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, 2023
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, 2023, 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 $8.61 for such shares on the Nasdaq Global Market on June 30, 2023) was approximately $5.6 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 21, 2024, the number of shares outstanding of the registrant's common stock, $0.0001 par value per share, was 7,594,863.

DOCUMENTS INCORPORATED BY REFERENCE

None.

ZYVERSA THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023
TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 current and future pandemics, such as the COVID-19 pandemic;
- 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 H1-2024, in which we expect to obtain patient proof-of-concept data more quickly than in an ESGS 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, is nearing completion of preclinical development. Our focus is on advancing IC 100 toward a currently planned IND submission in Q4-2024, followed by initiation of a Phase 1 trial. IC 100 has pharmacologic proof-of-concept data in animal models representative of multiple sclerosis ("MS") and acute respiratory distress syndrome ("ARDS"), and mechanistic proof of concept in animal models and/or tissue cultures representative of Alzheimer's disease, spinal cord injury, and traumatic brain injury. Studies are underway in animal models representing Parkinson's disease, atherosclerosis, and obesity. We anticipate that one or more lead indications for IC 100 will be selected based on data from our preclinical program.

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 can be substantial, as Medicare Fee-for-Service spending was $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, multiple sclerosis is associated with activation of AIM2, NLRP1, NLRP3, and NLRC4. The ASC component of inflammasomes is a promising drug target since it is a component of the six most common types of inflammasomes referenced above. We believe this is more advantageous than targeting a specific sensor protein, a component of 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 each of VAR 200 and IC 100, and through potential in-licensing of promising renal and anti-inflammatory product candidates.

Our current pipeline consists of the following:

1. Development Phase: Phase in which a drug formulation is developed that ensures the proper drug delivery parameters are met.
2. Pre-clinical Phase: Phase in which in vitro (laboratory) and in vivo (animal) studies are conducted to gather evidence to justify clinical trials in humans.
3. FDA concurred that a Phase 1 trial was not required for VAR 200 based on VAR 200's established historical safety profile.

For VAR 200, our lead renal indication is FSGS (VAR 200-01). For IC 100, we will select one or more lead indications prior to our IND filing planned for Q4-2024. This will be based on data from existing and future preclinical studies.

The 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

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

With the myriad of diverse diseases and conditions mediated by chronic inflammation, we believe IC 100 has potential to treat a multitude of inflammatory diseases. The following is a summary of the market for IC 100's current pipeline.

Condition	Overview	U.S. Prevalence	Unmet Needs
Acute Respiratory Distress Syndrome*	Life-threatening respiratory failure with rapid onset of widespread inflammation in the lungs, noncardiogenic pulmonary edema, hypoxemia refractory to oxygen therapy, and decreased lung compliance	190,600[1]	No drug proven beneficial in prevention or management of ARDS
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[2]	Current drugs don't effectively delay/halt disease progression, and none are neuroprotective
IgA Nephropathy*	Autoimmune kidney disease associated with renal deposition of IgA leading to inflammation and renal failure in up to 40%	127,360[3]	No disease-modifying drugs
Pancreatic Cancer*	Metastatic cancer that's the fourth leading cause of cancer death in U.S.	60,430[4]	No effective treatment options that substantially prolong life
Parkinson's Disease	Complex, multifaceted, neurodegenerative disorder involving aging, genetics, and environmental factors	~1 Million[5]	No neuroprotective or disease-modifying therapies
Huntington's Disease*	Hereditary, progressive, and fatal brain disorder causing uncontrolled movements, loss of cognitive abilities, and behavioral manifestations	30,000[6]	No disease-modifying therapies
Atherosclerosis	Chronic, progressive inflammatory disease characterized by the accumulation of lipids and fibrous elements in the large arteries.	18.3 Million[7]	No drugs effectively decrease morbidity and mortality
Alzheimer's Disease	Decline in mental function that progresses to dementia	6.7 Million[8]	No drugs delay prevention of impairment
Obesity	Abnormal or excessive fat accumulation that presents a risk to health (body mass index over 30)	107 Million[9]	Long-acting drugs that are safer and more effective

*Orphan Indications

1. Quintanilla E, et al. Front Genet. 2021 December
2. National Multiple Sclerosis Society
3. IgA Nephropathy Market. DelveInsight Report, October, 2021
4. National Cancer Institute
5. Parkinson's Foundation
6. Huntington's Disease Market. DelveInsight Report, October 2021
7. Klimchak AC. et al. Am J Prev Cardiol. 2020 May
8. Alzheimer's Association 2023
9. USDA National Institute of Food and Agriculture

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 H1-2024, 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 our Phase 2a/b protocol in patients with FSGS.
- ***Advance our Inflammasome ASC Inhibitor IC 100 preclinical program.*** We intend to advance our IC 100 preclinical program toward a planned IND submission in Q4-2024. We currently have non-GLP toxicology data in mice and non-human primates ("NHP") demonstrating no adverse effects nor anti-drug antibodies at doses as high as 300 mg/kg, and pharmacologic proof-of-concept data for IC 100 in animal models and/or tissue cultures representative of acute respiratory distress syndrome and multiple sclerosis, and mechanistic proof of concept in animal models representative of Alzheimer's disease, spinal cord injury, and traumatic brain injury. Studies are underway in animal models representing Parkinson's disease, atherosclerosis, and obesity. This will enable optimal selection of one or more lead indications to take into the clinic.

- ***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™ Platform, VAR 200, (including, FSGS, Alport Syndrome, and diabetic kidney disease), and eight potential indications for our Inflammasome ASC inhibitor IC 100 platform (including, ARDS, multiple sclerosis, IgA nephropathy, Parkinson's Disease, Huntington's Disease, atherosclerosis, early Alzheimer's disease, and obesity. 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 for 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

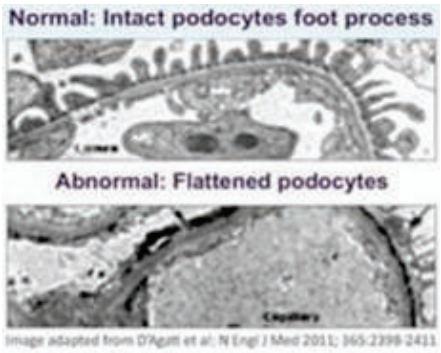
Cholesterol Efflux Mediator ™, VAR 200 (2-hydroxypropyl-beta-cyclodextrin, 2HPβCD)

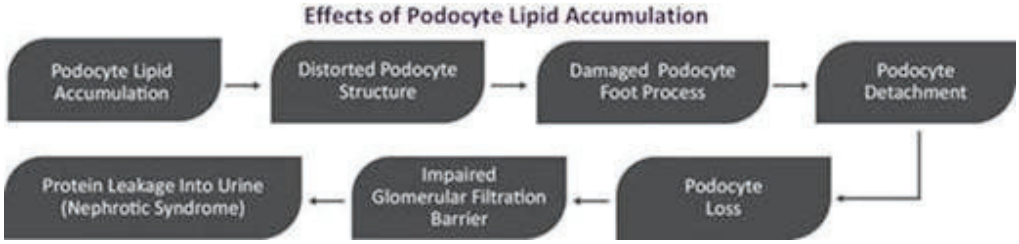
Cholesterol Efflux Mediator VAR 200 is an injectable drug in clinical development for treatment of chronic glomerular diseases, initially focusing on FSGS. Prior to initiating a Phase 2a trial in patients with FSGS, we are planning to conduct a small Phase 2a trial in patients with diabetic kidney disease, 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 with the intent to preserve renal structure and function and reduce proteinuria that leads to glomerular disease progression by mediating removal of excess cholesterol that damages renal glomeruli. 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 H1-2024, 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 by *in vitro* podocyte studies, in 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. We hypothesize that restoration of lipid homeostasis and podocyte integrity has the potential to slow ongoing kidney damage progression to kidney failure, and delay the need for dialysis and ultimately transplant.



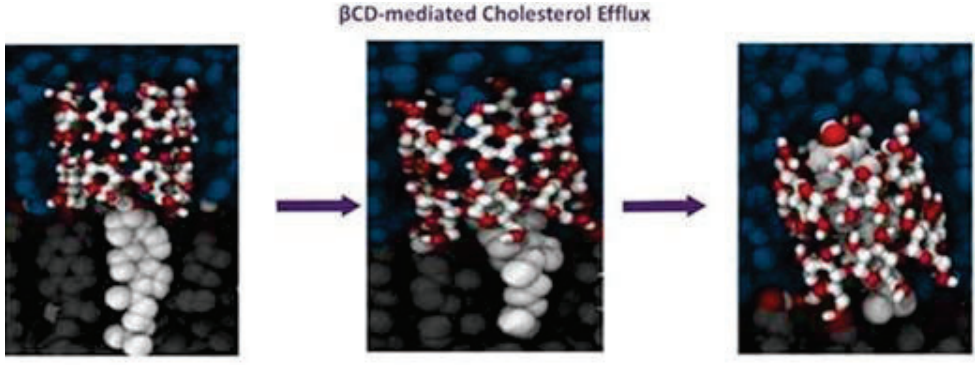


VAR 200 Mechanism of Action

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").



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 our *in vivo* studies and decades of use as an excipient. Additionally, it is our belief that 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.

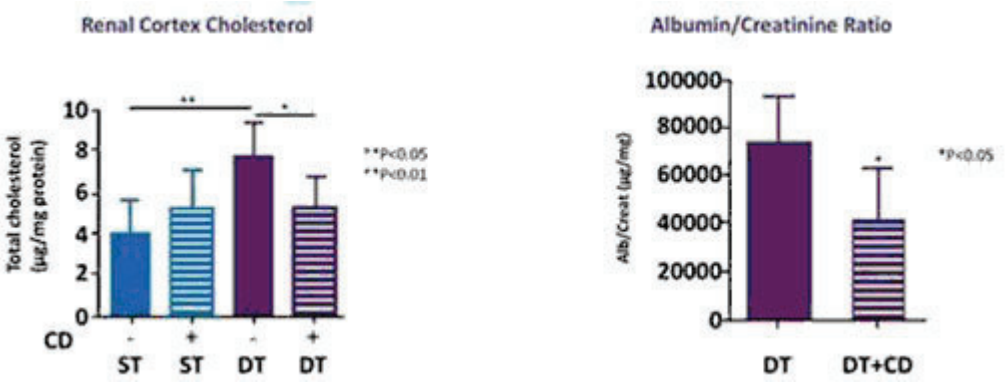
VAR 200 and FSGS

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

In a study to examine 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.

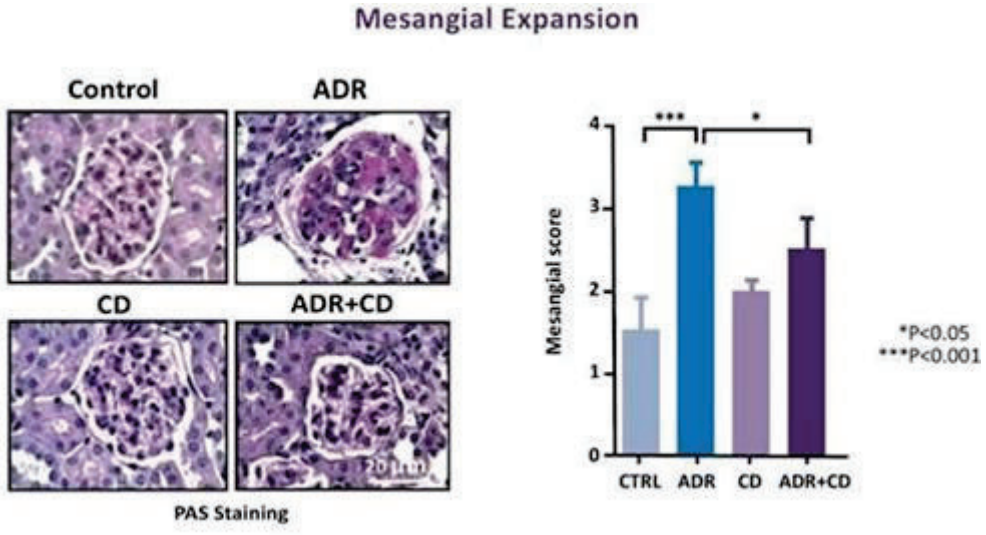
VAR 200 (indicated by "CD" in the graphs below) significantly reduced cholesterol in the renal cortex of FSGS mice compared to untreated double transgenic mice (indicated by "DT" in the graphs below). This was associated with a significant reduction in proteinuria (albumin/creatine ratio) as shown below.



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.

