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, current or former employees, consultants, collaborators, contractors and advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. The need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations. Enforcing a claim that a third party obtained illegally and is using trade secrets or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

In addition, these agreements typically restrict the ability of our employees, consultants, collaborators, contractors and advisors to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their former employers or their former or current customers.

As is common in the biotechnology and pharmaceutical industries, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. Even if we are successful in defending against any such claims, any such litigation could be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties and may potentially result in an unfavorable outcome.

If our patent term expires before or soon after our products are approved, or if manufacturers of generic or biosimilar drugs successfully challenge our patents, our business may be materially harmed.

Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally twenty (20) years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive medications, including generic or biosimilar medications.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, and similar legislation in the European Union. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension 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. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. Also, the scope of our right to exclude during any patent term extension period may be limited or may not cover a competitor's product or product use. As a result, our revenue from applicable products could be reduced, possibly materially.

Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Manufacturers of generic or biosimilar drugs may challenge the scope, validity, or enforceability of our patents in court or before a patent office, and we may not be successful in enforcing or defending those intellectual property rights and, as a result, may not be able to develop or market the relevant product exclusively, which would have a material adverse effect on any potential sales of that product. Upon the expiration of our issued patents or patents that may issue from our pending patent applications, we will not be able to assert such patent rights against potential competitors and our business and results of operations may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Our proprietary information may be lost, or we may suffer security breaches.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, clinical trial data, proprietary business information, personal data and personally identifiable information of our clinical trial subjects and employees, in our data centers and on our networks. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Although, to our knowledge, we have not experienced any such material security breach to date, any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, significant regulatory penalties, disrupt our operations, damage our reputation and cause a loss of confidence in us and our ability to conduct clinical trials, which could adversely affect our reputation and delay our clinical development of our product candidates.

Risks Related to Being a Public Company

Our management team has limited experience managing a public company and may not successfully manage our transition to public company status.

Most members of our management team have limited experience managing a publicly traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team may not successfully or efficiently manage the transition to being a public company that is subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could harm our business, results of operations and financial condition.

We incur significant increased expenses and administrative burdens as a public company, which could have an adverse effect on its business, financial condition and operating results.

As a public company, we face increased legal, accounting, administrative, and other costs and expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." The Sarbanes-Oxley Act, including the requirements of Section 404, as well as rules and regulations subsequently implemented by the SEC, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations promulgated and to be promulgated thereunder, the PCAOB and the securities exchanges and the listing standards of the Nasdaq, impose additional reporting and other obligations on public companies.

Compliance with public company requirements will increase costs and make certain activities more time-consuming. A number of those requirements will require us to carry out activities that we had not done previously. For example, we have created new board committees, entered into new insurance policies, and adopted new internal controls and disclosure controls and procedures. In addition, expenses associated with SEC reporting requirements will be incurred. Furthermore, if any issues in complying with those requirements are identified (for example, if management or our independent registered public accounting firm identifies material weaknesses in the internal control over financial reporting), we could incur additional costs rectifying those issues, the existence of those issues could adversely affect our reputation or investor perceptions of it and it may be more expensive to obtain director and officer liability insurance. Risks associated with our status as a public company may make it more difficult to attract and retain qualified persons to serve on our Board or as executive officers. In addition, as a public company, we may be subject to stockholder activism, which can lead to substantial costs, distract management, and impact the manner in which we operate our business in ways we do not currently anticipate. As a result of disclosure of information in this document and in filings required of a public company, our business and financial condition will become more visible, which may result in threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be materially adversely affected and even if the claims do not result in litigation or are resolved in our favor, these claims and the time and resources necessary to resolve them, could divert the resources of our management and adversely affect our business and results of operations. The additional reporting and other obligations imposed by these rules and regulations will increase legal and financial compliance costs and the costs of related legal, accounting, and administrative activities. These increased costs will require us to divert a significant amount of money that could otherwise be used to expand the business and achieve strategic objectives. Advocacy efforts by stockholders and third parties may also prompt additional changes in governance and reporting requirements, which could further increase costs.

The requirements of being a public company may strain our resources, divert management's attention and affect its ability to attract and retain qualified board members.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and any rules promulgated thereunder, as well as the rules of Nasdaq. The requirements of these rules and regulations increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls for financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight will be required and, as a result, management's attention may be diverted from other business concerns. These rules and regulations can also make it more difficult for us to attract and retain qualified independent members of our board of directors. Additionally, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. We may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. The increased costs of compliance with public company reporting requirements and our potential failure to satisfy these requirements can have a material adverse effect on our operations, business, financial condition or results of operations.

In order to satisfy our obligations as a public company, we will need to hire qualified accounting and financial personnel with appropriate public company experience.

As a newly established public company, we will need to improve and maintain effective disclosure and financial controls and make changes in our corporate governance practices. We may need to hire additional accounting and financial personnel with appropriate public company experience and technical accounting knowledge, and it may be difficult to recruit and retain such personnel. Even if we are able to hire appropriate personnel, our existing operating expenses and operations will be impacted by the direct costs of their employment and the indirect consequences related to the diversion of management resources from research and development efforts.

We are an emerging growth company and any decision to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as it continues to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including:

- not being required to have independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

As a result, the stockholders may not have access to certain information that they may deem important. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have at least $1.07 billion in annual revenue;
- the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates;
- the date on which we haves issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the 2021 Larkspur IPO.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We may elect to take advantage of this extended transition period and as a result, its financial statements may not be comparable with similarly situated public companies.

We cannot predict if investors will find our common stock less attractive if it chooses to rely on any of the exemptions afforded emerging growth companies. If some investors find our Common Stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our Common Stock and the market price of our Common Stock may be more volatile and may decline.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired, which may adversely affect investor confidence in us and, as a result, the market price of our common stock.

As a public company, we will be required to comply with the requirements of the Sarbanes-Oxley Act including, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We continue to develop and refine our disclosure controls and other procedures that are designed to ensure that information we are required to disclose in the reports that we will file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers.

We must continue to improve our internal control over financial reporting. We are required to make a formal assessment of the effectiveness of our internal control over financial reporting and once we cease to be an emerging growth company, we may be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with these requirements, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. There is a risk that we will not be able to conclude that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. Moreover, our testing, or the subsequent testing by our independent registered public accounting firm, may reveal additional deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

Any failure to implement and maintain effective disclosure controls and procedures and internal control over financial reporting, including the identification of one or more material weaknesses, could cause investors to lose confidence in the accuracy and completeness of our financial statements and reports, which would likely adversely affect the market price of our common stock. In addition, we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC and other regulatory authorities.

We may be subject to securities litigation, which is expensive and could divert management attention.

The per share price of our common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation, including class action litigation. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could have a material adverse effect on our business, financial condition, and results of operations. Any adverse determination in litigation could also subject us to significant liabilities.

Because we became a publicly traded company by means other than a traditional underwritten initial public offering, our stockholders may face additional risks and uncertainties.

Because we became a publicly traded company by means of consummating the Business Combination rather than by means of a traditional underwritten initial public offering, there is no independent third-party underwriter selling the shares of our common stock, and, accordingly, our stockholders will not have the benefit of an independent review and investigation of the type normally performed by an unaffiliated, independent underwriter in a public securities offering. Due diligence reviews typically include an independent investigation of the background of the company, any advisors and their respective affiliates, review of the offering documents and independent analysis of the plan of business and any underlying financial assumptions.

Although we performed a due diligence review and investigation of Old ZyVersa in connection with the Business Combination, the lack of an independent due diligence review and investigation increases the risk of investment in our securities because our due diligence review and investigation may not have uncovered facts that would be important to a potential investor.

In addition, because we did not become a publicly traded company by means of a traditional underwritten initial public offering, security or industry analysts may not provide, or be less likely to provide, coverage of us. Investment banks may also be less likely to agree to underwrite secondary offerings on behalf of us than they might otherwise be if we became a publicly traded company by means of a traditional underwritten initial public offering because they may be less familiar with us as a result of more limited coverage by analysts and the media. The failure to receive research coverage or support in the market for our common stock could have an adverse effect on our ability to develop a liquid market for our common stock.

Risks Related to Ownership of Our Securities

An active trading market for our Common Stock may never develop or be sustained.

Although our Common Stock is listed on Nasdaq, the market for our shares has demonstrated varying levels of trading activity. If an active trading market does not develop, or develops but is not maintained, you may have difficulty selling any of our Common Stock due to the limited public float. We cannot predict the prices at which our Common Stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our Common Stock may fall. Accordingly, we cannot assure you of your ability to sell your shares of our Common Stock when desired or at prices at or above the price you paid for your shares or at all.

Our common stock may be affected by limited trading volume and may fluctuate significantly.

Our common stock is traded on The Nasdaq Capital Market. Although an active trading market has developed for our common stock, there can be no assurance that an active trading market for our common stock will be sustained. Failure to maintain an active trading market for our common stock may adversely affect our shareholders' ability to sell our common stock in short time periods, or at all. Our common stock has experienced, and may experience in the future, significant price and volume fluctuations, which could adversely affect the market price of our common stock.

The market price of our Common Stock may be volatile, which could result in substantial losses for investors.

The trading price of our Common Stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control.

The market price of our Common Stock may fluctuate due to a variety of factors, including:

- the development and approval of our product candidates;
- the timing of the launch and commercialization of our product candidates, if they are approved, and the degree to which such launch and commercialization meets the expectations of securities analysts and investors;
- actual or anticipated fluctuations in our operating results, including fluctuations in our quarterly and annual results;
- operating expenses being more than anticipated;
- the failure or discontinuation of any of our product development and research programs;
- changes in the structure or funding of research at academic and research laboratories and institutions, including changes that would affect their ability to purchase our instruments or consumables;
- the success of existing or new competitive businesses or technologies;
- announcements about new research programs or products of our competitors;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- litigation and governmental investigations involving us, our industry or both;
- regulatory or legal developments in the United States and other countries;
- volatility and variations in market conditions in the life sciences technology sector generally, or the proteomics or genomics sectors specifically;
- investor perceptions of us or our industry;
- the level of expenses related to any of our research and development programs or products;
- actual or anticipated changes in our estimates as to our financial results or development timelines, variations in our financial results or those of companies that are perceived to be similar to us or changes in estimates or recommendations by securities analysts, if any, that cover our Common Stock or companies that are perceived to be similar to us;
- whether our financial results meet the expectations of securities analysts or investors;
- the announcement or expectation of additional financing efforts;
- sales of our Common Stock by us or by our insiders or other stockholders;
- the expiration of market standoff or lock-up agreements;
- general economic, industry and market conditions; and
- pandemics, natural disasters or major catastrophic events.

These market and industry factors may materially reduce the market price of our Common Stock regardless of our operating performance.

Recently, stock markets in general, and the market for life sciences technology companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our Common Stock, regardless of our actual operating performance. These fluctuations may be even more pronounced in the trading market for our Common Stock and warrants. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company.

Because of the potential volatility of the price of our Common Stock, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders.

Our issuance of additional capital stock in connection with financings, acquisitions, investments, our stock incentive plans or otherwise will dilute our stockholders. We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors, and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products, or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq.

If Nasdaq delists our shares of Common Stock from trading on its exchange for failure to meet Nasdaq's listing standards, we and our stockholders could face significant material adverse consequences including:

- a limited availability of market quotations for our securities;
- reduced liquidity for our securities;
- a determination that our Common Stock is a "penny stock" which will require brokers trading in our Common Stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of new and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our Common Stock.

Our Common Stock is currently listed for trading on The Nasdaq Capital Market. We must satisfy the continued listing requirements of Nasdaq, to maintain the listing of our Common Stock on The Nasdaq Capital Market.

If we fail to continue to meet all applicable Nasdaq Capital Market requirements in the future and Nasdaq determines to delist our Common Stock, the delisting could substantially decrease trading in our Common Stock; adversely affect the market liquidity of our Common Stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws; adversely affect our ability to obtain financing on acceptable terms, if at all; and may result in the potential loss of confidence by investors, suppliers, customers, and employees and fewer business development opportunities. Additionally, the market price of our Common Stock may decline further and stockholders may lose some or all of their investment.