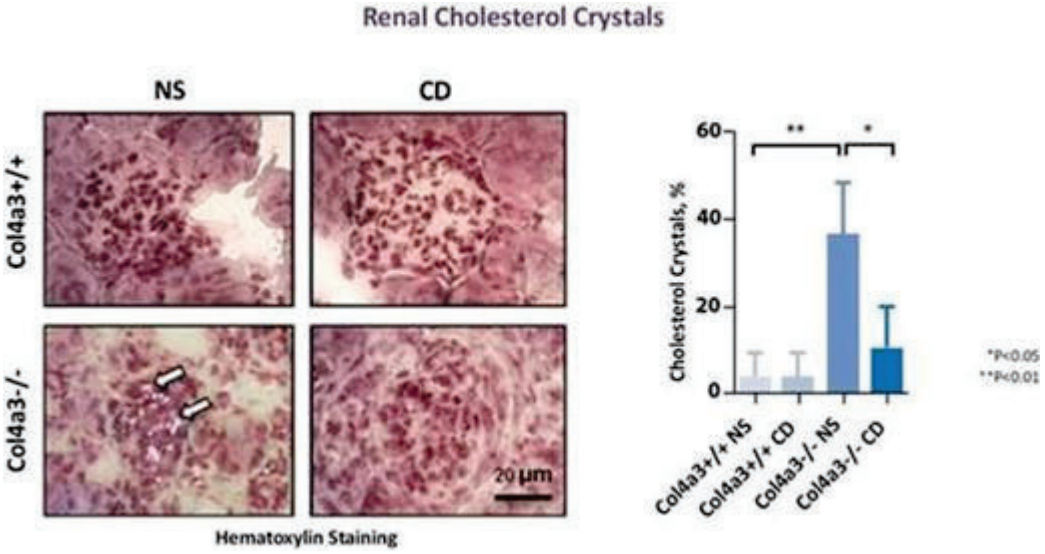
VAR 200 (indicated by "CD" in the graphs below) significantly reduced mesangial expansion, which is commonly associated with lipid deposition, compared to untreated ADR-induced mice as shown below. This was associated with a significant reduction in proteinuria (albumin/creatine) and blood urea nitrogen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



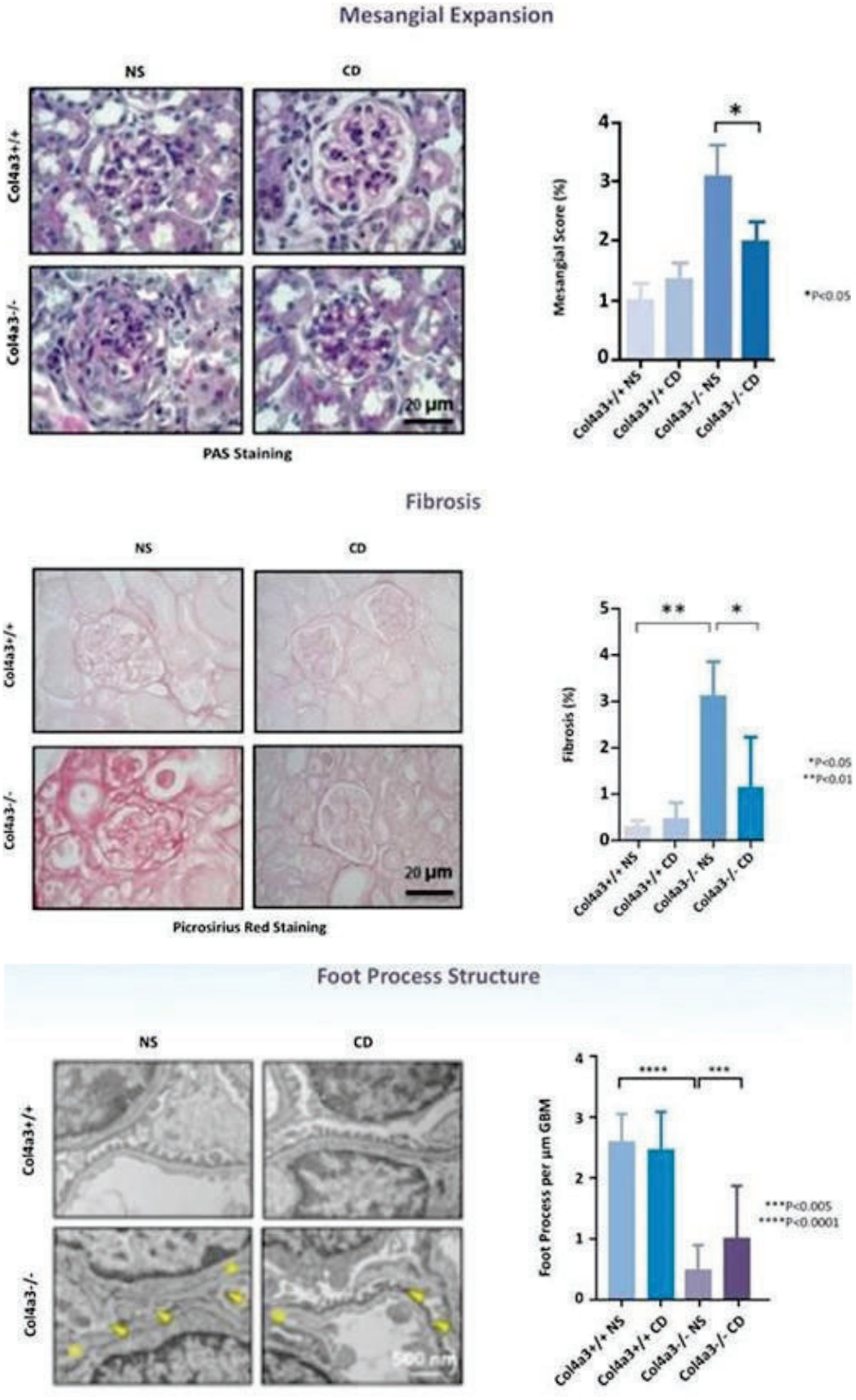
VAR 200 and Alport Syndrome

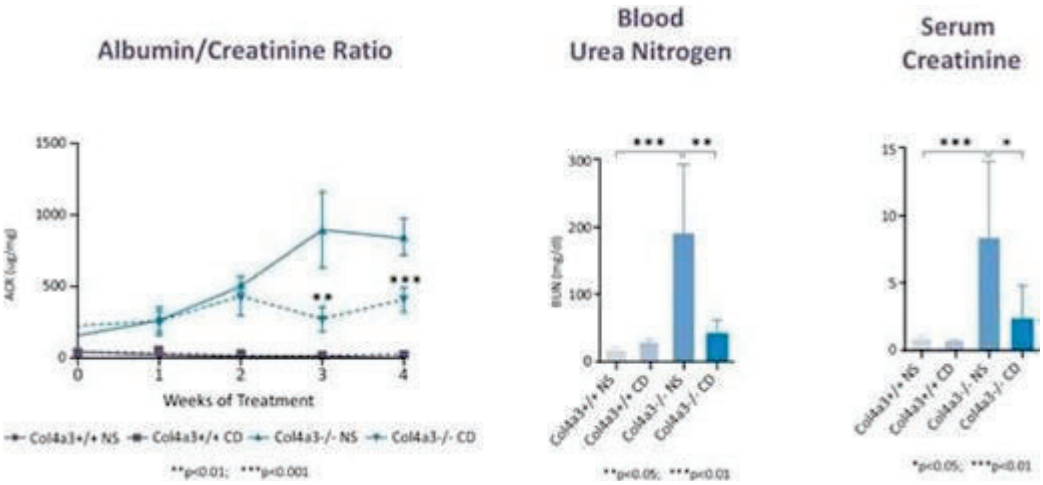
In another study, to evaluate whether VAR 200 has a protective effect in Alport Syndrome, researchers injected four-week-old female Col4a3 knockout (Col4a3−/−) mice with VAR 200 at 4000 mg/kg subcutaneously 3 times per week for 4 weeks. Wild type Col4a3 ("Col43+/+") mice served as controls.

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.

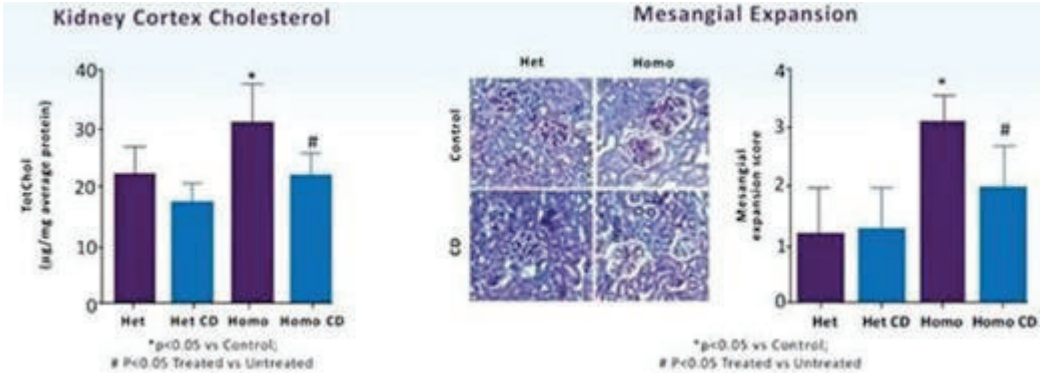


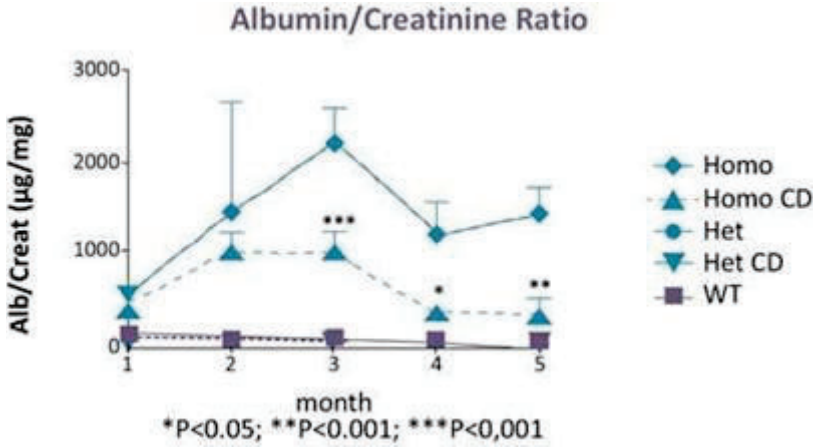


VAR 200 and Diabetic Kidney Disease

In another study 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

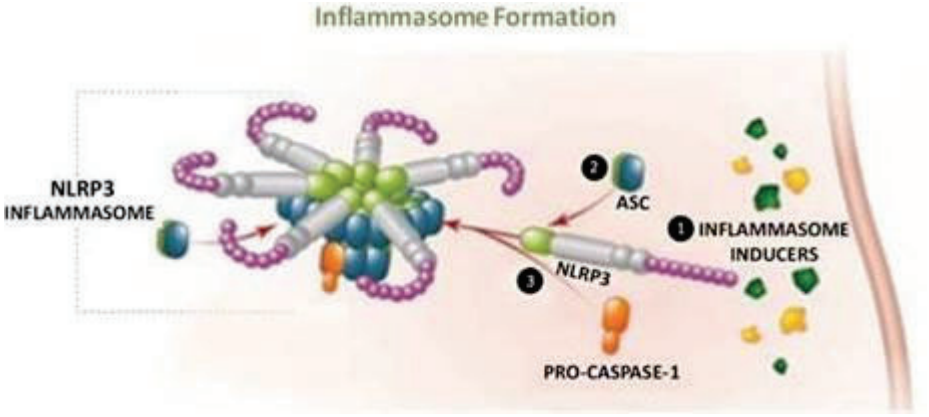
IC 100 is a humanized monoclonal antibody inflammasome ASC inhibitor in preclinical development for the treatment of numerous inflammatory diseases. IC 100 was developed with the intent of attenuating chronic aberrant inflammation that is pathogenic in a multitude of inflammatory diseases by blocking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

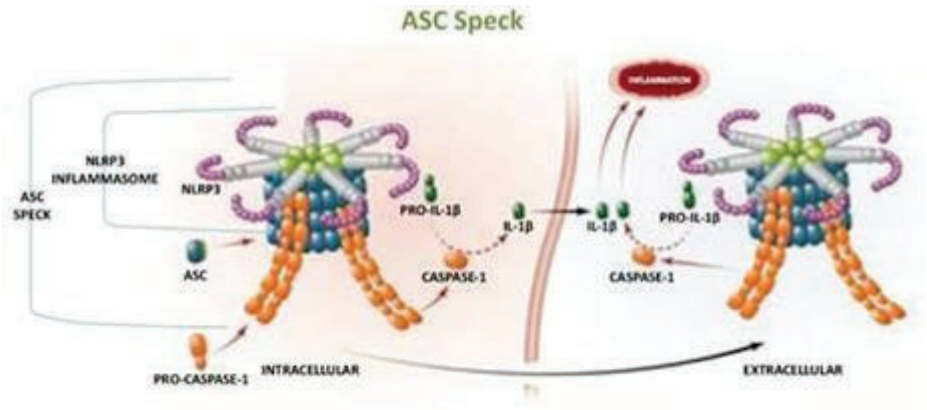
A lead indication has not yet been identified for IC 100. Our focus is on advancing IC 100 toward a planned submission of an IND application in Q4-2024, which we intend to be followed by initiation of a Phase 1 trial. IC 100 has pharmacologic proof-of-concept data in animal models representative of ARDS and MS, and mechanistic proof of concept in animal models and/or tissue cultures representative of Alzheimer's disease, spinal cord injury, and traumatic brain injury. Studies are underway in animal models representing Parkinson's disease, atherosclerosis, and obesity. One or more lead indications for IC 100 will be selected based on data from our preclinical program.

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 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.

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, multiple sclerosis is associated with activation of AIM2, NLRP1, NLRP3, and NLRC4.

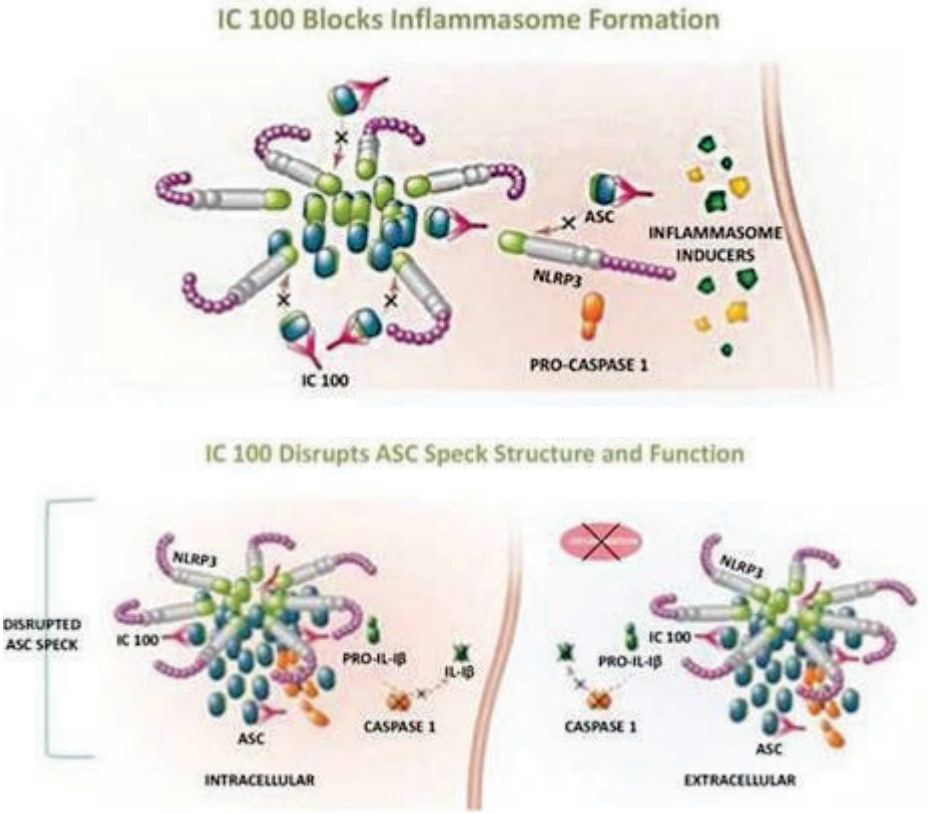




Inflammasome ASC Inhibitor IC 100 Mechanism of Action

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. This is consistent with preclinical studies conducted with IC 100, demonstrating reduced inflammatory activity, and improved histological and/or functional outcomes in models of traumatic brain injury and age-related brain inflammation (associated with conditions such as Alzheimer's disease), highlighted in the next sections below.