We have a history of failing to comply with the continued listing requirements of Nasdaq, although we have successfully cured all the pre-existing deficiency, we may not be able to cure any deficiency timely in the future. On February 5, 2024, we received a letter from the Nasdaq Listing Qualifications Staff (the "Staff") notifying us that we are not in compliance with Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement") because the closing bid price for our common stock was below the minimum $1.00 per share for 30 consecutive business days. On May 13, 2024, the Company received a letter from Nasdaq notifying the Company that it has regained compliance with the Minimum Bid Price Requirement. The Company will be subject to a Mandatory Panel Monitor for a period of one year, or until May 13, 2025, pursuant to Nasdaq Listing Rule 5815(d)(4)(B). If, within that one-year monitoring period, the Company fails to comply with the Minimum Bid Price Requirement, the Staff will not be permitted to grant additional time for the Company to regain compliance with respect to that deficiency, and the Company will not be afforded an applicable cure or compliance period pursuant to Nasdaq Listing Rule 5810(c)(3). Instead, the Staff will issue a delist determination letter and the Company will have an opportunity to request a new hearing with the initial Nasdaq hearings panel or a newly convened hearings panel if the initial panel is unavailable. The Company will have the opportunity to respond and present to the panel as provided by Nasdaq Listing Rule 5815(d)(4)(C). The Company's common stock may be at that time delisted from Nasdaq.

As of the date of this report, we believe that we have maintained compliance with the Minimum Bid Price Requirement for continued listing on The Nasdaq Capital Market. However, there can be no assurance that we will be able to maintain compliance with the Minimum Bid Price Requirement or other Nasdaq listing requirements. If we fail to maintain compliance with Nasdaq's continued listing standards in accordance with the panel's decision, our common stock will be subject to delisting from Nasdaq.

Unless our Common Stock continues to be listed on a national securities exchange it will become subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.

If we are unable to maintain the listing of our Common Stock on Nasdaq or another national securities exchange, our Common Stock could become subject to the so-called "penny stock" rules if the shares have a market value of less than $5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and "accredited investors" as defined by relevant SEC rules. These additional requirements may discourage broker-dealers from effecting transactions in securities that are classified as penny stocks, which could severely limit the market price and liquidity of such securities and the ability of purchasers to sell such securities in the secondary market. This means that if we are unable to maintain the listing of our Common Stock on a national securities exchange, the ability of stockholders to sell their Common Stock in the secondary market could be adversely affected.

If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer also must disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

The assumptions used in preparing the pro forma financial information may not prove to be accurate and other factors may affect our financial condition or results of operations in the future. Any potential decline in our financial condition or results of operations may cause significant variations in our stock price.

On January 27, 2023, we filed an amendment (the "Amendment") to our current report on Form 8-K/A filed on December 16, 2023 (the "Original 8-K/A"); the Amendment was filed solely to replace entirely the unaudited pro forma condensed combined financial information included on the Original 8-K/A and which was included in our registration statement on Form S-4 relating to the Business combination. The unaudited pro forma condensed combined financial information previously reflected management's estimates based on information available at the consummation of the Business Combination and was subject to change as additional information became available and analysis was performed. We updated the unaudited pro forma condensed combined financial information upon completion of our analysis to now reflect the Business Combination as a forward merger of Old ZyVersa as it was determined that Old ZyVersa is a variable interest entity. The unaudited pro forma condensed combined financial information and related notes thereto reflects fair value adjustments to the net assets of Old ZyVersa acquired by the Company, which primarily consist of in-process research and development intangible assets which are indefinite-lived. As a result of the changes to the unaudited pro forma condensed combined financial information, we may face potential litigation or other disputes which may include, among other things, litigation involving our shareholders, claims invoking the federal and state securities laws, contractual claims or other claims arising from such changes. As of the date of this document, we have no knowledge of any such claims, litigation or disputes. However, we can provide no assurance that such, claims, litigation or disputes will not arise in the future. Any such claims, litigation or disputes, whether successful or not, could have a material adverse effect on our business, results of operations and financial condition.

We are subject to business uncertainties that could affect the market price of our Common Stock.

Uncertainty about our business or operations may affect the relationship between us and our respective suppliers, users, distributors, licensors, and licensees. Any such impact may have an adverse effect on us and the market price of our Common Stock. These uncertainties may cause parties that deal with us to seek to change existing business relationships with them and to delay or defer decisions concerning us. Changes to existing business relationships, including termination or modification, could negatively affect each of our revenue, earnings and cash flow, as well as the market price of our Common Stock.

Additionally, matters may require commitments of time and resources that could otherwise have been devoted to other opportunities that might have been beneficial to us. Further, the Business Combination may give rise to potential liabilities, including as a result of pending and future stockholder lawsuits relating to the Business Combination. Any of these matters could adversely affect our business financial condition or results of operations.

Insiders own a significant percentage of our Common Stock and will be able to exercise significant influence over matters subject to stockholder approval.

Our directors, executive officers, holders of more than 5% of our outstanding shares of Common Stock and their respective affiliates beneficially own a significant percentage of the outstanding shares of Common Stock. As a result, these stockholders, if they act together, may significantly influence all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company that our other stockholders may believe is in their best interests. This in turn could have a material adverse effect on our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

Third parties may terminate or alter existing contracts or relationships with us.

Contracts with distributors, affiliates, landlords, licensors, and other business partners and third parties with which we currently have relationships may have the ability to terminate, reduce the scope of, or otherwise materially adversely alter their relationships with us. The pursuit of such rights may result in us suffering a loss of potential future revenue or incurring liabilities in connection with a breach of such agreements and losing rights that are material to our business. Any such disruptions could limit our ability to achieve the anticipated benefits of our business. The adverse effect of such disruptions could also impact our business and operations or the market price of our Common Stock.

We incurred substantial transaction fees and costs in connection with completing the Business Combination and integrating the businesses of Larkspur and Old ZyVersa.

We incurred material non-recurring expenses in connection with the Business Combination and the completion of the transactions contemplated by the Business Combination Agreement and related transaction agreements. While we have assumed that a certain level of expenses would be incurred in connection with the Business Combination, there are many factors beyond our control that have affected and could continue to affect the total amount of, or the timing of, such expenses with respect to our combined business. Additional unanticipated costs may continue to be incurred in the course of conducting our business following the Business Combination.

Our business and operations could be negatively affected if it becomes subject to any securities litigation or stockholder activism, which could cause us to incur significant expense, hinder execution of our business and growth strategy and impact our stock price.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of our Common Stock or other reasons may in the future cause it to become the target of securities litigation or stockholder activism. Securities litigation and stockholder activism, including potential proxy contests, could result in substantial costs and divert management's and the board of directors' attention and resources from our business. Additionally, such securities litigation and stockholder activism could give rise to perceived uncertainties as to our future, adversely affect its relationships with service providers and make it more difficult to attract and retain qualified personnel. We may also be required to incur significant legal fees and other expenses related to any securities litigation and activist stockholder matters. Further, our stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and stockholder activism.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they adversely change their recommendations regarding our Common Stock, the trading price or trading volume of our Common Stock could decline.

The trading market for our common stock will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. If one or more securities analysts initiate research with an unfavorable rating or downgrade our Common Stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our Common Stock price would likely decline. If few securities analysts commence coverage of us, or if one or more of these analysts cease coverage of us, or fail to publish reports on us on a regular basis, we could lose visibility in the financial markets and demand for our securities could decrease, which in turn could cause the price and trading volume of our common stock to decline.

We do not intend to pay cash dividends for the foreseeable future.

We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in future agreements and financing instruments, business prospects and such other factors as our board of directors deems relevant.

Our Charter provides, subject to limited exceptions, that the Court of Chancery will be the sole and exclusive forum for certain stockholder litigation matters, which could limit our stockholders' ability to obtain a chosen judicial forum for disputes with us or our directors, officers, employees or stockholders.

Our Second Amended and Restated Certificate of Incorporation ("Charter") requires, to the fullest extent permitted by law, that derivative actions brought in our name, actions against directors, officers and employees for breach of fiduciary duty and other similar actions may be brought in the Court of Chancery or, if that court lacks subject matter jurisdiction, another federal or state court situated in the State of Delaware. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to the forum provisions in our Charter. In addition, our Charter and amended and restated bylaws will provide that the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action under the Securities Act and the Exchange Act. While the exclusive forum provision does not restrict the ability of shareholders to bring claims under the Securities Act, it may limit shareholders' ability to bring a claim in the judicial forum that they find favorable and may increase certain litigation costs on the shareholders, which may discourage the filing of claims under the Securities Act against us, our directors and officers.

In March 2020, the Delaware Supreme Court issued a decision in *Salzburg et al. v. Sciabacucchi*, which found that an exclusive forum provision providing for claims under the Securities Act to be brought in federal court is facially valid under Delaware law. It is unclear whether this decision will be appealed, or what the final outcome of this case will be. We intend to enforce this provision, but we do not know whether courts in other jurisdictions will agree with this decision or enforce it.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in the Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Additionally, it is uncertain whether this choice of forum provision is enforceable. Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. In light of this uncertainty, investors bringing a claim may face certain additional risks, including increased costs and uncertainty of litigation outcomes.

Anti-takeover provisions in our organizational documents could delay or prevent a change of control.

Certain provisions of our Charter and Bylaws may have an anti-takeover effect and may delay, defer or prevent a merger, acquisition, tender offer, takeover attempt or other change of control transaction that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares held by our stockholders.

These provisions provide for, among other things:

- the ability of our board of directors to issue one or more series of preferred stock;
- a classified board;
- advance notice for nominations of directors by stockholders and for stockholders to include matters to be considered at our annual meetings;
- certain limitations on convening special stockholder meetings;
- limiting the persons who may call special meetings of stockholders;
- limiting the ability of stockholders to act by written consent; and
- our board of directors have the express authority to make, alter or repeal our Bylaws.

These anti-takeover provisions could make it more difficult or frustrate or prevent a third party from acquiring us, even if the third party's offer may be considered beneficial by many of our stockholders. Additionally, the provisions may frustrate or prevent any attempts by our stockholders to replace or remove its current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of its management. As a result, our stockholders may be limited in their ability to obtain a premium for their shares. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing and to cause us to take other corporate actions you desire. *See* "*Description of Our Securities*" filed as Exhibit 4.8 to this Annual Report on Form 10-K.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our organizational documents provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the General Corporation Law of the State of Delaware (the "DGCL"), our Bylaws and indemnifications agreements entered into with our directors and officers provide that:

- we will indemnify its directors and officers for serving us in those capacities or for serving other business enterprises at its request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;

- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;

- we will be required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;

- we will not be obligated pursuant to our Bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;

- the rights conferred in the Bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and

- we may not retroactively amend our Bylaws provisions to reduce its indemnification obligations to directors, officers, employees and agents.

Our reverse stock split may decrease the liquidity of the shares of our Common Stock.

We effected a 1-for-35 and a 1-for10 reverse stock split on December 4, 2023, and April 25, 2024, respectively. The liquidity of the shares of our Common Stock may be affected adversely by the reverse stock split given the reduced number of shares that are outstanding following the reverse stock splits. In addition, the reverse stock splits increase the number of stockholders who own odd lots (less than 100 shares) of our Common Stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales.

Following a reverse stock split, the resulting market price of our Common Stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our Common Stock may not improve.

Although we believe that a higher market price of our Common Stock may help generate greater or broader investor interest, there can be no assurance that a reverse stock split, including the 1-for-35 and 1-for-10 reverse stock split we effected on December 4, 2023, and April 25, 2024, respectively, will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our Common Stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our Common Stock may not necessarily improve. The primary intent for the reverse stock splits was that the anticipated increase in the price of our Common Stock immediately following and resulting from a reverse stock split due to the reduction in the number of issued and outstanding shares of Common Stock would help us meet the minimum bid price requirement pursuant to Nasdaq Listing Rules. It cannot be assured that reverse stock splits, will result in any sustained proportionate increase in the market price of our Common Stock, which is dependent upon many factors, including our business and financial performance, general market conditions, and prospects for future success, which are unrelated to the number of shares of our Common Stock outstanding. It is not uncommon for the market price of a company's common stock to decline in the period following a reverse stock split.

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. We believe that our existing facility is adequate for our current needs, but additional office space may be required in connection with any anticipated expansion of our staff.

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 trades on the Nasdaq Capital Market under the symbol "ZVSA". Trading of our common stock commenced on December 12, 2022 in connection with the consummation of our Business Combination. Prior to that time, there was no established public trading market for our common stock.

Holders

As of March 20, 2025, there were approximately 90 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.

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 products 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, with focal segmental glomerulosclerosis (FSGS) as the lead indication. Our anti-inflammatory drug candidate, which we refer to as Inflammasome ASC Inhibitor IC 100, is a humanized monoclonal antibody in development to treat multiple inflammatory diseases, with obesity with certain metabolic complications as the lead indication.

Business Combination

On December 12, 2022 (the "Closing Date"), we consummated the previously announced Business Combination pursuant to the terms of that certain Business Combination Agreement, by and among Old ZyVersa, the representative of Old ZyVersa's shareholders named therein (the "Securityholder Representative"), Larkspur Health Acquisition Corp., a Delaware corporation ("Larkspur") and Larkspur Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Larkspur ("Merger Sub"). Pursuant to the terms of the Business Combination Agreement (and upon all other conditions of the Business Combination Agreement being satisfied or waived), on the date of the consummation (the "Closing Date") of the Business Combination and transactions contemplated thereby (the "Business Combination"), (i) Larkspur changed its name to "ZyVersa Therapeutics, Inc.", a Delaware corporation (the "Company") and (ii) Merger Sub merged with and into Old ZyVersa (the "Merger"), with Old ZyVersa as the surviving company in the Merger and, after giving effect to such Merger, Old ZyVersa became a wholly-owned subsidiary of the Company.

Prior to the completion of the Business Combination, the Company was a shell company. Following the Business Combination, the business of Old ZyVersa is the business of the Company. The Company was incorporated in the state of Delaware on March 17, 2021 and its subsidiary, Old ZyVersa, was incorporated on March 11, 2014. Larkspur Merger Sub, Inc. was incorporated in the state of Delaware on July 13, 2022.

The Business Combination was accounted for as a forward merger of Old ZyVersa under U.S. GAAP, as it was determined that Old ZyVersa was a variable interest entity as of the Closing Date. Under this method of accounting, Old ZyVersa was treated as the "acquired" company for financial reporting purposes, and Larkspur was treated as the accounting acquirer, as it was determined that Larkspur was the primary beneficiary of Old ZyVersa.

Financial Operations Overview

We have not generated any revenue to date and have incurred significant operating losses. Our net losses were $9,413,435 and $98,297,946 for the year ended December 31, 2024 and December 31, 2023 respectively. As of December 31, 2024, we had an accumulated deficit of approximately $112.6 million and cash of $1.5 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.

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 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 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 any 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 as a result of 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 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 several 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 resource, information technology, office, and travel expenses.

We expect that our general and administrative expenses will increase in the future as we increase our general and administrative 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.

Other (Income) Expense

Interest expense includes interest on indebtedness.

Results of Operations

Comparison of the years ended December 31, 2024 and December 31, 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and December 31, 2023.

(in thousands)	For the Years Ended December 31, 2024	2023	Favorable (Unfavorable) $ Change	% Change
Operating expenses:				
Research and development	$ 1,779	$ 3,208	$ 1,429	44.5%
General and administrative	7,358	11,213	3,855	34.4%
Impairment of in-process research and development	-	81,438	81,438	0.0%
Impairment of goodwill	-	11,895	11,895	0.0%
Total Operating Expenses	9,137	107,754	98,617	91.5%
Loss from Operations	(9,137)	(107,754)	98,617	91.5%
Other (Income) Expense, Net	270	-	(270)	(100.0)%
Pre-tax net loss	(9,407)	(107,754)	98,347	91.3%
Income tax benefit	(6)	9,456	(9,462)	(100.0)%
Net loss	$ (9,413)	$ (98,298)	$ 88,885	90.4%

Research and development expenses

Research and development expenses were approximately $1.8 million for the year ended December 31, 2024, a decrease of approximately $1.4 million or 44.5% from the year ended December 31, 2023. The decrease is primarily attributable to a decrease of $1.4 million in the manufacturing and pre-clinical costs of IC 100 in order to conserve cash.

General and administrative expenses

General and administrative expenses were approximately $7.4 million for the year ended December 31, 2024, a decrease of approximately $3.9 million or 34.4% from the year ended December 31, 2023. The decrease is attributable to a $0.7 million decrease in professional fees due to reduced fees related to changes in public auditors and legal counsel, a $1.1 million decrease due to the 2023 lock up share agreement, a $0.6 million decrease in director and officer insurance due to reduced costs in the second year of being a public company, a $0.4 million decrease in registration delay fees, a $0.4 million decrease in stock-based compensation as a result of options becoming fully amortized in 2024, a $0.4 million decrease due to no employee bonus accrual in 2024, and a $0.1 million decrease in marketing costs.

Impairment of in-process research and development and Impairment of goodwill

For the year ended December 31, 2024, impairment of in-process research and development and impairment of goodwill were $0 compared to $81.4 million and $11.9 million, respectively for the year ended December 31, 2023. The impairment was a result of the decline in stock value and market capitalization of the Company during the year ended December 31, 2023. There was no impairment for the year ended December 31, 2024.

Other (income) expense

Interest expense was approximately $0.3 million for the year ended December 31, 2024, an increase of approximately $0.3 million from the year ended December 31, 2023. The increase is primarily attributable to interest charged by a vendor for outstanding amounts owed.

Cash Flows

The following table summarizes our cash flows from operating and financing activities for the years ended December 31, 2024 and 2023:

(in thousands)	For the Years Ended December 31, 2024	2023	Favorable/ (Unfavorable)
Net cash provided by (used in)			
Operating activities	$ (7,560)	$ (8,721)	$ 1,161
Financing activities	5,953	5,956	(3)
Net decrease in cash	$ (1,607)	$ (2,765)	$ 1,158

Cash Flows from Operating Activities

Net cash used in operating activities was approximately $7.6 million and approximately $8.7 million for the years ended December 31, 2024 and 2023, respectively. For the years ended December 31, 2024 and 2023, the net cash used in operating activities was primarily attributable to the net loss of approximately $9.4 million and $98.3 million, respectively, offset by $0.9 million and $87.0 million, respectively, of net non-cash expenses, and approximately $0.9 million and $2.6 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 $6.0 million each for the years ended December 31, 2024 and 2023, respectively. 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. Cash provided by financing activities during the year ended December 31, 2023 primarily represented $10.7 million in cash paid for the redemption of Series A Preferred Stock and $2.4 million in registration and issuance costs associated with common stock issuances. This was partially offset by $18.1 million in proceeds from the issuance of common stock in a public offering and $1.0 million of warrant exercise proceeds.

Liquidity and Capital Resources

The following table summarizes our total current assets, current liabilities and working capital deficiency at December 31, 2024 and 2023 respectively:

(in thousands)	December 31, 2024	December 31, 2023
Current Assets	$ 1,716	$ 3,353
Current Liabilities	$ 11,231	$ 10,195
Working Capital Deficiency	$ (9,515)	$ (6,842)

Since our inception in 2014 through December 31, 2024, 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 $1.5 million as of December 31, 2024 will only be sufficient to fund our operating expenses and capital expenditure requirements on a month-to-month basis. However, 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 the Company's 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. 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 of the company to continue as a going concern, which contemplates the continuation of operations, realization of assets and liquidation of liabilities in the ordinary course of business. We incurred a net loss of $9.4 million for the year ended December 31, 2024 and a net loss of $98.3 million for the year ended December 31, 2023, and we had an accumulated deficit of $112.6 million at December 31, 2024. 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. We believe that current cash is only sufficient to fund operations and capital requirements on a month-to-month basis. Additional financings will be needed by us to fund our operations, to complete development of and to commercially develop 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, 2024 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, 2024 include approximately $11.2 million for accounts payable and accrued expenses. There are no cash requirements for long term liabilities at December 31, 2024.

Capital Needs

We expect our cash on hand will enable us to make investments in our continued development of VAR200 and IC100 on a month-to-month basis. 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 on 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 paid to us 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 in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity while producing a modest return on investment. Accordingly, our cash equivalents will be invested primarily in money market funds.

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, subject to obtaining such approval, the eventual commercialization of our product candidates. 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, including personnel to support our planned product commercialization efforts. We also expect to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company.

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 trials for our product candidates;
- the clinical development plans we establish for each product candidate;
- the number and characteristics of product candidates that we develop or may 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 and develop additional products and product candidates to augment our internal development pipeline. 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. In addition, we may pursue development, acquisition or in-licensing of approved or development products in new or existing therapeutic areas or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations, or for general corporate purposes. Strategic transactions may require us to raise additional capital through one or more public or private debt or equity financings or could 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. In addition, 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 would apply to private companies. ZyVersa expects to use this extended transition period to enable it to comply 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 between us and 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 Long-Lived Assets and Goodwill

The Company reviews for the impairment of long-lived assets and goodwill whenever 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. 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 judgment and actual results may differ from assumed and estimated amounts.

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

Critical Accounting Policies

The following are not intended to be a comprehensive list of all of our accounting policies or estimates. Our accounting policies are more fully described in Note 3 – Summary of Significant Accounting Policies, in our financial statements included at the end of this Annual Report.

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, derivative liabilities, goodwill impairment, in-process research and development, share based compensation and acquired intangible assets, 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.

Long-Lived Assets and Goodwill

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 long-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.

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.

In determining whether a quantitative assessment is required, the Company will evaluate relevant events or circumstances to determine whether it is more likely than not that the fair value of a reporting unit 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 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.

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 Expenses

Research and development costs are expensed as incurred and include all direct and indirect costs associated with the development of our product candidates. These expenses include payments to third parties for research, development and manufacturing services, personnel costs and depreciation on manufacturing equipment. At the end of the reporting period, we compare payments made to third party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to service providers and the progress that we estimate have been made as a result of the service provided, we may record net prepaid or accrued expense relating to these costs.

Fair Value of Stock Options and Warrants

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.

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 will be valued using the market approach using the trading prices of the common stock on the Nasdaq Capital 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 is utilizing an expected volatility figure based on a review of the historical volatility of six comparable entities over a period of time equivalent to the expected life of the instrument being valued. 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.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Improvements to Reportable Segments Disclosures (Topic 280), which updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses on both an annual and interim basis. The guidance becomes effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Since this new ASU addresses only disclosures, this ASU did not have any material effects on its financial condition, results of operations or cash flows.

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-28 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, 2024. 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 ineffective.

Management's Report on Internal Controls over Financial Reporting

Our management, including our principal executive officer and principal financial officer, are responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the Internal Control-Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013 Framework). Based on this evaluation, management concluded that our internal control over financial reporting was ineffective as of December 31, 2024.

Specifically, management's conclusion was based on the following material weakness which existed as of December 31, 2024 and 2023:

- Business process controls across the entity's financial reporting processes were not effectively designed and implemented to properly address the risk of material misstatement, including controls without proper segregation of duties between preparer and reviewer

A material weakness is a control deficiency or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Notwithstanding the existence of the material weakness as described above, we believe that the financial statements in the December 31, 2024 Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows as of the dates, and for the periods presented, in conformity with GAAP.

Changes in Internal Control over Financial Reporting

Management has implemented additional controls to address the material weakness identified as of December 31, 2024. This includes the implementation of proper segregation of duties controls between preparer and reviewer. However, the material weakness will not be deemed to be remediated until the

controls have been operational for a period of time and have been verified to be operating effectively.