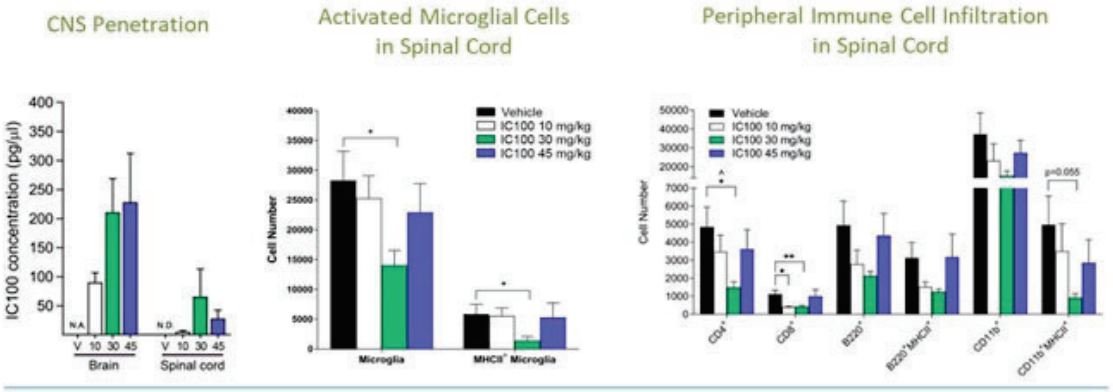
Preclinical Support for IC 100

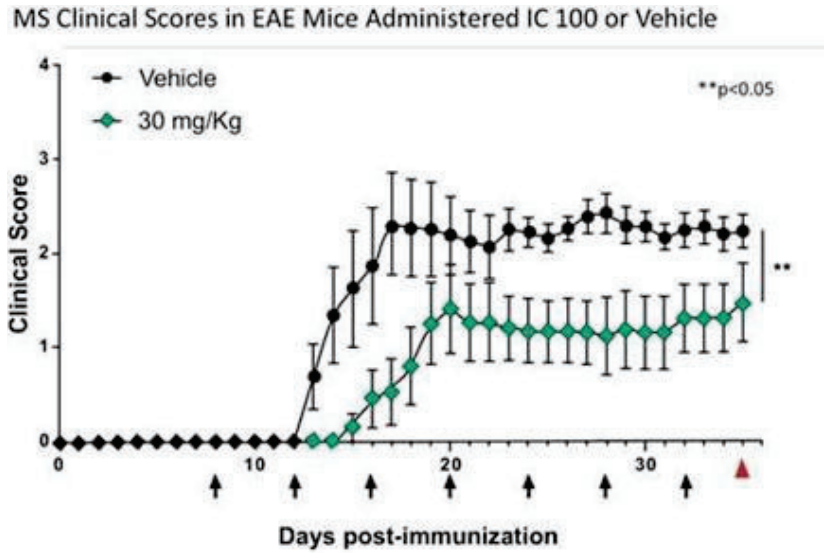
Non-GLP toxicology studies in mice and non-human primates demonstrate that IC 100 has a good safety profile. There were no drug-related adverse events at doses up to 300 mg/kg in either species. Likewise, epigenetic screening demonstrates a lower immunogenicity potential than many biologics. Based on our preclinical study in an animal model representing MS, inflammation was attenuated without immunosuppression. In addition to the studies in traumatic brain injury and age-related inflammation (early cognitive impairment) referenced above, IC 100 has pharmacologic proof-of-concept data in animal models representative of ARDS and MS, and mechanistic proof-of-concept data in animal models representative of spinal cord injury.

IC 100 and MS

In one study 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.

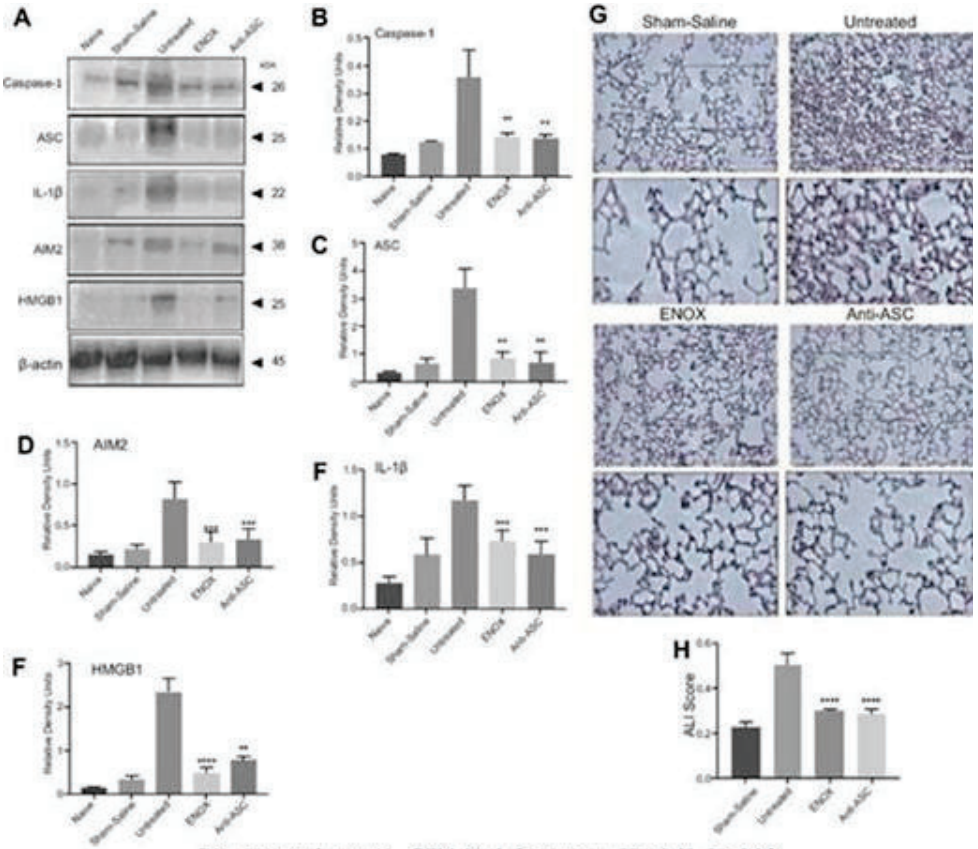




IC 100 and ARDS

In another study to determine if IC 100 can improve histopathological outcomes in ARDS, researchers induced acute lung injury and subsequent ARDS in naïve mice by delivering extracellular vesicles ("EV") from mice with traumatic brain injury, followed by IV administration of a functional prototype of IC 100 at 5 mg/kg 1 hour after EV delivery; animals were sacrificed 24 hours later. Data were compared to naïve, sham (saline), untreated, or enoxaparin at 3mg/kg experimental groups.

IC 100 inhibited inflammasome and cytokine activation in lungs as evidenced by a reduction in caspase-1, ASC, IL-1β, AIM2, HMGB1 when compared with untreated positive control animals. This was associated with improved histological outcomes and reduced acute lung injury scores indicative of decreased lung injury severity.



Data presented as mean – SEM. N=4–5 per group, **p<0.01, *p<0.05.

IC 100 Mechanistic Proof of Concept Data

Spinal Cord Injury

To determine the effects of ASC neutralization in spinal cord injury, researchers administered 50 mcg of anti-ASC tool antibody IV and IP 20 minutes after injury in Fischer rats subjected to moderate cervical spinal cord injury ("SCI"). Anti-ASC neutralizing antibodies decreased caspase-1 activation and cytokine levels, improved histopathological outcomes and decreased spinal cord lesion volume, and improves functional outcomes (e.g., motor skills) compared to controls.

Based on the promising results in animal models of various inflammatory diseases, we believe IC 100 has potential to mediate the persistent damaging inflammation associated with inflammatory disease and improve outcomes.

Traumatic Brain Injury

The effects of ASC neutralization in traumatic brain injury were evaluated in two different animal models, a penetrating ballistic-like brain injury model, and a fluid percussion injury model.

In the penetrating ballistic-like brain injury model, researchers performed IV administration of a functional prototype of IC 100 at 5 mg/kg four hours after injury in Sprague-Dawley rats receiving a penetrating ballistic-like brain injury. IC 100 decreased inflammasome activation, as evidenced by decreased caspase-1 activity, and pyroptosis in microglia and infiltrating leukocytes compared with vehicle control.

In the fluid percussion injury model, researchers performed IV administration of anti-ASC tool antibody at 15 mcg immediately after injury in Sprague — Dawley rats receiving a fluid-percussion injury. Immunoglobulin G ("IgG") served as a control. Neutralization of ASC interfered with NLRP1 inflammasome signaling, leading to a significant reduction caspase-1 compared with IgG. This was associated with a significant reduction in contusion volume.

Age-related Inflammation (Early Cognitive Impairment)

To determine the effects of IC 100 on age-related inflammation, which is representative of early cognitive impairment, a functional prototype of IC 100 was administered via IP injection at 10 mg/kg for 3 days to aged mice (i.e., 18 months old). Aged mice receiving saline control, and untreated young mice (i.e., 3 months old) served as controls. IC 100 reduced inflammasome protein levels (i.e., NLRP1, ASC, capsase-1) and ASC Specks associated with a reduction of IL-1β, indicating that IC 100 reduces inflammasome activation in the cortex of aged mice.

Alzheimer's Disease (AD)

To determine the role of inflammasome activation in AD and its progression, a panel of commercially available antibodies were used to identify Aβ and pTau, and the inflammasome proteins, NLRP1, NLRP3, and caspase-1 in postmortem human brains with and without intermediate AD neuropathological changes. Expression of inflammasome proteins NLRP1, NLRP3, ASC, and caspase-1 occurred early in AD, indicating that multiple inflammasome pathways are associated with AD development. NLRP1 was expressed primarily in neurons and NLRP3 was expressed primarily in microglia.

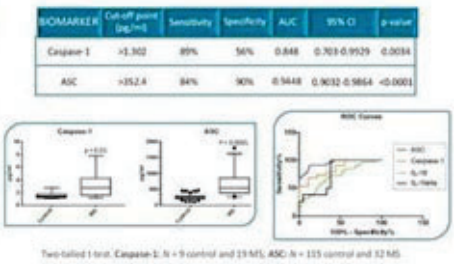
Additionally, IC 100, which targets ASC^{PYD} and a commercially available anti-ASC antibody targeting ASC^{card}, were used to determine the cell-type distribution of ASC in postmortem brains from donors with AD. Labeled IC 100, targeting ASC^{PYD} demonstrated binding to ASC in neurons, whereas labeled antibody targeting ASC^{card} demonstrated binding to ASC in microglia. Data suggest that IC 100 can target neurons in the early stages of AD, with potential to reduce inflammasome activation.

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 our lead product candidates have potential for treatment of diseases with significant unmet medical needs, including (i) our lead renal product candidate, VAR 200, in development for potential treatment of multiple renal indications such as focal segmental glomerulosclerosis (FSGS), and Alport Syndrome (orphan indications), and diabetic nephropathy; and (ii) our lead anti-inflammatory product candidate, IC 100, for treatment of multiple inflammatory diseases, including, but not limited to multiple sclerosis and acute respiratory distress syndrome. VAR 200 has not yet been granted orphan drug designation by the FDA for FSGS or Alport Syndrome.

Cholesterol Efflux Mediator™ VAR 200 Opportunity

FSGS Market

The total addressable market for disease-specific drug therapies for FSGS has not been established because there are no approved drug therapies specific to the condition (please see the next section which discusses the current treatment limitations). FSGS, an orphan indication, is estimated to affect around 40,000 people in the United States, with more than 5,400 new cases diagnosed annually, according to Nephcure Kidney International. FSGS is most common in adults 45 years of age and older and occurs in Black Americans at a rate that is four times higher than in Caucasian Americans.

Current FSGS Treatments and Limitations

At present, there are no commercially available disease-specific treatments for FSGS and there is no known cure. Current therapy focuses on maintaining adequate nutrition, controlling blood pressure and serum lipids, minimizing loss of protein in the urine, and preventing complications from edema, thereby stabilizing kidney function. The most common drug therapy includes diuretics for edema, ACE inhibitors and ARBs for reduction of proteinuria, other antihypertensive agents, and lipid lowering drugs. Steroids and calcineurin inhibitors are also used to induce partial remission of proteinuria.

We believe that there is a significant unmet need for effective FSGS-specific treatments that can delay disease progression, prevent end-stage renal disease, improve patients' quality of life, and reduce the health economic burden.

Alport Syndrome (AS)

AS, an orphan indication, is a progressive, inherited form of kidney disease that is often associated with hearing loss and abnormalities of the eye. It is caused by genetic mutations in genes encoding members of the type IV collagen family that ultimately cause lipid accumulation and scarring of the basement membranes of the kidney, or "glomerulus", the inner ear, or "cochlea", and the eye. A key, early feature of AS is blood in the urine, or "hematuria", with a progressive decline in kidney function ultimately resulting in kidney failure. Hearing loss affecting both ears occurs in late childhood or early adolescence, generally before the onset of kidney failure. Patients may also have misshapen lenses in the eyes (anterior lenticonus) and abnormal retina coloration, but these abnormalities seldom lead to vision loss. Prognosis for patients with AS is poor.

AS Market

The total addressable market for disease-specific drug therapies for AS has not been established because there are no FDA approved drug therapies specific to the condition (please see the next section which discusses the current treatment limitations). AS represents all geographic and ethnic groups. Although the overall incidence in the general population is unknown, U.S. data demonstrates AS accounts for three percent of children and 0.2% of adults with end-stage kidney disease. The gene frequency of AS in the United States has been estimated at 1:5,000 to 1:10,000 people, suggesting there are approximately 30,000 to 60,000 affected individuals, according to the National Organization of Rare Diseases.