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	65	Chief Executive Officer, President and Chairman
Karen A. Cashmere	73	Chief Commercial Officer
Peter Wolfe	57	Chief Financial Officer and Secretary
Pablo A. Guzman, M.D.	75	Chief Medical Officer and Senior Vice President of Medical Affairs
Robert G. Finizio	54	Director
Min Chul Park, Ph.D.	43	Director
James Sapirstein	63	Director
Gregory Freitag	63	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

Robert G. Finizio. Mr. Finizio has served as a member of our board of directors since December 2022. Mr. Finizio served in the same capacity at Old ZyVersa from September 2018 to December 2022. Mr. Finizio is currently the Executive Director of PleoPharma a, pharmaceutical development company focused on finding safe and effective FDA approved treatments for substance use disorders where therapies are lacking. Mr. Finizio is the Co-Founder of TherapeuticsMD Inc., an innovative women's health pharmaceutical company, and served as its Chief Executive Officer and Director from 2008 to November 2021. Mr. Finizio has over 20 years of healthcare experience. Mr. Finizio sits on the board of directors for two non-profit organizations, BioFlorida and the Boca Raton Police Foundation. Mr. Finizio graduated from the University of Miami with a Bachelor of Arts degree majoring in Premed and Psychology. Mr. Finizio was selected to serve on our board of directors based on his extensive experience with early-stage company development in the healthcare industry. Mr. Finizio was appointed to our board of directors by ZyVersa pursuant to the Business Combination Agreement.

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 of Onconetix, Inc (ONCO:NASDAQ). He served as Chairman and CEO of Entero Therapeutics (ENTO:NASDAQ) from October 2019 until February 2025. Mr. Sapirstein served as Chief Executive Officer of Contravir Pharmaceuticals from March 2014 until October 2018. All of these are publicly 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 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 sits on the Emerging Companies Section Governing Board and Health Section 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, 2024. During fiscal year ended December 31, 2024, each of Messrs. Finizio, Sapirstein, Freitag, Park, Glover, and Wolfe and 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, 2024.

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 2024 and 2023 for services rendered in all capacities to us and our subsidiaries during 2024 and 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards (1) ($)	Total Compensation ($)
Stephen C. Glover	2024	550,000	-	-	550,000
Co-Founder, Chief Executive Officer, President and Chairman	2023	550,000	225,000	218,217	993,217
Peter Wolfe	2024	395,000	-	-	395,000
Chief Financial Officer and Secretary	2023	395,000	82,500	95,859	573,359
Pablo A. Guzman, M.D.	2024	350,000	-	-	350,000
Chief Medical Officer and Senior Vice President of Medical Affairs	2023	320,833	-	185,367	506,200

(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, 2024 and December 31, 2023 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 2024

		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	152(4)	75(4)	5,726.00	2/3/2032
	5/24/2023	543(4)	1,084(4)	152.50	5/24/2033
Peter Wolfe	10/21/2015	29(4)	-	1,760.50	10/20/2025
Chief Financial Officer and Secretary	10/30/2017	29(3)	-	1,760.50	10/30/2027
	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	42(4)	21(4)	5,726.00	1/28/2032
	5/24/2023	239(4)	476(4)	152.50	5/24/2033
Pablo A. Guzman, M.D.	1/15/2015	9(2)	-	1,760.50	1/14/2025
Chief Medical Officer and	3/1/2015	29(4)	-	1,760.50	4/8/2025
Senior Vice President of Medical Affairs	4/2/2019	57(4)	-	4,053.00	4/1/2029
	10/31/2020	32(2)	-	5,726.00	10/31/2030
	12/31/2020	9(2)	-	5,726.00	12/31/2030
	3/31/2021	13(2)	-	5,726.00	3/31/2031
	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
	1/27/2023	96(4)	190(4)	738.50	1/27/2033

(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) One-third of the shares underlying each option vested on the grant date and the remaining vest in equal annual installments over two 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 2024, 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, 2024:

Name	Fees earned or paid in cash [1] ($)	Option awards ($)	Total ($)
Gregory Freitag	62,500	-	62,500
James Sapirstein	63,500	-	63,500
Robert Finizio	63,000	-	63,000
Min Chul Park	51,500	-	51,500

(1) All fees earned or paid in cash are included in accounts payable on the balance sheet of the consolidated financial statements included herein.

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. 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. Finizio earned $40,000 as a member of the Board, $15,000 as the Chairman of the Compensation Committee, and $8,000 as a member of the Audit Committee.

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.

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 October 29, 2024, 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 181,795 shares.

The following table provides information as of December 31, 2024 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]	9,288[2]	$ 2,301.04	177,638
Equity compensation plans not approved by security holders	-	$ -	-
Total	9,288	$ 2,301.04	177,638

(1) Includes the 2014 Plan, which we assumed in the 2024 Business Combination, and the 2022 Plan.
(2) Includes 5,131 and 4,157 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, 2024.
(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, 2024.

Security Ownership of Certain Beneficial Owners and Management [To be completed closer to filing]

The following table sets forth beneficial ownership of our Common Stock as of March 20, 2025 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 20, 2025. Shares subject to warrants or options that are currently exercisable or exercisable within 60 days of March 20, 2025 or subject to restricted stock units that vest within 60 days of March 20, 2025 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., 2200 N. Commerce Parkway, Suite 208, Weston, Florida 33326.

The beneficial ownership of our Common Stock is based on 2,568,191 shares of Common Stock issued and outstanding as of March 20, 2025.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Directors and executive officers		
Stephen C. Glover[(1)]	4,423	*
Min Chul Park, Ph.D.[(2)]	159	*
Robert G. Finizio[(3)]	216	*
Peter Wolfe[(4)]	715	*
Karen Cashmere[(5)]	459	*
Pablo A. Guzman, M.D[(6)]	468	*
James Sapirstein[(7)]	44	*
Gregory Freitag[(8)]	44	*
All directors and executive officers as a group (8 individuals)	6,528	*
Other 5% beneficial owners		
Armistice Capital Master Fund Ltd.[(9)]	285,037	9.99%

* 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 20, 2025 for 2,370 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 20, 2025 for 159 shares of Common Stock.

(3) Represents options that are exercisable as of or within 60 days of March 20, 2025 for 216 shares of Common Stock.

(4) Represents: (i) 127 shares of Common Stock; and (ii) options and warrants that are exercisable as of or within 60 days of March 20, 2025 for 536 and 52, respectively, shares of common stock.

(5) Represents options that are exercisable as of or within 60 days of March 20, 2025 for 459 shares of Common Stock.

(6) Represents: (i) 76 shares of Common Stock; and (ii) options and warrants that are exercisable as of or within 60 days of March 20, 2025 for 366 and 26, respectively, shares of Common Stock.

(7) Represents options that are exercisable as of or within 60 days of March 20, 2025 for 44 shares of common stock

(8) Represents options that are exercisable as of or within 60 days of March 20, 2025 for 44 shares of common stock

(9) Represents 285,037 shares of Common Stock issuable upon exercise of pre-funded warrants, but excludes 1,820,228 shares of Common Stock underlying such pre-funded warrants that are not currently exercisable as a result of a 9.99% beneficial ownership limitation blocker contained in such warrants. Also excludes warrants to purchase 3,062,465 shares of Common Stock, which become exercisable upon receipt of stockholder approval. 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

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	2024	2023
Audit Fees [1][2]	$ 290,775	$ 848,160
Audit-Related Fees [3]	-	-
Tax Fees [4]	-	-
All Other Fees	-	-
Total	**$ 290,775**	**$ 848,160**

(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, 2024 and 2023 include professional fees incurred by Ernst and Young of $56,775 and $663,160, respectively, and Marcum of $234,000 and $185,000, 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, 2023, and by Marcum for the year ended December 31, 2024, 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 Marcum LLP and Ernst & Young LLP, our independent registered public accounting firms, appear at pages F-1 through F-28 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 [TH to supplement the exhibit list in the next draft]

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 17, 2024).
3.3	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).
3.4	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).
3.5	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).
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	Inducement Letter, dated August 1, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 1, 2024).
10.19	Financial Advisory Agreement, dated August 1, 2024 (incorporated by reference to Exhibit 10.2 to the Company Current Report on Form 8-K filed with the SEC on August 1, 2024).
10.20	Inducement Letter, dated November 5, 2024 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 6, 2024).
10.21	Financial Advisory Agreement, dated November 5, 2024 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on November 6, 2024).
19.1*	Insider Trading Policies and Procedures.
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 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 27, 2025

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

Date: March 27, 2025

/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 27, 2025
/s/ Peter Wolfe Peter Wolfe	Chief Financial Officer and Secretary *(Principal Financial Officer and Principal Accounting Officer)*	March 27, 2025
/s/ Robert G. Finizio Robert G. Finizio	Director	March 27, 2025
/s/ Min Chul Park, Ph.D. Min Chul Park, Ph.D.	Director	March 27, 2025
/s/ James Sapirstein James Sapirstein	Director	March 27, 2025
/s/ Gregory Frietag Gregory Frietag	Director	March 27, 2025

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 sheets of Zyversa Therapeutics, Inc. (the "Company") as of December 31, 2024 and 2023 the related consolidated statements of operations**,** changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024 and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audits the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023 and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024 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**s**. 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 audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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**s** 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 audits 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 audits 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 audits provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2023

New York, NY,
March 27, 2025

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2024	**2023**
Assets		
Current Assets:		
Cash	$ 1,530,924	$ 3,137,674
Prepaid expenses and other current assets	184,873	215,459
Total Current Assets	1,715,797	3,353,133
Equipment, net	-	6,933
In-process research and development	18,647,903	18,647,903
Vendor deposit	178,476	98,476
Deferred offering costs	57,238	-
Operating lease right-of-use asset	-	7,839
Total Assets	$ 20,599,414	$ 22,114,284
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 9,337,267	$ 8,431,583
Accrued expenses and other current liabilities	1,894,041	1,754,533
Operating lease liability	-	8,656
Total Current Liabilities	11,231,308	10,194,772
Deferred tax liability	851,659	844,914
Total Liabilities	12,082,967	11,039,686
Commitments and Contingencies (Note 8)		
Stockholders' 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, 2024 and 2023	-	-
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of December 31, 2024 and 2023	1	1
Common stock, $0.0001 par value, 250,000,000 shares authorized; 2,508,198 and 405,212 shares issued at December 31, 2024 and 2023, respectively, and 2,508,191 and 402,205 shares outstanding as of December 31, 2024 and 2023	251	40
Additional paid-in-capital	121,155,922	114,300,849
Accumulated deficit	(112,632,559)	(103,219,124)
Treasury stock, at cost, 7 shares at December 31, 2024 and 2023	(7,168)	(7,168)
Total Stockholders' Equity	8,516,447	11,074,598
Total Liabilities and Stockholders' Equity	$ 20,599,414	$ 22,114,284

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

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2024	**2023**
Operating Expenses:		
Research and development	$ 1,779,275	$ 3,207,573
General and administrative	7,357,559	11,213,201
Impairment of in-process research and development	-	81,438,426
Impairment of goodwill	-	11,895,033
Total Operating Expenses	9,136,834	107,754,233
Loss From Operations	(9,136,834)	(107,754,233)
Other (Income) Expense:		
Interest (income) expense	269,856	(457)
Pre-Tax Loss	(9,406,690)	(107,753,776)
Income tax (provision) benefit	(6,745)	9,455,830
Net Loss	(9,413,435)	(98,297,946)
Deemed dividend to preferred stockholders	-	(7,948,209)
Net Loss Attributable to Common Stockholders	$ (9,413,435)	$ (106,246,155)
Net Loss Per Share		
- Basic and Diluted	$ (8.48)	$ (1,089.70)
Weighted Average Number of Common Shares Outstanding		
- Basic and Diluted	1,110,033	97,500

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

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

For the Years Ended December 31, 2024 and 2023

	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, 2022	8,635	$ 1	5,062	$ 1	25,760	$ 3	-	$ -	$ 104,584,170	$ (4,921,178)	$ 99,662,997
Reclassification of formerly redeemable common stock	-	-	-	-	188	-	-	-	331,331	-	331,331
Issuance of common stock pursuant to vendor agreements	-	-	-	-	10,457	-	-	-	671,621	-	671,620
Registration costs associated with preferred stock issuance	-	-	-	-	-	-	-	-	(5,500)	-	(5,500)
Registered equity offerings [1]	-	-	-	-	80,776	8	-	-	15,723,900	-	15,723,908
Redemption of Series A Preferred Stock	(8,550)	(1)	-	-	-	-	-	-	(10,295,048)	-	(10,295,049)
Conversion of Series A Preferred Stock into common stock	(35)	-	-	-	50	-	-	-	-	-	-
Shares issued as consideration for extension of lock-up period	-	-	-	-	8,698	1	-	-	1,156,777	-	1,156,778
Treasury stock acquired, at cost	-	-	-	-	-	-	(7)	(7,168)	-	-	(7,168)
Warrant modification	-	-	-	-	-	-	-	-	181,891	-	181,891
Exercise of pre-funded warrants	-	-	-	-	255,557	26	-	-	1,100	-	1,126
Warrant inducement offer - exercise proceeds [2]	-	-	-	-	20,346	2	-	-	757,644	-	757,647
Round up share adjustment due to reverse split	-	-	-	-	3,380	-	-	-	-	-	-
Stock-based compensation	-	-	-	-	-	-	-	-	1,192,963	-	1,192,963
Net loss	-	-	-	-	-	-	-	-	-	(98,297,946)	(98,297,946)
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	-	-	-	-	75,410	8	-	-	(8)	-	-

to reverse split											
Stock-based compensation	-	-	-	-	-	-	-	-	705,567	-	705,567
Warrant inducement offer - exercise proceeds [3]	-	-	-	-	1,057,800	106	-	-	(894,631)	-	(894,525)
Warrant modification	-	-	-	-	-	-	-	-	3,033,284	-	3,033,284
At the market stock issuance [4]	-	-	-	-	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

[1]Includes gross proceeds of $18,114,193 less issuance costs of $2,390,285

[2]Includes gross proceeds of $966,349 less issuance costs of $208,702

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

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

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

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CASHFLOWS

	For the Years Ended December 31,	
	2024	**2023**
Cash Flows From Operating Activities:		
Net loss	$ (9,413,435)	$ (98,297,946)
Adjustments to reconcile net loss to net cash used in operating activities:		
Impairment of in-process research and development	-	81,438,426
Impairment of goodwill	-	11,895,033
Stock-based compensation	705,567	1,192,963
Issuance of common stock pursuant to vendor agreements	196,770	671,620
Shares issued as consideration for extension of lock-up period	-	1,156,778
Depreciation of fixed assets	6,933	10,400
Non-cash rent expense	7,839	90,532
Deferred tax provision (benefit)	6,745	(9,479,069)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	30,586	56,547
Vendor deposits	(80,000)	136,524
Deferred offering costs	97,877	-
Accounts payable	750,569	2,405,938
Operating lease liability	(8,656)	(100,100)
Accrued expenses and other current liabilities	139,508	101,535
Net Cash Used In Operating Activities	(7,559,697)	(8,720,819)
Cash Flows From Financing Activities:		
Proceeds from issuance of common stock in public offering	-	18,114,193
Registration and issuance costs associated with common stock issuance	(588,045)	(2,417,095)
Redemption of Series A Preferred Stock	-	(10,695,611)
Purchase of treasury stock	-	(7,168)
Exercise of pre-funded warrants	-	1,126
Exercise of warrants	2,672,500	-
Warrant inducement offer - exercise proceeds	2,514,088	966,349
At the market issuance of stock proceeds	1,354,404	-
Registration and issuance costs associated with preferred stock issuance	-	(5,500)
Net Cash Provided By Financing Activities	5,952,947	5,956,294
Net Decrease in Cash	(1,606,750)	(2,764,525)
Cash - Beginning of Year	3,137,674	5,902,199
Cash - End of Year	$ 1,530,924	$ 3,137,674
Non-Cash Investing and Financing Activities:		
Reclassification of formerly redeemable common stock	$ -	$ 331,331
Accounts payable for deferred offering costs	$ 17,075	$ 44,892
Warrant modification - incremental value	$ -	$ 181,891
Warrant inducement offer - incremental value	$ 3,033,284	$ 134,591

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

Note 1 – Business Organization, Nature of Operations and Risks and Uncertainties

Organization and Operations

Larkspur Health Acquisition Corp. ("Larkspur"), a blank-check special purpose acquisition company, was incorporated in Delaware on March 17, 2021. On December 12, 2022, Larkspur consummated the Business Combination with ZyVersa Therapeutics, Inc. ("Predecessor") which was incorporated in the State of Florida on March 11, 2014 as Variant Pharmaceuticals, Inc. On the date of consummation of the Business Combination, Larkspur ("New Parent") changed its name to ZyVersa Therapeutics, Inc. and the Predecessor changed its name to ZyVersa Therapeutics Operating, Inc. (the "Operating Company") after merging with a subsidiary of the New Parent, with the Operating Company being the surviving entity, which resulted in it being incorporated in Delaware and it being a wholly-owned subsidiary of the New Parent (collectively the "Successor"). References to the "Company" or "ZyVersa" refer to the Successor for the Successor period from December 13, 2022 to December 31, 2022 and to the Predecessor for the Predecessor period from January 1, 2022 to December 12, 2022.

ZyVersa is 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.

Risks and Uncertainties

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. A statement by the Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts. The standard deposit insurance amount is up to $250,000 per depositor, per insured bank, for each account ownership category. Although we do not have any funds deposited with the aforementioned banks, we regularly maintain cash balances with other financial institutions in excess of the FDIC insurance limit. A failure of a depository institution to return deposits could impact access to our cash or cash equivalents and could adversely impact our operating liquidity and financial performance.

Note 2 – Going Concern and Management's Plans

As of December 31, 2024, the Company had cash of approximately $1.5 million and a working capital deficit of approximately $9.5 million. During the year ended December 31, 2024, the Company incurred a net loss of approximately $9.4 million and used cash in operations of approximately $7.6 million. The Company has an accumulated deficit of approximately $112.6 million as of December 31, 2024.

The Company has incurred losses each year since its inception and has a net working capital deficiency as of December 31, 2024. Based upon the cash on hand as of the date the financials were issued, the Company expects that the cash it currently has available will not fund its operations for 12 months from the issuance date of the financial statements. As a result, the Company will be required to raise additional funds through equity or debt financing, and there can be no assurance that it will be successful in securing additional capital. These 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.

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.

The Company's cash flow needs include the planned costs to operate its business, including amounts required to fund research and development, working capital, and capital expenditures. The Company's future capital requirements and the adequacy of its available funds will depend on many factors, including the Company's ability to successfully commercialize its products and services, competing technological and market developments, and the need to enter into collaborations with other companies or acquire other companies or technologies to enhance or complement our product and service offerings. We intend to raise additional capital in the future to fund operations. If the Company is unable to secure additional capital, it may be required to curtail its research and development initiatives and take additional measures to reduce costs in order to conserve its cash.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"), which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustment that might become necessary should the Company be unable to continue as a going concern.

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 United States Generally Accepted Accounting Principles ("U.S. GAAP") and pursuant to the accounting rules and regulations of the United States Securities and Exchange Commission ("SEC").

On December 4, 2023, the Company effected a reverse stock split of its common stock at a ratio of 1-for-35 (the "2023 Reverse Split"). Upon the effectiveness of the 2023 Reverse Split, every 35 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 was proportionally decreased, and the corresponding conversion price or exercise price was proportionally increased. No fractional shares were issued as a result of the 2023 Reverse Split.

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 was 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 2023 Reverse Split and the 2024 Reverse Split and adjustment of the conversion price or exercise price of each outstanding equity award, convertible security and warrant as if the transaction had occurred as of the beginning of the earliest period presented. See Note 9 – Stockholders' Permanent and Temporary Equity – Reverse Stock Split.

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 and acquired intangible assets, 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, 2024 and 2023, 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. See Note 1 – Risks and Uncertainties.

Business Combination

In applying the acquisition method of accounting for business combinations, amounts assigned to identifiable assets and liabilities acquired were 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 and Goodwill

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 long-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. The Company intends to perform its annual impairment testing during the fourth quarter of each year.

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.

In determining whether a quantitative assessment is required, the Company will evaluate 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 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. For the years ended on December 31, 2024 and 2023, equipment consisted of $52,000 of medical equipment, placed in service on September 1, 2019, less accumulated depreciation of $52,000 and $45,067 as of December 31, 2024 and 2023, respectively. During the years ended December 31, 2024 and 2023, the Company recognized depreciation expense of $6,933 and $10,400, respectively. Depreciation expense was included in general and administrative expenses in the statements of operations for all periods.

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, accrued expenses, 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.

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 Nasdaq Capital 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 is utilizing an expected volatility figure based on a review of the historical volatility of five comparable entities over a period of time equivalent to the expected life of the instrument being valued. 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 vested common shares outstanding during the period, plus the weighted average number of pre-funded warrants outstanding where common stock is issuable for little or no consideration. Diluted net income per common share is computed by dividing net income 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,	
	2024	2023
Warrants [1]	1,747,093	903,274
Options	9,612	10,243
Series A convertible preferred stock	72	72
Series B convertible preferred stock	2,067	2,067
Total potentially dilutive shares	1,758,844	915,657

[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, 2024 and 2023, accounts payable to one vendor accounted for 56% and 59%, respectively, of the accounts payable related to research and development. The Company relies on this vendor to perform critical research and development.

Segment Reporting

The Company operates and manages its business as one reportable and operating segment. All assets and operations are in the U.S. The Company's Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Improvements to Reportable Segments Disclosures (Topic 280), which updates reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses on both an annual and interim basis. The guidance becomes effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Since this new ASU addresses only disclosures, this ASU did not have any material effects on the Company's financial condition, results of operations or cash flows.

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.

Note 4 – Intangible Assets and Goodwill

Goodwill and in-process research and development ("IPR&D") were recorded in connection with the business combination. This IPR&D originally represented the current fair value of the IPR&D assets acquired. IPR&D recorded for book purposes is considered an indefinite-lived intangible asset until the completion or the abandonment of the research and development efforts.

Management reviewed the goodwill and IPR&D for impairment in accordance with its accounting policies. As a result of the Company's analysis, during the year ended December 31, 2023, the Company fully impaired its $11.9 million of goodwill and also recorded an $81.4 million impairment charge for its other indefinite-lived intangible assets, namely the IPR&D. There was no impairment for the year ended December 31, 2024.

Note 5 – Note Receivable

On December 13, 2020, the Company and L&F Research LLC ("L&F") entered into a promissory note agreement ("L&F Note Agreement") whereby the Company agreed to accept a note receivable in the principal amount of $351,579 from L&F ("L&F Note"). The L&F Note bears interest at a rate of 1.17% per annum, payable annually, and matures on the earliest of (a) the date on which the Company demands payment of all amounts outstanding under the L&F Note following an event of default and (b) December 15, 2025. L&F is required to immediately prepay the L&F Note and all accrued and unpaid interest on the L&F Note with the following: (a) 100% of the proceeds of the second $500,000 of milestone payments paid by ZyVersa to L&F pursuant to the terms of the license agreement (See Note 8 - Commitments and Contingencies), (b) 100% of the gross proceeds from the sale of common stock by L&F to ZyVersa pursuant to the terms of the Put Option (See Note 9 – Stockholders' Permanent and Temporary Equity), (c) 100% of the gross proceeds in excess of $1.00 per share from the sale of ZyVersa common stock by L&F to any party other than ZyVersa and (d) proceeds received in connection with certain liquidation events as defined in the agreement. Commencing on December 13, 2021 and, so long as the principal amount of the L&F Note remains outstanding, on each December 13 through December 13, 2025, the Company will pay L&F an annual administrative fee equal to $6,000.