Current AS Treatments and Limitations

There are currently no commercially available disease-specific treatments for AS. Current therapy focuses on minimizing loss of protein in the urine and preventing complications from edema to help stabilize kidney function. Angiotensin-converting enzyme ("ACE") inhibitor therapy or angiotensin receptor blocker ("ARB") therapy is recommended in individuals with AS who show overt proteinuria. We believe that there is a significant unmet need for effective AS-specific treatments that can delay disease progression, prevent end-stage renal disease and hearing loss, and improve patients' quality of life.

Diabetic Nephropathy

Kidney disease or "nephropathy" has been recognized as a common complication of diabetes since the 1950s. Currently, diabetic nephropathy is the leading cause of chronic kidney disease in the United States and other Western societies. It is also one of the most significant long-term complications in terms of morbidity and mortality for individual patients with diabetes. Diabetes is responsible for 30 to 40% of all end-stage renal disease ("ESRD") cases in the United States. Proteinuria is a predictor of morbidity and mortality. Patients with proteinuria have a 40-fold higher relative mortality rate. Microalbuminuria, (small quantities of albumin in the urine) independently predicts cardiovascular morbidity, and spillage of the protein, albumin into the urine (or "microalbuminuria and macroalbuminuria") increase mortality from any cause in diabetes mellitus.

Diabetic Nephropathy Market

The total addressable market for disease-specific drug therapies for Diabetic Nephropathy has not been established because there are no approved drug therapies specific to the condition (please see the next section which discusses the current treatment limitations). Up to 50% of patients who have had diabetes for more than 20 years have diabetic nephropathy. It is estimated that up to 12 million people in the United States according to the Center for Disease Control and Prevention.

Current Diabetic Nephropathy Treatments and Limitations

High blood sugar, or "hyperglycemia," has been shown to be a major determinant of the progression of diabetic nephropathy, so good blood glucose control is a key to management of the condition. As with other kidney diseases, there are no renal-specific drug therapies. Control of blood pressure using ACE inhibitors and ARBs is standard of care. New treatment guidelines recommend sodium-glucose co-transporter 2 ("SGLT2") inhibitors for patients with Type 2 diabetes and diabetic nephropathy. SGLT2 inhibitors have been proven to improve kidney and cardiovascular outcomes in this population, and are becoming standard of care.

Despite the addition of SGLT2 inhibitors to standard of care, there is still disease progression. We believe there is a significant unmet need for effective diabetic nephropathy-specific treatments that can delay disease progression, prevent end-stage renal disease, and improve patients' quality of life.

IC 100 Opportunity

Anti-Inflammatory Biologics Market

The global anti-inflammatory biologics market was valued at $64.84 billion in 2019 and is projected to reach $149.80 billion by 2027 according to Fortune Business Insights.

Multiple Sclerosis (MS)

MS is a potentially disabling disease of the brain and spinal cord, which occurs as a result of the immune system attacking the protective myelin sheath that covers nerve fibers, resulting in communication problems between the brain and the rest of the body. Eventually, the disease can cause permanent damage or deterioration of the nerves.

Signs and symptoms of MS vary widely and depend on the amount of nerve damage and the specific nerves are affected. Common symptoms include numbness or weakness in one or more limbs, electric-shock sensations with certain neck movements, tremor, lack of coordination, or unsteady gait. Some people with severe MS may lose the ability to walk independently or at all, while others may experience long periods of remission without any new symptoms. Vison problems are also common in patients with MS, including partial or complete loss of vision, usually in one eye at a time, prolonged double vision, or blurry vision. Other symptoms may include slurred speech, fatigue, dizziness, and tingling or pain in parts of the body. Significant disability occurs within 20 to 25 years in about 30% of patients.

MS Market

In 2019, U.S. disease modifying drugs for MS achieved $14.4 billion in sales according to a 2020 report by Cowan and Company. Based on current estimates, MS affects 1 million people in the United States and 2.8 million people worldwide, according to data from the National Multiple Sclerosis Society. According to the National Multiple Sclerosis Society, approximately 85% of patients with MS have relapsing-remitting MS, and experience periods of new symptoms or relapses that develop over days or weeks and usually improve partially or completely. These relapses are followed by quiet periods of disease remission that can last months or even years. About 60% to 70% of people with relapsing-remitting MS eventually develop a steady progression of symptoms, with or without periods of remission, known as secondary-progressive MS. Some people with MS experience a gradual onset and steady progression of signs and symptoms without any relapses. This is known as primary-progressive MS.

Current MS Treatments and Limitations

Current treatment of MS includes immunomodulatory therapy (“IMT”) to address the underlying immune disorder and therapies to relieve or modify symptoms. The goal of IMT is to reduce the frequency of relapses and slow disease progression. Although there are numerous disease-modifying agents on the market, most have been approved for use only in relapsing forms of MS. There is only one FDA approved IMT for treatment of primary progressive MS. We believe there is a significant need for drugs that are effective in treating progressive MS, and we believe that IC 100 has potential to address this unmet need.

Acute Respiratory Disease Syndrome (ARDS)

ARDS is a life-threatening form of respiratory failure characterized by rapid onset of widespread inflammation in the lungs, noncardiogenic pulmonary edema, hypoxemia refractory to oxygen therapy, diffuse abnormalities on chest radiographs, and decreased lung compliance. Patients require prolonged ICU stays and hospitalizations, consuming significant healthcare resources. Prognosis is poor with numerous complications, and high mortality; survivors have significant functional impairment for years following recovery. The most common causes of ARDS are COVID-19, pneumonia, aspiration of gastric contents, and sepsis.

ARDS Market

The total addressable drug therapy market for ARDS has not been established because drug therapy is currently not used for treatment (please see the next section which discusses the current treatment limitations).ARDS affects approximately 90,600 patients per year in the United States, with mortality up to 45% according to Quintanilla et al (2021 publication). Globally, ARDS accounts for 10% of intensive care unit admissions, representing more than 3 million patients with ARDS annually. While the incidence of ARDS does not differ by gender, it increases with advancing age.

Current ARDS Treatments and Limitations

There are no commercially available drug treatments for ARDS. Current treatment of ARDS is focused on the underlying condition, supportive care, noninvasive or mechanical ventilation using low tidal volumes, and conservative fluid management. We believe IC 200 has potential to treat the widespread inflammation pathogenic in ARDS.

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

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"), exercisable in the aggregate for 25,113 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) 5,714 shares of our common stock to the University of Miami, (ii) and four (4) warrants to InflamaCORE (the "InflamaCORE Warrants") exercisable in the aggregate for 28,571 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 $5.4 million for the Predecessor period from January 1, 2022 through December 12, 2022 and $0.4 million for the Successor Period from December 13, 2022 through December 31 2022 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, an internal marketing group and distribution support. In order 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, 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 the inflammasome pathway, some of which have clinical trials underway in multiple indications. Among these competitors, we are aware of a number of products in various stages of development, including those with Phase 2 clinical trials underway or completed, encompassing indications such as gout, Schnitzler's Syndrome, COVID-19 respiratory symptoms, symptomatic knee osteoarthritis, familial cold auto-inflammatory syndrome, corneal epithelial defects, dry/wet macular degeneration, diabetic retinal disease, and melanoma. Additionally, there are a number of Phase 1 clinical trials underway encompassing indications such as CAPS, mild COVID-19, systolic heart failure, and solid tumors, in addition to healthy subjects. 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 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 14 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 5 issued United States patents, 10 foreign granted patents or allowed applications and 58 pending applications. These patents, and any patents that issue from the pending applications, are anticipated to have a term 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.

On February 24, 2023, we filed two trademark applications for (1) Cholesterol Efflux Mediator™ and (2) Lipid Efflux Mediator™ for pharmaceutical preparations for treatment of renal diseases and disorders. No other applications for trademark protection have been filed for any names or logos for products or technologies in development. We plan to seek trademark protection inside and outside of the United States where available and when appropriate. 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 a 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 the results of their clinical trials after completion. 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.

Properties

On January 18, 2019, the Company entered into a lease agreement (the "Lease") for approximately 3,502 square feet of office space located at 2200 North Commerce Parkway, Suite 208, Weston, Florida 33326. The lease term is for 60 months beginning in January 2019 and ends in January 2024. On January 15, 2024, the Company extended the lease for an additional year for a total base rent lease commitment of $112,064. 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.

Employees

As of December 31, 2023, 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.

Legal Proceedings

We are not currently party to or aware of being 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, which could have a material adverse effect on our business, financial condition or results of operations. Regardless of outcome, litigation could impact our business due to defense and settlement costs, diversion of management resources and other factors.

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 our business combination (the "Business Combination') 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 ™ 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, 2023, our accumulated net loss was approximately $170 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, 2023, 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 through the second quarter of 2024. 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.

The Company identified a material weakness in its internal control over financial reporting. If the Company is not able to remediate the material weakness and otherwise 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.

During the audit for the 2023 fiscal year, we identified a material weakness due to insufficient segregation of duties in our finance and accounting function because of our limited personnel.

Our management plans to establish procedures to monitor and evaluate the effectiveness of our internal controls on an ongoing basis and are committed to taking further action and implementing necessary enhancements or improvements. Management expects to complete its assessment of the design and operating effectiveness of its internal controls over financial reporting during 2023. However, the material weakness will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

If our steps are insufficient to successfully remediate the material weaknesses and otherwise establish and maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be materially and adversely affected. Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. For as long as we are a "smaller reporting company" under the U.S. securities laws, our independent registered public accounting firm will not be required to attest to the effectiveness of its internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Moreover, we do not expect that disclosure controls or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. The failure of our control systems to prevent error or fraud could materially adversely impact us.

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

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19 could cause a disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. In December 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19, surfaced in Wuhan, China and has since spread worldwide. The coronavirus pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third-party partners, including our preclinical studies or clinical trial operations, will also depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations in the U.S. and abroad, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19. For example, similar to other biopharmaceutical companies, we may experience delays in enrolling our current and/or planned clinical trials. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. In addition, the patient populations that our lead and other core product candidates target may be particularly susceptible to COVID-19, which may make it more difficult for us to identify patients able to enroll in our future clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Additionally, timely enrollment in planned clinical trials is dependent upon clinical trial sites which could be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our product candidates in geographies which are currently being affected by the coronavirus. Some factors from the coronavirus outbreak that will delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- the potential negative effect on the operations of our third-party manufacturers;
- interruption in global shipping, affecting the transport of raw materials for our products, clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including having all of our employees to work remotely, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business. We cannot presently predict the scope and severity of the planned and potential shutdowns or disruptions of businesses and government agencies, such as the SEC or FDA.

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.

Recently enacted and future healthcare legislative or regulatory reform measures, including government restrictions on pricing and reimbursement, may increase the difficulty and cost for us to obtain marketing approval, and could have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, under the Medicare Modernization Act, or MMA, Medicare Part D provides coverage to the elderly and disabled for outpatient prescription drugs by approving and subsidizing prescription drug plans offered by private insurers. The MMA also authorizes Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. The Part D plans use their formulary leverage to negotiate rebates and other price concessions from drug manufacturers. Also under the MMA, Medicare Part B provides coverage to the elderly and disabled for physician-administered drugs on the basis of the drug's average sales price, a price that is calculated according to regulatory requirements and that the manufacturer reports to Medicare quarterly. Both Congress and the Centers for Medicare & Medicaid Services ("CMS"), the agency that administers the Medicare program, from time to time consider legislation, regulations, or other initiatives to reduce drug costs under Medicare Parts B and D. For example, under the ACA, drug manufacturers are required to provide a 50% discount on prescriptions for branded drugs filled while the beneficiary is in the Medicare Part D coverage gap, also known as the "donut hole." There have been legislative proposals to repeal the "non-interference" provision of the MMA to allow CMS to leverage the Medicare market share to negotiate larger Part D rebates. Further cost reduction efforts could decrease the coverage and price that we receive for our drug candidates and could seriously harm our business. Private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement under the Medicare program may result in a similar reduction in payments from private payors.

The Patient Protection and Affordable Care Act of 2010 (the "ACA") is intended to broaden access to health insurance and reduce or constrain the growth of healthcare spending. Further, the Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products. It also increased the amount of the rebates drug manufacturers must pay to state Medicaid programs, required that Medicaid rebates be paid on managed Medicaid utilization, and increased the additional rebate on "line extensions" (such as extended-release formulations) of solid oral dosage forms of branded products. The law also contains substantial provisions affecting fraud and abuse compliance and transparency, which may require us to modify our business practices with healthcare practitioners and incur substantial costs to ensure compliance.

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.

For example, in the United States, the ACA, substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of the ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act (the "PHS"). Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of the ACA. There is continued uncertainty about the implementation of the ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.

In addition, other legislative changes that affect the pharmaceutical industry have been proposed and adopted in the United States since the ACA was enacted. For example, the Inflation Reduction Act of 2022 included, among other things, a provision that authorizes CMS to negotiate a "maximum fair price" for a limited number of high-cost, single-source drugs

every year, and another provision that requires drug companies to pay rebates to Medicare if prices rise faster than inflation. In addition, various states have adopted or are considering adopting laws that require pharmaceutical companies to provide notice prior to raising prices and to justify price increases. We expect that additional healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

There has also been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the now-departed Trump administration proposed numerous prescription drug cost control measures. Similarly, the new Biden administration has made lowering prescription drug prices one of its priorities. The Biden administration has not yet proposed any specific plans, but we expect that these will be forthcoming in the near term. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Other examples of proposed changes include, but are not limited to, expanding post-approval requirements, changing the Orphan Drug Act, and restricting sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for any of our current or future product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our product candidates. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

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.

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.

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. In addition, we have been impacted and could be further impacted by the ongoing COVID-19 pandemic, which could cause talented employees to change locations, and may make it more challenging to attract and retain skilled professionals. 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 business continuity and cyber risks that could significantly harm our business and operations.

The COVID-19 pandemic has caused us to modify our business practices by migrating to a primarily remote workforce where our employees are accessing our servers remotely through home or other networks to perform their job responsibilities. While most of our operations can be performed remotely and are operating effectively at present, there is no guarantee that this will continue or that we will continue to be as effective while working remotely because our team is dispersed, many employees may have additional personal needs to attend to (such as looking after children as a result of school closures or a family member who becomes sick), and employees may become sick themselves and be unable to work. As conditions improve and restrictions

are lifted, similar uncertainties exist with the return-to-work process. Additionally, while we put in place additional safeguards to protect data security and privacy, a remote workforce places additional pressure on our user infrastructure and third parties that are not easily mitigated. These risks include home internet availability affecting work continuity and efficiency, and additional dependencies on third-party communication tools, such as instant messaging and online meeting platforms.