The L&F Note was outstanding as of December 31, 2022 as the Company had not received payment from L&F of the amount due, nor had the Company made any required payments to L&F in connection with the license agreement described in Note 8 – Commitments and Contingencies, and such amount was recorded as a contra-liability against the milestone payments due to L&F in connection with the license agreement, which was included in accrued expenses and other current liabilities (see Note 6 – Accrued Expenses and other Current Liabilities). In recording the L&F Note receivable as a contra-liability, the Company considered the commercial substance, the intent of the parties and the overall contractual agreements between ZyVersa and L&F Research, which afford both parties the legal right to set-off the milestone liability owed by the Company to L&F Research with the L&F Note receivable to the Company. The Company determined that the amounts could be offset in the balance sheet because i) the amounts owed by and to the Company are determinable, ii) the Company has a legal right to set off the milestone liability owed to L&F Research by the amount of the L&F Note due to the Company, iii) the Company intends to set off the L&F Note receivable against the milestone liability, and iv) the set off right is enforceable by law.

On March 29, 2023, the Company paid the $648,421 of cash to L&F, thus meeting the conditions of Waiver A (see Note 8 – Commitments and Contingencies), 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.

Note 6 – Accrued Expenses and Other Current Liabilities

As of December 31, 2024 and 2023, accrued expenses and other current liabilities consisted of the following:

	For the Years Ended December 31,	
	2024	2023
L&F milestone payment liability	$ -	$ 500,000
Payroll accrual	1,039,338	668,803
Other accrued expenses	310,942	41,969
Bonus accrual	536,500	536,500
Registration delay liability [1]	7,261	7,261
Total accrued expenses and other current liabilities	$ 1,894,041	$ 1,754,533

[1] See Note 9 – "Stockholders' Permanent and Temporary Equity – Effectiveness Failure" for details of the registration delay liability.

Note 7 – Income Taxes

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

The provision for income taxes consists of the following (benefits) provisions:

	For the Years Ended December 31,	
	2024	2023
Current tax benefit:		
Federal	$ -	$ -
State	-	23,240
	-	23,240
Deferred tax benefit:		
Federal	(1,688,265)	(19,104,800)
State	(164,376)	(4,468,170)
	(1,852,641)	(23,572,970)
Change in valuation allowance	1,859,386	14,093,900
Provision for income taxes	$ 6,745	$ (9,455,830)

The provision for income taxes differs from the Federal statutory rate as follows:

	For the Years Ended December 31,	
	2024	2023
Federal statutory rate	21.0%	21.0%
State tax rate, net of federal benefit	3.0%	3.8%
Permanent items	0.0%	(2.8)%
Stock-based compensation	(3.2)%	0.0%
Effect of change in state rate	0.2%	(0.1)%
Prior period adjustments and other	(1.3)%	0.0%
Change in valuation allowance	(19.8)%	(13.1)%
Other	0.0%	0.0%
Effective income tax rate	(0.1)%	8.8%

Deferred tax assets and liabilities consist of the following:

	As of December 31,	
	2024	2023
Net operating loss carryforwards	$ 12,544,318	$ 9,974,075
Stock-based compensation expense	3,155,058	3,258,463
Capitalized research and development costs	1,753,207	2,182,104
Capitalized start-up costs	781,342	1,033,504
Capitalized licensing costs	609,669	647,489
Capitalized patents	392,691	351,721
Warrants	135,319	134,341
Accrued payroll	394,406	299,487
Contributions carryforward	2,878	2,857
Operating lease liability	-	2,151
Deferred tax assets	19,768,888	17,886,192
Valuation allowance	(15,953,288)	(14,093,900)
	3,815,600	3,792,292
Operating lease right-of-use asset	-	(1,948)
In-process research and development	(4,667,259)	(4,633,535)
Fixed assets	-	(1,723)
Deferred tax liabilities	(4,667,259)	(4,637,206)
Deferred tax assets, net	$ (851,659)	$ (844,914)

On December 31, 2024 and 2023, the Company had approximately $51,987,494 and $41,465,440 Federal net loss (“NOL”) carryforwards, respectively, and $37,444,050 and $30,035,239 of State NOLs, respectively.

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, 2024 and 2023. The Company does not expect any significant changes in its unrecognized tax benefits within twelve months of the reporting date.

No tax audits were commenced or were in process during the years ended December 31, 2024 and 2023 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.

Note 8 – Commitments and Contingencies

Litigations, Claims and Assessments

In the normal course of business, 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 $992,176 and $162,800, 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 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. The Company received additional invoices, dated July 31, 2024 thru December 31, 2024, which included $268,972 of interest for those same periods. 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. As such, the Company included the calculated interest from July 1, 2024 to December 31, 2024 of $268,972 within accrued expenses and other current liabilities on the consolidated balance sheet at December 31, 2024. The vendor also updated certain interest calculations such that, at December 31, 2024, the vendors interest claim that has not been accrued by the Company is $924,627.

License Agreements

L&F Research LLC

The Company 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 granted the Company 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 focal segmental glomerulosclerosis. The term of the license agreement shall commence on the effective date and, unless earlier terminated in accordance with the terms of the agreement, continue until the expiration of the last-to-expire of all royalty payment obligations of licensee.

The license agreement contains an up-front cash payment of $200,000 (paid and recognized as research and development expense in 2015), $21.5 million in aggregate milestone cash payments (the Company will recognize expense associated with the milestone cash payments when such milestones become probable of being achieved; $1,500,000 of expense was recognized during 2020 (of which, $500,000 was originally due and payable in 2021) related to the U.S. Food and Drug Administration ("FDA") acceptance of an investigational new drug application as well as commencement of Phase 2a clinical trials; the next milestone of $2,500,000 is earned upon a positive end of Phase 2 meeting with the FDA), royalties ranging from 5%-10% on sales of the product when it comes to market (the Company will recognize royalty expense if and when sales occur; none recognized to-date) and warrants to purchase an aggregate of 500 shares of common stock at an exercise price of $1,760.50 per share that were issued in 2015 with a grant date fair value of $766,384 that become exercisable for a period of five years from the date of achievement of specified milestones (a warrant to purchase 200 shares of common stock was exercisable upon its issuance in 2015 and, accordingly, the Company recognized its grant date fair value of $306,411 during 2015 as research and development expense with a corresponding credit to additional paid-in capital and was subsequently exercised on December 13, 2020; the Company will recognize expense associated with the remaining warrants when it is probable that the associated performance conditions will be achieved; a warrant to purchase 100 shares of common stock became exercisable in January 2020 upon the FDA acceptance of an investigational new drug application for a compound or product, as defined, at which time the Company recognized expense equal to the grant date fair value of $153,324; warrants to purchase 200 shares of common stock were not exercisable as of December 31, 2024 as the milestones were not achieved). For the consideration above that has yet to have been expensed or paid, the Company will recognize associated expense when such items become both probable of being achieved and such value is estimable.

On January 9, 2020, an amendment was entered into for the license agreement that provided for the following amendments: (i) partially extended the timing of payment of $1,000,000 of milestone cash payments associated with the successful completion of Phase 1 clinical trials ($500,000 payable upon commencement of Phase 2a clinical trials (the "Phase 1/2 Milestone") and $500,000 payable upon the one year anniversary of the Phase 1/2 Milestone ("First Anniversary Milestone"); and (ii) upon the condition that L&F exercises its warrant upon achievement of the Phase 1/2 Milestone, the $351,579 exercise price is to be withheld from the cash payment due to L&F in connection with the Phase ½ Milestone. See Note 5 – Note Receivable for further details about the promissory note agreement entered into upon the exercise of warrants by L&F and Note 9 – Permanent and Temporary Stockholders' Equity – Redeemable Common Stock and Put Option for discussion about the put option agreement entered into by the Company and L&F in connection with the L&F Note Agreement.

On March 7, 2022, August 26, 2022 and December 23, 2022, the Company and L&F executed a Waiver Agreement that waives L&F's right to terminate the license agreement or any other remedies, for non-payment of the $1,500,000 of milestone payments, collectively through March 31, 2023. All other terms of the license agreement remain in effect.

On February 28, 2023, the Company and L&F executed an Amendment and Restatement Agreement that waived L&F's right to terminate the L&F License Agreement or any other remedies, for non-payment of the First Milestone Payment, 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 milestone payments ("Waiver B"). Waiver A was contingent upon (i) forgiveness by the Company of $351,579 in aggregate principal amount outstanding under a certain convertible note, and (ii) a cash payment by the Company to L&F in the amount of $648,421, on or before March 31, 2023. Waiver B is contingent upon a cash payment by the Company to L&F in the amount of $500,000 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 remain in effect. See Note 5 – Note Receivable for further details around the promissory note agreement entered into upon the exercise of warrants by L&F and Note 9 – Stockholders' Permanent and Temporary Equity – Redeemable Common Stock and Put Option for discussion about the put option agreement entered into by the Company and L&F in connection with the L&F Note Agreement.

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.

InflamaCORE

On April 18, 2019, the Company entered into a license agreement with InflamaCORE, LLC ("InflamaCORE") whereby InflamaCORE agreed to grant the Company an exclusive license to the InflamaCORE Program Technology for the development and commercialization of IC 100, for the treatment of inflammation. The term of the license agreement shall commence on the effective date and, unless earlier terminated in accordance with the terms of the agreement, continue until the expiration of the last-to-expire of all royalty payment obligations of licensee. In conjunction with this license agreement, InflamaCORE entered into an agreement with the University of Miami to aggregate all of the intellectual property and technology developed by InflamaCORE scientists, who are all employees of the University of Miami, under the InflamaCORE umbrella. The term of the agreement shall commence on the effective date and shall remain in effect until the later of (a) the date on which all issued patents and filed patent applications within the patent rights have expired or been abandoned and no royalties are due or (b) twenty (20) years, unless earlier terminated in accordance with the terms of the agreement. The two agreements were executed with the understanding that ZyVersa will further develop the intellectual property and technology under the license agreement.

In consideration for the license, the Company agreed to pay an up-front fee to InflamaCORE in the amount of $346,321 to cover the patent cost reimbursement to the University of Miami. InflamaCORE is also entitled to six milestone payments totaling $22,500,000 (the first milestone payment of $200,000 is triggered by the submission of an investigational new drug application for the first indication of a therapeutic licensed product). ZyVersa is required to pay sales royalties to InflamaCORE between 5% and 10%, which expire upon the latest of: (a) expiration of the last-to-expire of a patent or (b) expiration of regulatory exclusivity, as defined in the agreement. ZyVersa is required to pay sales royalties to the University of Miami between 3% and 6%. Finally, InflamaCORE received five-year warrants to purchase an aggregate of 568 shares of common stock, of which, a warrant to purchase 227 shares of common stock, with an issue date fair value of $815,822, which was recorded as research and development expenses, was issued at the execution of the agreement at an exercise price of $4,053.00 per share and the remaining warrants to purchase 341 shares of common stock are to be issued at a price per share equal to the fair value of the common stock at the time of issuance upon the satisfaction of certain milestones, unless the Company closes an initial public offering ("IPO"), defined as the initial public offering of the Predecessor's Common Stock or other equity securities, at which point all warrants will be issued. If the Company completes its IPO within the three-year period immediately prior to the expiration date, the expiration date shall automatically be extended until the third anniversary of the effective date of the Company's IPO. The Company determined that the Business Combination didn't meet the definition of an IPO. The University of Miami also received 114 shares of common stock, with a grant date fair value of $460,000, which was recorded as research and development expenses, under the agreement. As of December 31, 2024, the Successor did not pay or owe any royalties, the performance milestones associated with the cash payments and issuance of warrants were not achieved and the Company did not accrue for any payments or issue the remaining warrants associated with the license agreement.

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 Company recognized rent expense in connection with its operating lease for the year ended December 31, 2024 and 2023 of $170,022 and $154,841, respectively.

A summary of the Company's right-of-use assets and liabilities is as follows:

	For the Years Ended December 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating activities	$ 8,656	$ 100,099
Right-of-use assets obtained in exchange for lease obligations		
Operating leases	$ -	$ -
Weighted average remaining lease term		
Operating leases	-	0.08 years
Weighted average discount rate		
Operating leases	-	6.5%

Note 9 – Stockholders' Permanent and Temporary Equity

Reverse Stock Split

On December 4, 2023 and April 25, 2024, the Company effected the 2023 Reverse Split and 2024 Reverse Split, respectively. See Note 3 – Summary of Significant Accounting Policies, Basis of Presentation and Principles of Consolidation for additional details.