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 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 its internal control over financial reporting and once we cease to be an emerging growth company, we will 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.

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.

On June 9, 2023, the Company received a letter from Nasdaq indicating that, based upon the closing bid price of the Company's Common Stock for the last 30 consecutive business days, the Company is not currently in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Global Market (the "Minimum Bid Price Requirement"), as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Notice").

We were provided a compliance period of 180 calendar days from the date of the Notice, or until December 6, 2023, to regain compliance with the Minimum Bid Price Requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A).

On November 14, 2023, Nasdaq issued a letter to the Company that as of November 13, 2023, it determined that the Company's securities had a closing bid price of $0.10 or less for ten consecutive trading days. Accordingly, the Company is subject to the provisions contemplated under Listing Rule 5810(c)(3)(A)(iii). As a result, Nasdaq had determined to delist the Company's securities from The Nasdaq Global Market, on November 16, 2023, unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel").

To regain compliance with the Minimum Bid Price Requirement, the Company effected a reverse stock split at a ratio of 1-for-35 on December 5, 2023 (the "2023 Reverse-Stock-Split"). The 2023 Reverse Stock Split caused the Company's common stock to trade above $1.00, however, it dropped below $1.00, but the common stock did not close at a price of over $1.00 for 10 consecutive trading days in order to regain compliance with the Minimum Bid Price Requirement. Following the 2023 Reverse Stock Split, the Company regained compliance with the Low Priced Stock Rule.

The Company subsequently requested and received a hearing (the "Nasdaq Hearing") from the Panel. Following the Nasdaq Hearing, which was held on January 25, 2024, The Panel, by written decision dated February 5, 2024, granted the Company's request for an exception to the Minimum Bid Price Requirement until May 3, 2024.

Accordingly, we believe that effecting a subsequent reverse split is our best option for meeting the Minimum Bid Price Requirement for continued listing on The Nasdaq Global Market. A decrease in the number of outstanding shares of our common stock resulting from a reverse split should, absent other factors, assist in ensuring that the per share market price of our common stock remains above the requisite price for continued listing. However, we cannot provide any assurance that our minimum bid price would remain over the Minimum Bid Price Requirement of The Nasdaq Global Market following a reverse split.

Moreover, on September 1, 2023, the Company received a letter from Nasdaq stating that for the last 30 consecutive business days, the Company is not in compliance with the requirement of a minimum Market Value of Publicly Held Shares ("MVPHS") of $5,000,000 for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(b)(1)(C).

In accordance with Nasdaq Listing Rule 5810(c)(3)(D), the Company has a period of 180 calendar days, or until February 28, 2024, to regain compliance with the minimum MVPHS requirement. To regain compliance, the minimum MVPHS of the Company's Common Stock must meet or exceed $5,000,000 for a minimum of ten consecutive business days during this 180-calendar day compliance period.

If we fail to continue to meet all applicable Nasdaq Global 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.

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 reverse stock split on December 4, 2023. 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 reverse stock split we effected on December 4, 2023, 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 1-for-35 reverse stock split we effected on December 4, 2023 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 a reverse stock split, including the 1-for-35 reverse stock split we effected on December 4, 2023, 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 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 for a total base rent lease commitment of $112,064. 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 Nasdaq 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 21, 2024, there were approximately 95 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

Except as listed below, 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, 2023.

- On December 14, 2023 we issued 90,000 shares of our common stock to a consultant in consideration of services rendered at a deemed issuance price of $0.738 per share.
- On January 2, 2024 we issued 90,000 shares of our common stock to a consultant in consideration of services rendered at a deemed issuance price of $0.880 per share.

The issuance of the shares of common stock as described above were not registered under the Securities Act, or the securities laws of any state, and the shares of the common stock were issued in reliance on the exemption from registration under the Securities Act pursuant to Section 4(a)(2) of the Securities Act.

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 "Selected Historical Financial Information" and 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 Statement 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 lead renal drug candidate, which we refer to as Cholesterol Efflux Mediator™ VAR 200 (2-hydroxypropyl-beta-cyclodextrin or "2HβCD"), is in development to treat multiple renal indications. Our lead 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.

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 $98,297,946 for the year ended December 31, 2023 and $75,018 for the period from December 13, 2022 through December 31, 2022 (the "Successor" periods) and $14,047,607 for the period from January 1, 2022 through December 12, 2022 (the "Predecessor" period). As of December 31, 2023, we had an accumulated deficit of approximately $103.2 million and cash of $3.1 million. We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses. We expect our expenses will increase in connection with our ongoing activities as we:

- progress development of VAR 200 and IC 100
- prepare and file regulatory submissions;
- begin to manufacture our product candidates for clinical trials;
- hire additional research and development, finance, and general and administrative personnel; and
- 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 and accretion of debt discount which are associated with the Predecessor unsecured convertible promissory notes which bear interest at a rate equal to 6% per annum.

Change in fair value of derivative liability represents the periodic mark-to-market of the Predecessor derivative liabilities. The Company recorded derivative liabilities that were measured at fair value at issuance, related to the redemption features and put options of certain Predecessor convertible notes payable.

Results of Operations

Comparison of the years ended December 31, 2023 and December 31, 2022

The following table summarizes our results of operations for the Successor for the year ended December 31, 2023 (the "2023 Period") and for the Successor period December 13, 2022 through December 31, 2022 and for the Predecessor for the period from January 1, 2022 through December 12, 2022 (collectively the "2022 Period"):

	Successor		Predecessor
(in thousands)	For the Twelve Months Ended December 31, 2023	For the period December 13 through December 31, 2022	For the period January 1 through December 12, 2022
Operating expenses:			
Research and development	$ 3,208	$ 400	$ 5,408
General and administrative	11,213	420	7,605
Impairment of in-process research and development	81,438	-	-
Impairment of goodwill	11,895	-	-
Total Operating Expenses	107,754	820	13,013
Loss from Operations	(107,754)	(820)	(13,013)
Other Income (Expense), Net	-	-	(1,035)
Pre-tax net loss	(107,754)	(820)	(14,048)
Income tax benefit	9,456	745	-
Net loss	$ (98,298)	$ (75)	$ (14,048)

Research and development expenses

Research and development expenses for the 2023 Period were $3.2 million, a decrease of $2.6 million or 44.8% from $5.8 million for the 2022 Period. The decrease in research and development expenses was primarily due to spending for materials supplies for manufacturing in 2022 that were not required in 2023 as manufacturing was completed in 2022.

General and administrative expenses

General and administrative expenses for the 2023 Period were $11.2 million, an increase of $3.2 million or 39.7% from $8.0 million for the 2022 Period. The increase is primarily attributed to increased costs for legal and professional fees of $2.7 million, investor and public relations fees of $1.2 million, and increased director and officer insurance of $1.3 million, all due to increased costs associated with being a public company. These were offset by reduced business combination transaction costs of $2.2 million.

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

Impairment of in-process research and development and impairment of goodwill were $81.4 million and $11.9 million, respectively for the 2023 Period. The impairment is a result of the decline in stock value and the resulting market capitalization of the Company during the 2023 Period.

Other (income) expense

Total other expense, net for the 2023 Period was $0 as compared to $1.0 million for the 2022 Period. The 2022 Period included interest expense of approximately $0.4 million as a result of Predecessor convertible debt (converted to equity at the time of the Business Combination), plus a change in the fair value of the derivative liabilities of $0.6 million in the 2022 Period.

Cash Flows

The following table summarizes our cash flows from operating and financing activities for the 2023 Period and 2022 Period:

	Successor		Predecessor
(in thousands)	For the Twelve Months Ended December 31, 2023	For the period December 13 through December 31, 2022	For the period January 1 through December 12, 2022
Net cash provided by (used in)			
Operating activities	$ (8,721)	$ (3,394)	$ (1,495)
Financing activities	5,956	-	1,865

Cash Flows from Operating Activities

Net cash used in operating activities for the 2023 Period was $8.7 million, a increase of $3.8 million or 78.4% from $4.9 million for the 2022 Period. The net cash used in operating activities during the 2023 Period and the 2022 Period was primarily attributable to the net loss of $98.3 million and $14.1 million, respectively, partially offset by $87.0 million and $3.6 million, respectively, of net non-cash expenses, and approximately $2.6 million and $5.6 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 for the 2023 Period was $6.0 million, a decrease of $4.1 million or 219% from $1.9 million for the 2022 Period. Cash provided by financing activities during the 2023 Period represented net proceeds of $15.7 million from the issuance of common stock in a public offering and $1.0 million of exercise proceeds from a warrant inducement offer, partially offset by a $10.7 million redemption of Series A preferred stock. During the 2022 Period we received $2.0 million from the issuance of preferred stock in a private placement.

Liquidity and Capital Resources

The following table summarizes our total current assets, current liabilities and working capital deficiency at December 31, 2023 and 2022, respectively:

	Successor	
(in thousands)	December 31, 2023	December 31, 2022
Current Assets	$ 3,353	$ 6,363
Current Liabilities	$ 10,195	$ 8,188
Working Capital Deficiency	$ (6,842)	$ (1,825)

Since our inception in 2014 through December 31, 2023, 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 $3.1 million as of December 31, 2023 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 $98.3 million for the 2023 Period and a net loss of $14.1 million for the 2022 Period and we had an accumulated deficit of $103.2 million at December 31, 2023. Subsequent to December 31, 2023, we received proceeds of $2.7 million upon the exercise of certain warrants. 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, 2023 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, 2023 include approximately $10.2 million for accounts payable and accrued expenses. There are no cash requirements for long term liabilities at December 31, 2023.

Post-Business Combination Capital Needs

We expect our cash on hand will enable us to make investments in our continued development of VAR200 and IC100 through at least the first half of 2024. 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. 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.

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 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. Successor common stock will be valued using the market approach using the trading prices of the common stock on the Nasdaq Capital Market. During 2022, the fair value of the Predecessor common stock was determined using a market approach based on the status of the business combination agreement arm's length discussions with the acquirer at each valuation date and which agreement was ultimately entered into on July 20, 2022 with a Predecessor valuation of $85 million. 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.

Recent Accounting Pronouncements Adopted

In December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes," which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. ASU 2019-12 is effective for fiscal years beginning after December 15, 2021. This standard was adopted on January 1, 2022 and did not have a material impact on the Company's financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. This new standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Companies should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. This standard was adopted on January 1, 2022 and did not have a material impact on the Company's financial statements.

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)." ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This amendment will be effective for private companies and emerging growth companies for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The FASB issued ASU No. 2018-10 "Codification Improvements to Topic 842, Leases" and ASU No. 2018-11 "Leases (Topic 842) Targeted Improvements" in July 2018, and ASU No. 2018-20 "Leases (Topic 842) - Narrow Scope Improvements for Lessors" in December 2018. ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company adopted ASU 2016-02 on December 31, 2022, effective January 1, 2022 and the adoption of this ASU resulted in the recording of right-of-use assets and lease liabilities for the Company's operating leases in the approximate amounts of $182,732 and $199,642 and derecognizing deferred rent in the approximate amount of $16,910.

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, 2023. Based upon their evaluation and due to the material weakness cited below, 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

This Report does not include a report of management's assessment regarding internal control over financial reporting because management did not have sufficient resources to complete such an assessment. The Company intends to complete a management assessment regarding internal control over financial reporting as of December 31, 2024. This Report also does not contain an attestation report of our independent registered public accounting firm regarding internal control over financial reporting since the Company, as an "emerging growth company," is not required to provide such report.

Our management is 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. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Although a formal assessment has not yet been completed, management believes that the Company's internal controls over financial reporting were not effective as of December 31, 2023. Specifically, management's conclusion was based on the following material weakness which existed as of December 31, 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 this Annual Report 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.

Remediation Plan

Our management has begun to establish procedures to monitor and evaluate the effectiveness of our internal controls over financial reporting on an ongoing basis and are committed to taking further action and implementing necessary enhancements or improvements, including those actions already taken to address the material weakness, related to design and implement effective controls over the accounting for significant and complex non-routine transactions, cited in the Company's December 31, 2022 Form 10-K and identified through the process as of December 31, 2023. Management expects to complete its assessment of the design and operating effectiveness of its internal controls over financial reporting, including the development and implementation of its remediation plan, during 2024.

Changes in Internal Control over Financial Reporting

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

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	64	Chief Executive Officer, President and Chairman
Karen A. Cashmere	72	Chief Commercial Officer
Peter Wolfe	56	Chief Financial Officer and Secretary
Pablo A. Guzman, M.D.	74	Chief Medical Officer and Senior Vice President of Medical Affairs
Robert G. Finizio	53	Director
Min Chul Park, Ph.D.	42	Director
James Sapirstein	62	Director
Gregory Freitag	61	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 we 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, Chief Executive Officer and President of First Wave BioPharma (NASDAQ: FWBI). 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 $300 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. In addition to being a board member of First Wave Bio Pharma, Mr. Sapirstein currently holds board positions on Enochian Biosciences (NASDAQ: ENOB) and Blue Water Vaccines (NASDAQ: BWV). 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. 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 is also on 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.

Committees of the Board of Directors

The standing committees of our board of directors consists of an audit committee, a compensation committee, and a nominating and corporate governance committee. Our board of directors may from time to time establish other committees. The Company's chief executive officer and other executive officers regularly report to the non-executive directors and the audit, the compensation and the nominating and corporate governance committees to ensure effective and efficient oversight of our activities and to assist in proper risk management and the ongoing evaluation of management controls. We believe that the leadership structure of our board of directors provides appropriate risk oversight of the Company's activities.

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 the Nasdaq Listing Rules and the independence requirements of Rule 10A-3 under the Exchange Act. At least one member of the audit committee 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*).