Authorized Capital

The Company was authorized to issue 110,000,000 shares of common stock, par value of $0.0001 per share, and 1,000,000 shares of preferred stock, par value $0.0001 per share. The holders of the common stock are entitled to one vote per share.

Effective November 30, 2023, the Company amended its certificate of incorporation to increase the authorized shares of common stock from 110,000,000 to 250,000,000.

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, 181,795 shares of common stock are authorized for issuance as of December 31, 2024. 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, 2024, there were 177,638 shares available for future issuance under the 2022 Plan.

On January 1, 2025, the total number of shares under the 2022 Omnibus Equity Incentive Plan automatically increased to 282,122.

Common Stock

On June 5, 2023, the Company issued 8,698 shares of common stock valued at $1.2 million to certain investors in a private placement (including to certain members of the Company's sponsor) in exchange for increasing the duration of their lockup period until July 31, 2023 with respect to an aggregate of 5,651 shares of common stock underlying all securities of the Company held by such investors. The $1,156,778 fair value of the common stock issued was recorded in general and administrative expense in the Statement of Operations during the year ended December 31, 2023.

During the year ended December 31, 2023, the Company entered into marketing agreements with three vendors in which the Company issued an aggregate of 10,457 shares of common stock and cash in exchange for marketing services. The fair value of the common stock was established as a prepaid expense and the Company is recognizing $574,800 of the expense over the six month term of one of the contracts, $30,400 of the expense over the twelve month term of the second contract, and $66,420 over the six month term of the final contract.

During the year ended December 31, 2024, the Company entered into marketing agreements with three vendors in which the Company issued an aggregate of 60,000 shares of common stock in exchange for marketing services. The fair value of the common stock was established as a prepaid expense and the Company is recognizing $79,200 of the expense over the six month term of one of the contracts, $48,570 of the expense over the six month term of the second contract, and $69,000 of the expense over the three month term of the third contract.

Registered Equity Offerings

On April 28, 2023, the Company completed a registered offering of 31,473 shares of common stock and warrants to purchase 31,473 shares of common stock for gross proceeds of $11.0 million (the "April 2023 Offering"). Each share of common stock was sold together with a five-year warrant to purchase one share of common stock at an exercise price of $350.00 per share, which was exercisable upon issuance. The Company determined that the warrant should be equity-classified, primarily because it is indexed to the Company's own stock and it met the requirements for equity classification. Accordingly, because both the common stock and the warrant are equity-classified, it wasn't necessary to allocate the proceeds or the issuance costs to the respective securities. Total issuance costs were $1,184,482 including $440,620 placement fees, $455,332 of legal fees, $259,774 of accounting and professional service costs related to the offering, and $28,756 of other costs.

On July 26, 2023, the Company completed a registered offering of 9,303 shares of common stock, pre-funded warrants (the "July 2023 Pre-Funded Warrants") to purchase 27,061 shares of common stock and common warrants (the "July 2023 Warrants") to purchase 36,364 shares of common stock at a combined public offering price of $57.75 per share (less $0.04 for each July 2023 Pre-Funded Warrant) which resulted in gross proceeds of $2.1 million (the "July 2023 Offering"). The July Pre-Funded Warrants are exercisable immediately, may be exercised at any time until all July 2023 Pre-Funded Warrants are exercised in full, and have an exercise price of $0.04 per share. The July 2023 Warrants are exercisable immediately for a term of five years and have an exercise price of $57.75 per share. The Company determined that both warrants should be equity-classified, primarily because they are indexed to the Company's own stock and they met the requirements for equity classification. Accordingly, because the common stock and both warrants are equity-classified, it wasn't necessary to allocate the proceeds or the issuance costs to the respective securities. Total issuance costs were $523,115 including $125,943 of placement fees, $236,091 of legal fees, $87,037 of accounting and professional service costs related to the offering, $26,744 of other costs, and $47,300 incremental fair value of the modified warrants as compared to the original warrants (see Stock Warrants below).

On December 11, 2023, the Company completed a registered offering of 40,000 shares of common stock, pre-funded warrants (the "December 2023 Pre-Funded Warrants") to purchase 360,000 shares of common stock, Series A common warrants (the "December 2023 Series A Warrants") to purchase 400,000 shares of common stock, and Series B common warrants (the "December 2023 Series B Warrants") to purchase 400,000 shares of common stock at a combined public offering price of $12.50 per share (less $0.001 for each December 2023 Pre-Funded Warrant) which resulted in gross proceeds of $5.0 million (the "December 2023 Offering"). The December 2023 Pre-Funded Warrants are exercisable immediately, may be exercised at any time until all Pre-Funded Warrants are exercised in full, and have an exercise price of $0.001 per share. The December 2023 Series A Warrants are exercisable immediately for a term of five years and have an exercise price of $12.50 per share. The December 2023 Series B Warrants are exercisable immediately for a term of 18-months and have an exercise price of $12.50 per share. The Company determined that all warrants should be equity-classified, primarily because they are indexed to the Company's own stock and they met the requirements for equity classification. Accordingly, because the common stock and warrants are equity-classified, it wasn't necessary to allocate the proceeds or the issuance costs to the respective securities. Total issuance costs were $653,514 including $299,978 of placement fees, $232,336 of legal fees, $94,325 of accounting and professional service costs related to the offering, and $26,875 of other costs.

At-The-Market Offering

In October and November 2024, the Company received approximately $1.35 million in gross proceeds from the sale of 564,495 shares of its common stock pursuant to its ATM Agreement with A.G.P. for its "at-the-market" facility.

Redeemable Common Stock and Put Option

On December 13, 2020 (the "Effective Date"), in connection with the L&F Note Agreement (see Note 5 – Note Receivable for details), the Predecessor and L&F entered into an agreement to provide L&F with a put option to cause the Company to purchase up to 331,331 shares of Predecessor common stock ("Put Shares") at a price of $1.00 per share ("Put Option"). The put option expires at the earlier of (A) the date that the L&F Note is repaid in full; or (B) the fifth (5th) anniversary of the Effective Date. The parties agreed that, in the event of an exercise by L&F, in lieu of paying L&F for the Put Shares, the Company shall reduce the amount of the receivable then owed by L&F to the Company under the L&F Note Agreement. The Put Option was sold to L&F for total consideration of $331, which was recorded within additional paid-in capital.

On December 12, 2022, the Company closed on the Business Combination whereby the 331,331 shares of Predecessor common stock subject to the Put Option were exchanged for 188 shares of Successor common stock at a price of $1762.80 per share. The put option has the practical effect of making the underlying shares of Successor common stock redeemable. As a result, they were classified as temporary equity on the December 31, 2022 balance sheet.

On March 29, 2023, the Company forgave $351,579 in aggregate principal amount outstanding on the L&F Note and paid $648,421 of cash to L&F, thus meeting the conditions of Waiver A. L&F's put option expired upon meeting the Waiver A conditions, which resulted in a reclassification of 188 shares of Successor common stock and $331,331 classified as temporary equity to permanent equity.

Preferred Stock

Series A Preferred Stock Financing

In connection with the Business Combination, the Company sold 8,635 shares of Series A Preferred Stock and five-year warrants to purchase 2,465 shares of common stock at an exercise price of $4,025.00 per share (the "PIPE Warrants"), to certain purchasers at a price of $1,000 per share for net proceeds of $8,635,000 (the "PIPE" financing).

The Series A Preferred Stock is convertible, at the option of the holder, at any time into a number of shares of common stock equal to the face value divided by the conversion price then in effect (initially $3,500.00). In addition, for five years following the issuance of the Series A Preferred Stock, the conversion price is automatically adjusted to the greater of (a) $700.00; and (b) the lowest price of any subsequent offerings of securities at a price less than the conversion price.

The conversion price also resets at both 90 days and 150 days following the effectiveness of the registration of the Series A Preferred Stock (each a "Commencement Date") to the greater of (a) $700.00; and (b) 85% of the lowest of the ten consecutive daily volume-weighted average prices commencing on, and including, each Commencement Date.

The Series A Preferred stockholders have no voting rights and dividends will only be paid on an as-converted basis when, and if paid to common stockholders. In the event of any liquidation, dissolution or winding up of the Company, each Series A Preferred stockholder shall be entitled to be paid out of the assets of the Company legally available for distribution, the stated value of their holdings, plus any accrued and unpaid dividends. The balance of any proceeds shall be distributed to Series A Preferred stockholders on an as-converted basis *pari passu* with the Company common stockholders.

The Series A Preferred Stock is not redeemable at the election of the holder and, therefore, it is classified as permanent equity. However, subject to the holder's right to elect to convert, the Company has the right to redeem the Series A Preferred Stock anytime at 120% of the face value. The Company determined that the embedded conversion options were clearly and closely related to the preferred stock host and, therefore, the embedded conversion options need not be bifurcated. However, if the conversion price is reset in connection with a subsequent issuance of securities, the Company will need to assess the accounting for the price reset. Due to the Company's adoption of ASU 2020-06 on January 1, 2021, it wasn't necessary to assess the embedded conversion options for a beneficial conversion feature.

On or about April 28, 2023, cash proceeds from the April 2023 Offering in the amount of $10.5 million were used to redeem 8,400 shares of Series A Preferred Stock. The loss on the extinguishment of preferred stock is accounted for in a manner similar to the treatment of dividends paid on preferred stock. The loss on extinguishment is calculated as the difference between (a) the fair value of the negotiated $10.5 million of cash transferred to the holders of the Series A Preferred Stock (which also settled the Company's obligation to make Effectiveness Failure payments (See Note 9 – "Stockholders' Permanent and Temporary Equity – Effectiveness Failure" for details of Effectiveness Failure)), and (b) the $3.7 million net carrying amount of the Series A Preferred Stock. Accordingly, the redemption resulted in the recognition of a $6.4 million deemed dividend for the purposes of calculating the Company's loss per common share. Because the Company has an accumulated deficit, both the debit and the credit associated with the dividend are to additional paid-in-capital, so there is no balance sheet effect.

On August 3, 2023, the Company entered into a redemption agreement and release with an investor which resulted in the Company, on August 4, 2023, redeeming 150 of the 200 remaining shares of Series A Convertible Preferred Stock and warrants to purchase 247 shares of common stock at an exercise price of $20.00 per share for a cash payment of $230,000. The Company recognized an $32,373 deemed dividend during the year ended December 31, 2023, as a result of the extinguishment accounting associated with the redemption.

As a result of the April 2023 Offering, (a) the exercise price of the Series A Warrants to purchase 2,465 shares of common stock at an exercise price of $4,025.00 per share that were issued to participants in the original PIPE financing had the exercise price reset to its floor price of $700.00 per share, while becoming exercisable for 14,186 shares of common stock (which resulted in the recognition of a $1.4 million deemed dividend); and (b) the remaining 235 shares of Series A Preferred Stock had their $3,500.00 original conversion price reset to the floor conversion price of $700.00 per share of common stock (which resulted in the recognition of a $37,000 deemed dividend).

Following the triggering of the down round provision, the holders of 35 shares of Series A Preferred Stock converted into 50 shares of common stock at the new conversion price of $700.00 per share.

Preferred Series B Issuance

In connection with the Business Combination, the Company issued 5,062 shares of Series B Preferred Stock to certain vendors that provided services to the Company at a price of $1,000 per share in exchange for the satisfaction of $5,062,000 of Company liabilities.

The Series B Preferred Stock is convertible, at the option of the holder, at any time into a number of shares of common stock equal to the face value divided by the conversion price then in effect (initially $3,500.00). In addition, for five years following the issuance of the Series B Preferred Stock, the conversion price is automatically adjusted to the greater of (a) $2,450.00; and (b) the lowest price of any subsequent offerings of securities at a price less than the conversion price.

The conversion price also resets at 150 days following the effectiveness of the registration of the Series B Preferred Stock (each a "Commencement Date") to the greater of (a) $2,450.00; and (b) the lowest of the five consecutive daily volume-weighted average prices commencing on, and including, the Commencement Date.