Compensation Committee

The compensation committee consists of Robert G. Finizio, serving as the chairperson, Min Chul Park, Ph.D. and James Sapirstein. Our board of directors has adopted a written charter for the compensation committee, which is available free of charge on our corporate website (*www.zyversa.com*). The purpose of the compensation committee is to assist our board of directors in discharging its responsibilities relating to (1) setting the Company's compensation program and compensation of its executive officers and directors; (2) monitoring the Company's incentive and equity-based compensation plans; and (3) preparing the compensation committee report required to be included in any proxy statement or prospectus required to be filed by the Company under the rules and regulations of the SEC.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee consists of James Sapirstein, serving as the chairperson, Gregory Freitag, and Min-chul Park. Our board of directors has adopted a written charter for the nominating and corporate governance committee, which is available free of charge on our corporate website (*www.zyversa.com*). The purpose of the nominating and corporate governance committee is to assist our board of directed in discharging its responsibilities relating to (1) identifying, reviewing the qualifications of, and recommending to the Board proposed nominees for election to the Board consistent with criteria approved by the Board, (2) selecting, or recommending that the Board select, the director nominees for the next annual meeting of stockholders, (3) overseeing the annual evaluation of the Board and management, and (4) recommending to the Board director nominees for each committee of the Board.

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.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee was at any time during fiscal year 2023, or at any other time, one of our officers or employees. None of our executive officers have served as a director or member of a compensation committee (or other committee serving an equivalent function) of any entity, one of whose executive officers served as a director of our board of directors or member of our compensation committee.

Independence of the Board of Directors

Nasdaq rules generally require that independent directors must comprise a majority of a listed company's board of directors. Based upon information requested from and provided by each proposed director concerning his or her background, employment, and affiliations, including family relationships, we have determined that Rob G. Finizio, Min Chul Park, Ph.D. James Sapirstein, and Gregory Freitag, representing four (4) of our five (5) directors, are "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing requirements and rules of the Nasdaq.

Limitations of Liability and Indemnification Matters

Our Charter contains provisions that limit the liability of our directors for monetary damages for breach of their fiduciary duties, except for liability that cannot be eliminated under the DGCL. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following:

- any breach of their duty of loyalty to the corporation or its stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

The Charter and the Second Amended and Restated Bylaws (the "Bylaws") also provide that we shall indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. We believe that indemnification under the Bylaws covers at least negligence and gross negligence on the part of indemnified parties. The Bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether the Bylaws would permit indemnification.

We have entered into separate indemnification agreements with our directors and executive officers, in addition to indemnification provided for in our charter documents. These agreements, among other things, provide for indemnification of our directors and executive officers for expenses, judgments, fines and settlement amounts incurred by this person in any action or proceeding arising out of this person's services as a director or executive officer or at our request. We believe that these provisions and agreements are necessary to attract and retain qualified persons as directors and executive officers.

ITEM 11. EXECUTIVE COMPENSATION

As we are an emerging growth company, we have opted to comply with the executive compensation disclosure rules applicable to emerging growth companies. The scaled down disclosure rules are those applicable to "smaller reporting companies," as such term is defined in the rules promulgated under the Securities Act, which require compensation disclosure for our (i) principal executive officer, (ii) our two most highly compensated executive officers, other than the principal executive officer, whose total compensation for 2023 exceeded $100,000 and who were serving as executive officers as of December 31, 2023, and (iii) any other executive officer that would have been included in item (ii) above but for the fact that they were not an executive officer of the Company at December 31, 2023. We refer to these individuals as "named executive officers," or "NEOs" Our named executive officers for the year ended December 31, 2023, were:

- Stephen C. Glover, our Chief Executive Officer, President and Chairman;
- Peter Wolfe, our Chief Financial Officer and Secretary;
- Karen A. Cashmere, our Chief Commercial Officer; and
- Nicholas A. Labella, Jr., M.S., our former Chief Scientific Officer and Senior Vice-President of Research and Development.

Summary Compensation Table

The following Summary Compensation Table sets forth information regarding the compensation paid to, awarded to, or earned by our NEOs in 2023 and 2022 for services rendered in all capacities to us and our subsidiaries during 2023 and 2022.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards [1] ($)	Total Compensation ($)
Stephen C. Glover	2023	550,000	225,000	218,217	993,217
Co-Founder, Chief Executive Officer, President and Chairman	2022	450,500	-	1,027,948	1,478,448
Karen A. Cashmere	2023	320,000	90,000	76,687	486,687
Chief Commercial Officer	2022	300,000	-	282,622	582,622
Peter Wolfe	2023	395,000	82,500	95,859	573,359
Chief Financial Officer and Secretary	2022	275,000	-	282,622	557,622
Nicholas A. LaBella, Jr. [2]	2023	218,576	112,000	63,904	394,480
Former Chief Scientific Officer and Sr. Vice-President of Research and Development	2022	325,000	-	385,394	710,394

[1] The amounts reported represent the aggregate grant date fair value of the stock options awarded to our directors under our 2022 Omnibus Equity Incentive Plan and 2014 Equity Incentive Plan in the years ended December 31, 2023 and December 31, 2022, 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.

[2] Mr. Labella resigned from all his positions with the Company effective August 18, 2023.

Narrative Disclosure to Summary Compensation Table

Executive Employment Agreements

Stephen C. Glover

On January 1, 2019, we entered into an employment agreement with Stephen C. Glover (the "Glover Employment Agreement"). Under the terms of the Glover Employment Agreement, he holds the position of Chief Executive Officer and receives a base salary of $450,000 annually, which base salary amount is subject to periodic adjustment by the board of directors or the compensation committee. In addition, Mr. Glover is eligible to receive an annual bonus, with a target amount equal to fifty percent (50%) of Mr. Glover's base salary. The actual amount of each annual bonus will be based upon the level of achievement of our corporate objectives and Mr. Glover's individual objectives, in each case, as established by us and Mr. Glover for the calendar year with respect to which the annual bonus relates. The determination of the level of achievement of the corporate objectives and the Mr. Glover's individual performance objectives for a year shall be made by us in our reasonable discretion. In addition, pursuant to the terms of the Glover Employment Agreement, Mr. Glover is eligible to receive, from time to time, equity awards under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future, and the terms and conditions of such awards, if any, will be determined by our board of directors or Compensation Committee, in their discretion. Mr. Glover is also eligible to participate in any executive benefit plan or program we adopt.

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 Glover Employment Agreement) upon 60 days prior written notice to Mr. Glover. Mr. Glover may terminate his employment for Good Reason (as that term is defined in Mr. Glover's employment agreement) upon 90 days 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's employment is terminated without Cause or for Good Reason other than during a Post-Change in Control Period (as defined in the Glover Employment Agreement), Mr. Glover will be entitled to receive (i) the Accrued Obligations (as defined in the Glover Employment Agreement), (ii) severance payments equal to 15 months of Mr. Glover's base salary (to be paid in a lump sum on the next regular payroll date within 60 days of Mr. Glover's termination), and (iii) if elected, the Company will reimburse Mr. Glover for certain COBRA health benefits for 15 months.

Notwithstanding the above, if Mr. Glover's employment is terminated without Cause or he resigns for Good Reason within 12 months after a Change of Control (as defined in the Glover Employment Agreement), Mr. Glover will receive (i) the Accrued Obligations, (ii) severance payments equal to 36 months of Mr. Glover's base salary (to be paid in bimonthly payments commencing on the next regular payroll date within 60 days of Mr. Glover's termination), (iii) any deferred compensation due to Mr. Glover, (iv) if elected, the Company will reimburse Mr. Glover for certain COBRA health benefits for 24 months, (v) a payment equal to Mr. Glover's target annual bonus amount for the calendar year in which the termination occurs, (vi) in lieu of shares of common stock issuable upon exercise of outstanding options granted to Mr. Glover, Mr. Glover shall receive an amount in cash equal to the product of (A) the excess of the closing price of our common stock as reported on Nasdaq (if not so reported, on the basis of the average of the lowest asked and highest bid prices on or nearest the date of termination), over the per share exercise price of each option held by Mr. Glover (whether or not then fully exercisable) plus the amount of any applicable cash appreciation rights, times (B) the number of shares of common stock covered by each such option, and (vii) a payment equal to the amount of any and all legal fees incurred by Mr. Glover as a result of such termination.

Pursuant to the Glover Employment Agreement, we may terminate Mr. Glover's employment at any time for Cause upon written notice to Mr. Glover. Mr. Glover may voluntarily terminate his employment at any time without Good Reason upon ninety (90) days prior written notice to the Company; provided, however, that we reserve the right, upon written notice to Mr. Glover, to accept Mr. Glover's notice of resignation and to accelerate such notice and make Mr. Glover's resignation effective immediately, or on such other date prior to Mr. Glover's intended last day of work as we deem appropriate. If Mr. Glover's employment is terminated with Cause or without Good Reason, he is entitled to receive (i) his earned but unpaid base salary through the final day of his employment, (ii) his accrued, but unused, vacation, (iii) expenses reimbursable under the employment agreement incurred on or prior to the last day of his employment, and (iv) any amounts or benefits that are vested amounts or benefits that Mr. Glover is entitled to receive under any of our equity compensation plans.

Pursuant to the Glover Employment Agreement, we may terminate Mr. Glover's employment at any time for Cause upon written notice to Mr. Glover. Mr. Glover may voluntarily terminate his employment at any time without Good Reason upon two weeks prior written notice to us.

On July 20, 2022, we entered into a new executive employment agreement with Stephen C. Glover (the "New Glover Agreement") that became effective upon consummation of the Business Combination, pursuant to which we agreed to continue to retain Mr. Glover as our Chief Executive Officer following the closing of the Business Combination, subject to the terms and conditions of the New Glover Agreement. The New Glover Agreement has superseded the Glover Employment Agreement. Under the New Glover Agreement, the conditions of Mr. Glover's employment include, among other things, his agreement and execution of a Proprietary Information & Restrictive Covenant Agreement.

Under the terms of the New Glover Agreement, Mr. Glover will continue to hold the position of Chief Executive Officer and receive 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, with a target amount equal to fifty-five percent (55%) of Mr. Glover's base salary, subject to review and adjustment 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 New Glover 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 New Glover Agreement, we may terminate Mr. Glover's employment at any time without Cause (as that term is defined in the New Glover Agreement) upon 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 New Glover Agreement) upon 60 days 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 New Glover Agreement. In the event Mr. Glover resigns for Good Reason, and provided that such termination constitutes a Separation from Service (as that term is defined in the New Glover Agreement), then subject to Mr. Glover's compliance with his obligations under the New Glover Agreement, Mr. Glover shall be eligible to receive the Severance Benefits (as that term is defined in the New Glover Agreement) on the same terms and conditions as he would be entitled for our termination of his employment without Cause.

In the event we terminate Mr. Glover's employment at any time without Cause, or if Mr. Glover resigns for Good Reason, provided that such termination constitutes a Separation from Service, then Mr. Glover shall be entitled to receive the Accrued Obligations (as that term is defined in the New Glover Agreement) and, subject to Mr. Glover's compliance with his obligations under the New Glover Agreement, Mr. Glover shall also be entitled to receive the following Severance Benefits: (i) an amount equal to Mr. Glover's then current base salary for 24 months, paid in equal instalments on our regularly scheduled payroll dates following the Release Effective Date (as that term is defined in the New Glover Agreement); (ii) an amount equal to any unpaid bonus earned for the preceding year in which Mr. Glover's termination occurs, paid in a single lump sum payment within 60 days following Mr. Glover's termination; (iii) an amount equal to the greater of (a) the bonus paid for the performance year ending prior to Mr. Glover's termination, and (b) the bonus that Mr. Glover would have earned for the performance year in which such termination occurs, in each case prorated for the period of Mr. Glover's employment through the date of his termination, paid as a single lump sum payment within 60 days following Mr. Glover's termination; (iv) any equity awards issued to Mr. Glover that are outstanding as of the date of Mr. Glover's termination will become 100% vested and any stock options outstanding will remain exercisable until the earliest of (A) 18 months following Mr. Glover's termination, or (B) the original expiration date for such vested options as provided in the applicable award agreement; and (iv) if elected, we will reimburse Mr. Glover for certain COBRA health benefits for up to 18 months, subject in each case to the terms and conditions of the New Glover 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 New Glover Agreement, Mr. Glover shall be eligible to receive the Severance Benefits on the same conditions as he would be entitled for our termination of his employment without Cause; provided, however, that Mr. Glover shall receive a bonus for the year in which his termination occurs equal to fifty-five percent (55%) of Mr. Glover's base salary; and provided further, 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.

Pursuant to the New Glover Agreement, we may terminate Mr. Glover's employment at any time for Cause upon written notice to Mr. Glover. In the event Mr. Glover's employment is terminated at any time for Cause, Mr. Glover will not receive Severance Benefits or any other 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 Severance Benefits or any other 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

On July 20, 2022, we entered into an executive employment agreement with Peter Wolfe (the "Wolfe Employment Agreement") that became effective upon consummation of the Business Combination, pursuant to which we agreed to continue to retain Mr. Wolfe as our Chief Financial Officer following the closing of the Business Combination, subject to the terms and conditions of the Wolfe Employment Agreement. Under the Wolfe Employment Agreement, the conditions of Mr. Wolfe's employment include, among other things, his agreement and execution of a Proprietary Information & Restrictive Covenant Agreement.

Under the terms of the Wolfe Employment Agreement, Mr. Wolfe will hold the position of Chief Financial Officer and receive 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, with a target amount equal to forty percent (40%) of Mr. Wolfe's base salary, subject to review and adjustment 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 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. In the event Mr. Wolfe resigns for Good Reason, and provided that such termination constitutes a Separation from Service (as that term is defined in the Wolfe Employment Agreement), then subject to Mr. Wolfe's compliance with his obligations under the Wolfe Employment Agreement, Mr. Wolfe shall be eligible to receive the Severance Benefits (as that term is defined in the Wolfe Employment Agreement) on the same terms and conditions as he would be entitled for our termination of his employment without Cause.

In the event we terminate Mr. Wolfe's employment at any time without Cause, or if Mr. Wolfe resigns for Good Reason, provided that such termination constitutes a Separation from Service, then Mr. Wolfe shall be entitled to receive the Accrued Obligations (as that term is defined in the Wolfe Employment Agreement) and, subject to Mr. Wolfe's compliance with his obligations under the Wolfe Employment Agreement, Mr. Wolfe shall also be entitled to receive the following Severance Benefits: (i) an amount equal to Mr. Wolfe's then current base salary for 12 months, paid in equal instalments on our regularly scheduled payroll dates following the Release Effective Date (as that term is defined in the Wolfe Employment Agreement); (ii) an amount equal to any unpaid bonus earned for the preceding year in which Mr. Wolfe's termination occurs, paid in a single lump sum payment within 60 days following Mr. Wolfe's termination; and (iv) if elected, we will reimburse Mr. Wolfe 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, Mr. Wolfe shall be eligible to receive the Severance Benefits on the same conditions as he would be entitled for our termination of his employment without Cause and each of the following, 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: (i) Mr. Wolfe shall receive a bonus for the year in which his termination occurs equal to forty percent (40%) of Mr. Wolfe's base salary, paid as a single lump sum payment within 60 days following Mr. Wolfe's termination; and (ii) in the event that any equity awards issued by us to Mr. Wolfe are outstanding as of the closing of such Change in Control are assumed or continued (in accordance with their terms) by the surviving entity in such Change in Control, then 100% of the unvested portion of such equity awards shall become vested as of Mr. Wolfe's termination.

Pursuant to the Wolfe Employment Agreement, we may terminate Mr. Wolfe's employment at any time for Cause upon written notice to Mr. Wolfe. In the event Mr. Wolfe's employment is terminated at any time for Cause, Mr. Wolfe will not receive Severance Benefits or any other 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 Severance Benefits or any other 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.

Karen Cashmere

On July 20, 2022, we entered into an executive employment agreement with Karen Cashmere (the "Cashmere Employment Agreement") that became effective upon consummation of the Business Combination, pursuant to which we agreed to continue to retain Ms. Cashmere as our Chief Commercial Officer following the closing of the Business Combination, subject to the terms and conditions of the Cashmere Employment Agreement. Under the Cashmere Employment Agreement, the conditions of Ms. Cashmere's employment include, among other things, her agreement and execution of a Proprietary Information & Restrictive Covenant Agreement.

Under the terms of the Cashmere Employment Agreement, Ms. Cashmere will hold the position of Chief Commercial Officer and receive a base salary of $320,000 annually, subject to our standard payroll practices. Ms. Cashmere's base salary and future increases in compensation are subject to periodic review and approval by the board of directors. In addition, Ms. Cashmere is eligible to receive an annual performance-based cash bonus, with a target amount equal to thirty percent (30%) of Ms. Cashmere's base salary, subject to review and adjustment by the board of directors based upon Ms. Cashmere's achievement of certain performance goals. Ms. Cashmere's receipt of an annual bonus is also contingent upon Ms. Cashmere'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 Cashmere Employment Agreement, Ms. Cashmere 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 Ms. Cashmere. Ms. Cashmere is also eligible to participate on the same basis as similarly situated employees in our benefit plans in effect from time during her employment.

Pursuant to the Cashmere Employment Agreement, we may terminate Ms. Cashmere's employment at any time without Cause (as that term is defined in the Cashmere Employment Agreement) upon written notice to Ms. Cashmere. Provided Ms. Cashmere has not previously been notified of our intention to terminate her employment, Ms. Cashmere may resign from her employment with us for Good Reason (as that term is defined in the Cashmere Employment Agreement) upon 30 days written notice to us, upon which notice we have 30 days to cure the conditions that Ms. Cashmere considers to be Good Reason, subject to certain conditions set forth in the Cashmere Employment Agreement. In the event Ms. Cashmere resigns for Good Reason, and provided that such termination constitutes a Separation from Service (as that term is defined in the Cashmere Employment Agreement), then subject to Ms. Cashmere's compliance with her obligations under the Cashmere Employment Agreement, Ms. Cashmere shall be eligible to receive the Severance Benefits (as that term is defined in the Cashmere Employment Agreement) on the same terms and conditions as she would be entitled for our termination of her employment without Cause.

In the event we terminate Ms. Cashmere's employment at any time without Cause, or if Ms. Cashmere resigns for Good Reason, provided that such termination constitutes a Separation from Service, then Ms. Cashmere shall be entitled to receive the Accrued Obligations (as that term is defined in the Cashmere Employment Agreement) and, subject to Ms. Cashmere's compliance with her obligations under the Cashmere Employment Agreement, Ms. Cashmere shall also be entitled to receive the following Severance Benefits: (i) an amount equal to Ms. Cashmere's then current base salary for 12 months, paid in equal instalments on our regularly scheduled payroll dates following the Release Effective Date (as that term is defined in the Cashmere Employment Agreement); (ii) an amount equal to any unpaid bonus earned for the preceding year in which Ms. Cashmere's termination occurs, paid in a single lump sum payment within 60 days following Ms. Cashmere's termination; and (iv) if elected, we will reimburse Ms. Cashmere for certain COBRA health benefits for up to 12 months, subject in each case to the terms and conditions of the Cashmere Employment Agreement and applicable laws and regulations.

Notwithstanding the above, if we (or any surviving or acquiring corporation) terminate Ms. Cashmere's employment without Cause or Ms. Cashmere resigns for Good Reason within 90 days before and 24 months following the effective date of a Change of Control (as defined in the Cashmere Employment Agreement), then Ms. Cashmere will be entitled to receive the Accrued Obligations and, subject to Ms. Cashmere's compliance with her obligations under the Cashmere Employment Agreement, Ms. Cashmere shall be eligible to receive the Severance Benefits on the same conditions as she would be entitled for our termination of her employment without Cause and each of the following, 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: (i) Ms. Cashmere shall receive a bonus for the year in which her termination occurs equal to thirty percent (30%) of Ms.

Cashmere's base salary, paid as a single lump sum payment within 60 days following Ms. Cashmere's termination; and (ii) in the event that any equity awards issued by us to Ms. Cashmere are outstanding as of the closing of such Change in Control are assumed or continued (in accordance with their terms) by the surviving entity in such Change in Control, then 100% of the unvested portion of such equity awards shall become vested as of Ms. Cashmere's termination.

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

Ms. Cashmere's entitlement to receive certain Severance Benefits is conditioned upon, among other things, her obligation to sign and deliver an effective Release (as that term is defined in the Cashmere 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 2023

	Option Awards(1)				
Name	Grant Date	Securities underlying unexercised options exercisable (#)	Securities underlying unexercised options unexercisable (#)	Options exercise price ($)	Options expiration date
Stephen C. Glover.....	4/11/2014	3,971(2)	-	176.05	4/11/2024
Co-Founder, Chief Executive					
Officer, and Chairman	10/28/2016	4,822(6)	-	176.05	10/28/2026
	4/2/2019	7,567(9)	-	405.3	4/2/2029
	2/8/2021	2,403(10)	1,201(10)	572.6	2/8/2031
	2/3/2022	757(14)	1,513(14)	572.6	2/3/2032
	5/24/2023	-	16,261(15)	15.25	5/24/2033
Nicholas A. LaBella, Jr.....	4/11/2014	568(2)	-	176.05	4/11/2024
Chief Scientific Officer and	6/9/2015	1,135(4)	-	176.05	6/9/2025
Sr. Vice-President of	10/30/2017	1,702(7)	-	176.05	10/30/2027
Research and Development	4/2/2019	1,135(9)	-	405.3	4/2/2029
	2/8/2021	851(11)	-	572.6	2/8/2031
	1/28/2022	851(13)	-	572.6	1/28/2032
	5/24/2023	4286(16)	-	15.25	5/24/2033
Karen A. Cashmere.....	9/10/2014	284(3)	-	176.05	9/10/2024
Chief Commercial Officer	10/30/2017	568(7)	-	176.05	10/30/2027
	4/2/2019	851(9)	-	405.3	4/2/2029
	2/8/2021	416(10)	208(10)	572.6	2/8/2031
	1/28/2022	208(12)	416(12)	572.6	1/28/2032
	5/24/2023	-	5,715(15)	15.25	5/24/2033
Peter Wolfe.....	10/21/2015	284(5)	-	176.05	10/20/2025
Chief Financial Officer	10/30/2017	284(8)	-	176.05	10/30/2027
and Secretary	4/2/2019	1,135(9)	-	405.3	4/2/2029
	2/8/2021	416(10)	208(10)	572.6	2/8/2031
	1/28/2022	208(12)	416(12)	572.6	1/28/2032
	5/24/2023	-	7,143(15)	15.25	5/24/2033

(1) All of the outstanding stock option awards described in this table (the "ZyVersa Options") were granted under the ZyVersa 2014 Stock Plan (the "2014 Plan"), for all awards issued prior to January 1, 2023 and under the ZyVersa 2022 Stock Plan (the "2022 Plan") for all awards issued after January 1, 2023, and are exercisable for shares of ZyVersa Common Stock. Certain of the options are subject to acceleration upon certain events as described in "- Potential Payments Upon Termination or Change of Control." The number of shares underlying the options and the exercise prices have been adjusted to give effect to the Business Combination.

(2) On April 11, 2014, we granted ten-year stock options to purchase an aggregate of 4,539 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $176.05 per share, which represents the market price of our Common Stock on the date of grant.

(3) On September 10, 2014, we granted ten-year stock options to purchase an aggregate of 284 shares of common stock, which vest in equal annual installments over three years and have an exercise price of $176.05 per share, which represents the market price of our Common Stock on the date of grant.

(4) On June 9, 2015, we granted ten-year stock options to purchase 1,135 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $176.05 per share, which represents the market price of our Common Stock on the date of grant.

(5) On October 21, 2015, we granted ten-year stock options to purchase 284 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $176.05 per share, which represents the market price of our Common Stock on the date of grant.

(6) On October 28, 2016, we granted ten-year stock options to purchase 4,822 shares of Common Stock, which vest immediately and have an exercise price of $176.05 per share, which represents the market price of our Common Stock on the date of grant.

(7) On October 30, 2017, we granted ten-year stock options to purchase an aggregate of 2,270 shares of Common Stock, of which one-third vests immediately and the remaining vest in equal annual installments over two years and have an exercise price of $176.05 per share, which represents the market price of our Common Stock on the date of grant.

(8) On October 30, 2017, we granted ten-year stock options to purchase an aggregate of 284 shares of Common Stock, of which 25% vest immediately and the remaining vest in equal annual installments over three years and have an exercise price of $176.05 per share, which represents the market price of our common stock on the date of grant.

(9) On April 2, 2019, we granted ten-year stock options to purchase an aggregate of 10,688 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $405.30 per share, which represents the market price of our Common Stock on the date of grant.

(10) On February 8, 2021, we granted ten-year stock options to purchase an aggregate of 4,852 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $572.60 per share, which represents the market price of our Common Stock on the date of grant.

(11) On February 8, 2021, we granted ten-year stock options to purchase 851 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $572.60 per share, which represents the market price of our Common Stock on the date of grant. On August 18, 2023, Mr. Labella resigned from all his positions with the Company and all unvested options immediately vested.

(12) On January 28, 2022, the Company granted ten-year stock options to purchase an aggregate of 1,248 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $572.60 per share, which represents the market price of our Common Stock on the date of grant.

(13) On January 28, 2022, the Company granted ten-year stock options to purchase 851 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $572.60 per share, which represents the market price of our Common Stock on the date of grant. On August 18, 2023, Mr. Labella resigned from all his positions with the Company and all unvested options immediately vested.

(14) On February 3, 2022, the Company granted ten-year stock options to purchase an aggregate of 2,270 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $572.60 per share, which represents the market price of our Common Stock on the date of grant.

(15) On May 24, 2023, the Company granted ten-year stock options to purchase an aggregate of 29,119 shares of Common Stock, which vest in equal annual installments over three years and have an exercise price of $15.25 per share, which represents the market price of our Common Stock on the date of grant.

(16) On May 24, 2023, the Company granted ten-year stock options to purchase an aggregate of 4,286 shares of Common Stock, which vest immediately and have an exercise price of $15.25 per share, which represents the market price of our Common Stock on the date of grant

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 2023, 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 Company also granted stock options to its non-employee directors under the 2022 Plan.

The following table sets forth the compensation earned by all non-employee directors during the fiscal year ended December 31, 2023:

Name	Fees earned or paid in cash [2] ($)	Option awards [1] ($)	Total ($)
Gregory Freitag	62,500	17,638	80,138
James Sapirstein	55,266	17,638	72,904
Robert Finizio	63,000	17,638	80,638
Min Chul Park	48,756	17,638	66,394

(1) The options granted to our non-employee directors vest over three years with 33 1/3% of the options vesting and becoming exercisable on the one-year anniversary of the option grant date, 33 1/3% vest and become exercisable on the two-year anniversary of the option grant date and 33 1/3% vest and become exercisable on the three-year anniversary of the option grant date, subject to the non-employee directors remaining on our Board through the applicable vesting dates.

(2) 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 2023, are as follows:

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

Mr. Sapirstein earned $40,000 as a member of the Board, $7,500 as a member of the Compensation Committee, $2,744 as a member of the Nominating and Corporate Governance Committee, $2,511 as the Chairman of the Nominating and Corporate Governance Committee, and $2,511 as a member of the Audit Committee. Mr. Sapirstein also received an initial and annual option grant pursuant to the 2022 Plan.

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. Mr. Finizio also received an initial and annual option grant pursuant to the Company's 2022 Plan.

Dr. Park earned $40,000 as a member of the Board, $7,500 as a member of the Compensation Committee, and $1,256 as a member of the Corporate Governance Committee. Dr. Park also received an initial and annual option grant pursuant to the 2022 Plan.

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

Securities Authorized for Issuance Under Equity Compensation Plans

2014 Equity Incentive Plan

The Predecessor was authorized to issue awards under its 2014 Equity Incentive Plan (the "2014 Plan"), as amended on October 9, 2018, February 2, 2019 and February 2, 2021. Under the 2014 Plan, 102,651 shares of Predecessor common stock of the Company are authorized for issuance as of December 12, 2022. The number of shares of common stock available for issuance under the 2014 Plan shall automatically increase on the first trading day of January each calendar year during the term of the 2014 Plan, beginning with calendar year 2019, by an amount equal to five percent (5%) of the total number of shares of common stock outstanding on the last trading day in December of the immediately preceding calendar year. The 2014 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 2014 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, 2023, there were no shares available for future issuance under the 2014 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 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, seeks 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 31, 2023, the Company approved an amendment and restatement of the 2022 Plan to increase the number of shares of common stock reserved for issuance thereunder by 114,286 shares.

The following table provides information with respect to our compensation plans under which equity compensation was authorized as of December 31, 2023.