The Series B Preferred stockholders have no voting rights and dividends will only be paid on an as-converted basis when, and if paid to common stockholders. In the event of any liquidation, dissolution or winding up of the Company each Series B Preferred stockholder shall be entitled to be paid out of the assets of the Company legally available for distribution, the stated value of their holdings, plus any accrued and unpaid dividends. The balance of any proceeds shall be distributed to Series B Preferred stockholders on an as-converted basis *pari passu* with the Company common stockholders.

The Series B Preferred Stock is not redeemable and, therefore, it is classified as permanent equity. The Company determined that the embedded conversion options were clearly and closely related to the preferred stock host and, therefore, the embedded conversion options need not be bifurcated. However, if the conversion price is reset in connection with a subsequent issuance of securities, the Company will need to assess the accounting for the price reset. Due to the Company's adoption of ASU 2020-06 on January 1, 2021, it wasn't necessary to assess the embedded conversion options for a beneficial conversion feature.

As a result of the April 2023 Offering, the $3,500.00 original conversion price of the 5,062 shares of Series B Preferred Stock issued in connection with the Business Combination reset to its floor price of $2,450.00 per share of common stock (which resulted in the recognition of a $0.1 million deemed dividend).

Stock-Based Compensation

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.

For the year ended December 31, 2023, the Company recorded stock-based compensation expense of $1,192,963 (of which, $132,767 was included in research and development and $1,060,196 was included in general and administrative expense) related to options issued to employees and consultants.

Stock Options

The grant date fair value of stock options granted during the years ended December 31, 2024 and December 31, 2023 was determined using the Black Scholes method, with the following assumptions used:

	For the Years Ended December 31,	
	2024	2023
Fair value of common stock on date of grant	N/A	$152.50 - $791.00
Risk free interest rate	N/A	3.53% - 4.27%
Expected term (years)	N/A	5.00 - 6.00
Expected volatility	N/A	120% - 123%
Expected dividends	N/A	0.00%

A summary of the option activity for the year ended December 31, 2024 is presented below:

	Number Of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2024	10,243	$ 2,218.51		
Granted	-	-		
Exercised	-	-		
Expired	(631)	1,760.50		
Outstanding, December 31, 2024	9,612	$ 2,248.58	6.3	$ -
Exercisable, December 31, 2024	6,770	$ 2,991.15	5.4	$ -

The following table presents information related to stock options as of December 31, 2024:

Options Outstanding			Options Exercisable	
Exercise Price	Outstanding Number Of Options	Weighted Average Remaining Life In Years	Exercisable Number Of Options	
$ 152.50	4,157	8.4	1,674	
$ 738.50	286	8.1	96	
$ 791.00	38	8.2	13	
$ 1,760.50	1,279	1.9	1,279	
$ 3,965.50	37	7.5	37	
$ 4,053.00	2,095	4.3	2,095	
$ 5,726.00	1,720	6.4	1,576	
	9,612	5.4	6,770	

Stock Warrants

On July 26, 2023, in connection with the July 2023 Offering (see Registered Equity Offerings above), the Company amended the exercise price of certain warrants to purchase 3,938 shares of common stock for three investors from $350.00 to $57.75 per share and the expiration date was modified from April 28, 2028 to July 28, 2028. The $47,300 incremental fair value of the modified warrants as compared to the original warrants was recognized as an additional issuance cost of the July 2023 Offering.

On August 2, August 8 and September 8, 2023, a July 2023 Offering investor exercised pre-funded warrants to purchase an aggregate of 27,057 shares of common stock at an exercise price of $0.04 per share for total proceeds of $947.

Between September 13 and September 18, 2023, the Company initiated a limited time program, which at the election of the warrant holder, would permit them to immediately exercise their July 2023 Warrants at a reduced exercise price of $47.50 per share and they would also be granted new 5.5-year warrants to purchase an equal number of shares of common stock at an exercise price of $47.50 per share. The new warrants are not exercisable for the first six months. Under the program, warrants to purchase an aggregate of 20,347 shares of common stock were exercised on September 14, 2023 for gross proceeds of $966,400 less total issuance costs of $208,702. Issuance costs include placement agent fees of $57,980, legal costs of $16,131, and warrant modification costs of $134,591. 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 $134,591 modification date incremental value of the modified warrants and additional warrants issued as compared to the original warrants, as an issuance cost of the warrant exercise.

Between February 26, 2024 and March 6, 2024, investors in the registered offering completed on December 11, 2023 (the “December 2023 Offering”) exercised warrants to purchase 213,800 shares of common stock at an exercise price of $12.50 per share for total proceeds of $2,672,500.

Between January 17 and February 23, 2024, a December 2023 Offering investor exercised pre-funded warrants to purchase 131,500 shares of common stock on a cashless basis and received 131,481 shares of common stock at an exercise price of $0.001 per share.

On August 1, 2024, the Company initiated a limited time program, which was immediately accepted by the warrant holder, that permitted the holder to exercise its December 2023 Offering warrants at a reduced exercise price of $3.46 per share and granted new warrants to purchase up to (i) 392,000 shares of common stock which became exercisable upon stockholder approval with an exercise term of five years and (ii) 86,600 shares of common stock which became exercisable upon stockholder approval with an exercise term of 18 months. The Company received stockholder approval for the warrants on October 29, 2024 and the warrants have an exercise price of $3.46 per share. Under the program, the warrant holder submitted an exercise notice and the related aggregate cash exercise price to purchase 239,300 shares of common stock on August 1, 2024 for gross proceeds of $827,978 less issuance costs of $427,054. Issuance costs included placement agent fees of $50,000, placement agent legal fees of $50,000, Company legal fees of $57,267, other expenses of $22,875 and warrant modification costs of $246,912. 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 $246,912 modification date incremental value of the modified warrants and additional warrants issued as compared to the original warrants, as an issuance cost of the warrant exercise.

On November 5, 2024, the Company initiated a limited time program, which was immediately accepted by the warrant holder, that permitted the holder to exercise 339,900 of its December 2023 and 478,600 of its August 2024 Common Stock Purchase warrants at a reduced exercise price of $2.06 per share from $12.50 and $3.46 per share, respectively. New warrants were granted to purchase 1,637,000 shares of common stock at an exercise price of $2.06 per share with an exercise term of 5 years from stockholder approval. Under the program, the warrant holders submitted exercise notices and the related aggregate cash exercise price to purchase an aggregate of 818,500 shares of common stock on November 5, 2024 for gross proceeds of $1,686,110. Issuance costs include financial advisor fees of $110,000, reimbursement to the financial advisor for non-accountable fees of $10,000, legal and other fees of $75,187, and warrant modification costs of $2,786,372. Because the Existing Warrants and the shares issued in connection with their exercise were equity classified, and because the Reload Warrants are equity classified, and because the Existing Warrant modification was in connection with an equity financing transaction to raise capital, the Company recognized the $2,786,372 modification date incremental value of the modified warrants and additional warrants issued as compared to the original warrants, as an issuance cost of the warrant exercise.

The issuance date fair value of stock warrants issued during the years ended December 31, 2024 and 2023 was determined using the Black Scholes method, with the following assumptions used:

	For the Years Ended December 31,	
	2024	2023
Fair value of common stock on date of grant	$2.54 - $3.46	$47.50 - $350.00
Risk free interest rate	3.62% - 4.62%	3.51% - 4.42%
Expected term (years)	0.6 - 5.3 years	5 years
Expected volatility	87% - 111%	121% - 123%
Expected dividends	N/A	N/A

A summary of the warrant activity for the year ended December 31, 2024 is presented below:

	Number Of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2024 [1]	903,320	$ 123.44		
Issued	2,115,600	2.38		
Forfeited	(227)	4,053.00		
Exercised [2]	(1,271,600)	4.08		
Repriced - Old [3]	(239,300)	12.50		
Repriced - New [3]	239,300	3.46		
Repriced - Old [4]	(339,900)	12.50		
Repriced - New [4]	339,900	2.06		
Repriced - Old [5]	(478,600)	3.46		
Repriced - New [5]	478,600	2.06		
Outstanding, December 31, 2024	1,747,093	$ 59.59	5.06	$ -
Exercisable, December 31, 2024	109,893	$ 913.41	3.34	$ -

[1] Warrants outstanding and exercisable exclude 131,500 Pre-Funded Warrants with an exercise price of $0.001.
[2] Warrants exercised exclude 131,500 December 2023 Pre-Funded Warrants exercised with an exercise price of $0.001.
[3] Warrants represent the reset of the exercise price of certain December 11, 2023 Series A and Series B warrants to purchase 239,300 shares of common stock to a price of $3.46 per share.
[4] Warrants represent the reset of the exercise price of certain December 11, 2023 Series A and Series B warrants to purchase 339,900 shares of common stock to a price of $2.06 per share.
[5] Warrants represent the reset of the exercise price of certain August 1, 2024 Series A-1 and Series B-1 warrants to purchase 478,600 shares of common stock to a price of $2.06 per share.

The following table presents information related to stock warrants as of December 31, 2024:

Warrants Outstanding		Warrants Exercisable	
Exercise Price	Outstanding Number Of Warrants	Weighted Average Remaining Life In Years	Exercisable Number Of Warrants
$ 2.06	1,637,000	-	-
$ 12.50	7,000	2.47	7,000
$ 47.50	20,347	4.20	20,347
$ 57.75	19,965	3.52	19,965
$ 350.00	27,551	3.32	27,551
$ 700.00	13,944	2.95	13,944
$ 1,760.50	300	0.02	100
$ 2,415.00	3,651	2.95	3,651
$ 4,025.00	17,335	2.95	17,335
	1,747,093	3.34	109,893

Effectiveness Failure

In connection with the Business Combination, the Company conducted the Series A Preferred Stock Financing. On or about February 20, 2023, the Company failed to have the SEC declare a registration statement effective (the "Effectiveness Failure") which covered the Series A Preferred Stock registrable securities within the time period prescribed by the Securities Purchase Agreement (the "SPA"). The SPA entitles the investors to receive registration delay payments ("Registration Delay Payments") equal to 1.5% of each investor's purchase price on the date of the Effectiveness Failure and every thirty days thereafter that the Effectiveness Failure persists. Failure to make the Registration Delay Payments on a timely basis result in the accrual of interest at the rate of 2.0% per month. On April 28, 2023, the proceeds from the April 2023 Offering were used to make most of the Registration Delay Payments and redeem substantially all of the Series A Preferred Stock (see Series A Preferred Stock Financing above). As of December 31, 2024, the Company has accrued additional Registration Delay Payments of approximately $7,261 in the aggregate.

Note 10 – 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 11 – 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.

Private Placement

On March 7, 2025, the Company entered into a private placement (the "Private Placement") with an institutional investor, pursuant to which the Company agreed to sell 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 $2.0 million. In addition, the Company and the investor entered into an amendment to certain November 5, 2024 common share purchase warrants to reduce the exercise price of the warrants to purchase 957,200 shares of common stock from $2.06 per share to $1.00 per share. 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. The March 2025 Common Warrants are exercisable upon Stockholder Approval for a term of five years following stockholder approval and have an exercise price of $1.00 per share. Issuance costs include financial advisor fees of 6.5% of gross proceeds plus reimbursement of certain non-accountable and other expenses.

Exhibit 19.1

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.

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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. Who is an Insider?

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. What is Material Information?

"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. <u>What is Nonpublic Information?</u>

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. What Are the Consequences of Violations of This Policy?

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. Trading Windows and Pre-Clearance.

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

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of ZyVersa Therapeutics, Inc. on Form S-3 (File No. 333-281913, File No. 333-281914, File No. 333-283993) and S-8 (File No. 333-272106 File No. 333-277062, File No. 333-284475)**,** of our report dated March 27, 2025, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of ZyVersa Therapeutics, Inc. as of December 31, 2024 and for the years ended December 31, 2024 and 2023 which report is included in this Annual Report on Form 10-K of ZyVersa Therapeutics, Inc. for the year ended December 31, 2024.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 27, 2025

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 27, 2025

/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 27, 2025

/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, 2024 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 27, 2025

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

Date: March 27, 2025

/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.