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]	98,522[2]	$ 220.65[3]	114,286[4]
Equity compensation plans not approved by security holders	-	$ -	-
Total	98,522	$ 220.65	114,286

[1] The amounts shown in this row include securities under the 2014 Equity Incentive Plan and the 2022 Omnibus Equity Incentive Plan.

[2] Includes 56,999 and 41,523 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, 2023.

[3] In accordance with the "evergreen" provision in our 2022 Omnibus Equity Incentive Plan, an additional 162,082 shares were automatically made available for issuance on the first day of 2024, which represents 4% of the number of shares outstanding on December 31, 2023; these shares are excluded from this calculation.

[4] Includes 0 and 114,286 shares of Common Stock available for issuance under the 2014 Equity Incentive Plan and the 2022 Omnibus Equity Incentive Plan, respectively, as of December 31, 2023.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth beneficial ownership of our Common Stock as of March 21, 2024 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 21, 2024. Shares subject to warrants or options that are currently exercisable or exercisable within 60 days of March 21, 2024 or subject to restricted stock units that vest within 60 days of March 21, 2024 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 7,594,863 shares of Common Stock issued and outstanding as of March 21, 2024.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Directors and executive officers		
Stephen C. Glover[(1)]	41,981	*
Min Chul Park, Ph.D.[(2)]	1,040	*
Robert G. Finizio[(3)]	1,608	*
Peter Wolfe[(4)]	4,534	*
Karen Cashmere[(5)]	2,743	*
Pablo A. Guzman, M.D[(6)]	4,041	*
James Sapirstein	-	-
Gregory Freitag	-	-
All directors and executive officers as a group ([8] individuals)	55,947	*
Other 5% beneficial owners		
Anson Investments Master Fund LP[(7)]	825,103	9.99%
Armistice Capital Master Fund Ltd.[(8)]	842,936	9.99%
Walleye Opportunities Master Fund [(9)]	424,213	5.31%

* Indicates beneficial ownership of less than 1%.

(1) Includes 18,190 shares of Common Stock held by Stephen C. Glover and affiliates, consisting of (i) 13,076 shares of Common Stock held of record by Stephen C. Glover; (ii) 1,253 shares of Common Stock held of record by MedicaRx Inc.; (iii) 2,442 shares of common stock held of record by Asclepius Life Sciences Fund, LP; and (iv) 1,419 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 21, 2024 for 21,477 and 2,314, 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 21, 2024 for 1,040 shares of Common Stock.

(3) Represents options that are exercisable as of or within 60 days of March 21, 2024 2023 for 1,608 shares of Common Stock.

(4) Represents: (i) 1,275 shares of Common Stock; and (ii) options and warrants that are exercisable as of or within 60 days of March 21, 2024 for 2,743 and 516, respectively, shares of common stock.

(5) Represents options that are exercisable as of or within 60 days of March 21, 2024 for 2,743 shares of Common Stock.

(6) Represents: (i) 744 shares of Common Stock; and (ii) options and warrants that are exercisable as of or within 60 days of March 21, 2024 for 3,039 and 258, respectively, shares of Common Stock.

(7) Consists of (i) 160,671 shares of Common Stock as disclosed in a Schedule 13G filed on February 14, 2024 and (ii) warrants to purchase 664,432 shares of Common Stock, but excludes warrants to purchase 2,655,568 shares of Common Stock that are not currently exercisable as a result of the 9.99% beneficial ownership limitation blocker contained in such warrants but given the increase in outstanding shares of the Company since such filing, all warrants held are disclosed here. The securities are held of record by Anson Investments Master Fund LP. Amin Nathoo and Moez Kassam are directors of Anson Advisors, Inc., and Tony Moore is principal of Anson Fund Management LP, each has voting and dispositive power over the securities held by Anson Investments Master Fund LP. The business address for Anson Investments Master Fund LP is 181 Bay Street, Suite 4200, Toronto, ON, M5J 2T3.

(8) Consists of warrants to purchase 842,936 shares of Common Stock but excludes warrants to purchase 1,550,064 shares of Common Stock that are not currently exercisable as a result of the 9.99% beneficial ownership limitation blocker contained in such warrants but given the increase in outstanding shares of the Company since such filing, all warrants held are disclosed here. 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.

(9) Consists of (i) 25,864 shares of Common Stock, per S-1/A filing on December 6, 2023 and (ii) warrants that are exercisable as of or within 60 days of March 21, 2024 for 398,349 shares of Common Stock. The securities are held of record by Walleye Opportunities Master Fund. William England, Chief Investment Officer of the Member of Walleye Opportunities Master Fund Ltd, has sole voting and dispositive power over the securities held by Walleye Opportunities Master Fund Ltd. The business address for Walleye Opportunities Master Fund is 190 Elgin Ave., George Town, Grand Cayman KY-9008, Cayman Islands.

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.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Type of Fees	2023	2022-Successor	2022-Predecessor
Audit Fees [1][2]	$ 848,160	$ 228,000	$ 810,353
Audit-Related Fees [3]	-	-	-
Tax Fees [4]	-	-	19,054
Total	$ 848,160	$ 228,000	$ 829,587

(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 Securities and Exchange Commission, comfort letters, consents and certain accounting and consultations in connection with the audits.

(2) Audit fees for the year ended December 31, 2023 include professional fees incurred by Ernst and Young of $663,160 and Marcum of $185,000.

(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.

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

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	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).
3.3	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).
3.4	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).
3.5	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 8K filed with the SEC on November 30, 2023).
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*	Description of the Company's Securities.
4.9	Form of Warrant (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement filed with the SEC on April 24, 2023).

Exhibit Number	Description
4.10	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).
4.11	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).
4.12	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).
4.13	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).
4.14	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).
4.15	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).
4.16	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).
4.17	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).
10.1	Amended and Restated Registration Rights Agreement, dated as of December 12, 2022, by and among the Company and each of the purchasers identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.2	Form of Shareholder Support Agreement, dated as of July 20, 2022, by and among Larkspur Health Acquisition Corp., ZyVersa Therapeutics, Inc. and certain of the stockholders of ZyVersa Therapeutics, Inc., identified on the signature pages thereto (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on July 22, 2022).
10.3	Form of Lock-Up Agreement, dated as of July 20, 2022, by and among the Company and the parties listed on Schedule A thereto (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on July 22, 2022).
10.4	Registration Rights Agreement, relating to Series A Preferred Stock, dated as of December 12, 2022, by and among the Larkspur Health Acquisition Corp. and each of the PIPE Investors (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.5	Registration Rights Agreement, relating to Series B Preferred Stock, dated as of December 12, 2022, by and among the Company and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.6	Business Combination Advisor Agreement, dated December 20, 2021, by and between the Company and A.G.P (incorporated by reference to Exhibit 1.2 to the Company's Current Report on Form 8-K filed with the SEC on December 23, 2021).
10.7+†	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).
10.8+†	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).
10.8.1	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).
10.8.2	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 February 3, 2023).
10.9+†	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).
10.10#	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).
10.11#	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).
10.12#	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).

Exhibit Number	Description
10.13#	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).
10.14#	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).
10.15#	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).
10.16#	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).
10.17#	Executive Employment Agreement, by and between the Company and Nicholas A. LaBella (incorporated by reference to Exhibit 10.17 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.18#	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).
10.19#	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).
10.21#	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).
10.22#	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).
10.23	Form of Placement Agency Agreement (incorporated by reference to Exhibit 1.1 to Company's Registration Statement on Form S-1 filed with the SEC on April 24, 2023).
10.24	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.22 to Company's Registration Statement on Form S-1 filed with the SEC on April 24, 2023).
10.25	Form of Escrow Agreement (incorporated by reference to Exhibit 10.23 to Company's Registration Statement on Form S-1 filed with the SEC on April 24, 2023).
10.26	Placement Agency Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 26, 2023).
10.27	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1/A filed with the SEC on July 7, 2023).
10.28	Form of Inducement Letter (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 14, 2023).
10.29	Form of Securities Purchase Agreement, dated as of December 6, 2023, between the Company and each purchaser named in the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on December 11, 2023).
10.30	Placement Agency Agreement, dated as of December 6, 2023, between the Company and A.G.P (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on December 11, 2023).
16.1	Letter dated December 22, 2023 from Ernst & Young LLP to the U.S. Securities and Exchange Commission (incorporated by reference to Exhibit 16.1 to the Company's Form 8-K filed with the SEC on December 22, 2023).
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
23.2*	Consent of Ernst & Young 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.
99.1	Securities Purchase Agreement, dated as of July 20, 2022, by and among Larkspur Health Acquisition Corp. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).

Exhibit Number	Description
99.2	Securities Purchase Agreement, dated as of December 12, 2022, by and among Larkspur Health Acquisition Corp. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
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 25, 2024

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

Date: March 25, 2024

/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 25, 2024
/s/ Peter Wolfe Peter Wolfe	Chief Financial Officer and Secretary *(Principal Financial Officer and Principal Accounting Officer)*	March 25, 2024
/s/ Robert G. Finizio Robert G. Finizio	Director	March 25, 2024
/s/ Min Chul Park, Ph.D. Min Chul Park, Ph.D.	Director	March 25, 2024
/s/ James Sapirstein James Sapirstein	Director	March 25, 2024
/s/ Gregory Frietag Gregory Frietag	Director	March 25, 2024

ZYVERSA THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of ZyVersa Therapeutics, Inc. (the "Company") as of December 31, 2023, the related consolidated statements of operations, changes in stockholders' equity and cash flows for the one year period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the one year period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

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

Basis for Opinion

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

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

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

/s/ Marcum LLP

We have served as the Company's auditor since 2023.

New York, NY
March 25, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of ZyVersa Therapeutics, Inc. (the Company) as of December 31, 2022 (Successor), the related consolidated statements of operations, changes in stockholders' equity and cash flows for the period from December 13, 2022 through December 31, 2022 (Successor), and the related consolidated statements of operations, changes in stockholders' deficiency and cash flows for the period from January 1, 2022 through December 12, 2022 (Predecessor), and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022, and the results of its operations and its cash flows for the period from December 13, 2022 through December 31, 2022 (Successor), and the period from January 1, 2022 through December 12, 2022 (Predecessor), in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations, has a working capital deficiency, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We served as the Company's auditor from 2019 until 2023.

Orlando, Florida
March 31, 2023, except for the effects of the reverse stock split discussed in Note 3 to the consolidated financial statements, as to which the date is December 4, 2023

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	Successor	
	December 31,	
	2023	2022
Assets		
Current Assets:		
Cash	$ 3,137,674	$ 5,902,199
Prepaid expenses and other current assets	215,459	225,347
Vendor deposits	-	235,000
Total Current Assets	3,353,133	6,362,546
Equipment, net	6,933	17,333
In-process research and development	18,647,903	100,086,329
Goodwill	-	11,895,033
Security deposit	98,476	46,659
Operating lease right-of-use asset	7,839	98,371
Total Assets	$ 22,114,284	$ 118,506,271
Liabilities, Temporary Equity and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 8,431,583	$ 6,025,645
Accrued expenses and other current liabilities	1,754,533	2,053,559
Operating lease liability	8,656	108,756
Total Current Liabilities	10,194,772	8,187,960
Deferred tax liability	844,914	10,323,983
Total Liabilities	11,039,686	18,511,943
Commitments and contingencies (Note 8)		
Redeemable common stock, subject to possible redemption, 0 and 1,880 shares outstanding as of December 31, 2023 and 2022, respectively	-	331,331
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 1,000,000 shares authorized:		
Series A preferred stock, 8,635 shares designated, 50 and 8,635 shares issued and outstanding as of December 31, 2023 and 2022, respectively	-	1
Series B preferred stock, 5,062 shares designated, 5,062 shares issued and outstanding as of December 31, 2023 and 2022, respectively	1	1
Common stock, $0.0001 par value, 250,000,000 shares authorized; 4,052,119 and 257,604 shares issued at December 31, 2023 and 2022, respectively, and 4,052,057 and 257,604 shares outstanding as of December 31, 2023 and 2022, respectively	405	26
Additional paid-in-capital	114,300,484	104,584,147
Accumulated deficit	(103,219,124)	(4,921,178)
Treasury stock, at cost, 62 and 0 shares at December 31, 2023 and 2022, respectively	(7,168)	-
Total Stockholders' Equity	11,074,598	99,662,997
Total Liabilities, Temporary Equity and Stockholders' Equity	$ 22,114,284	$ 118,506,271

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

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF OPERATIONS

	Successor		Predecessor
	For the Year Ended December 31, 2023	For the period December 13 through December 31, 2022	For the period January 1 through December 12, 2022
Operating Expenses:			
Research and development	$ 3,207,573	$ 399,894	$ 5,407,859
General and administrative	11,213,201	420,174	7,605,205
Impairment of in-process research and development	81,438,426	-	-
Impairment of goodwill	11,895,033	-	-
Total Operating Expenses	107,754,233	820,068	13,013,064
Loss From Operations	(107,754,233)	(820,068)	(13,013,064)
Other (Income) Expense:			
Interest (income) expense	(457)	-	427,542
Change in fair value of derivative liabilities	-	-	607,001
Pre-Tax Loss	(107,753,776)	(820,068)	(14,047,607)
Income tax benefit	9,455,830	745,050	-
Net Loss	(98,297,946)	(75,018)	(14,047,607)
Deemed dividend to preferred stockholders	(7,948,209)	-	(10,015,837)
Net Loss Attributable to Common Stockholders	$ (106,246,155)	$ (75,018)	$ (24,063,444)
Net Loss Per Share - Basic and Diluted	$ (108.97)	$ (0.29)	$ (0.99)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	975,035	257,604	24,194,270

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

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

	For the Year Ended December 31, 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
Successor											
Balance - December 13, 2022	8,635	$ 1	5,062	$ 1	257,604	$ 26	-	-	$104,527,814	$ (4,846,160)	$ 99,681,682
Stock-based compensation									56,333		56,333
Net loss	-	-	-	-	-	-	-	-	-	(75,018)	(75,018)
Balance - December 31, 2022	8,635	1	5,062	1	257,604	26	-	-	104,584,147	(4,921,178)	99,662,997
Reclassification of formerly redeemable common stock	-	-	-	-	1,880	-	-	-	331,331	-	331,331
Issuance of common stock pursuant to vendor agreements	-	-	-	-	104,571	10	-	-	671,610	-	671,620
Registration costs associated with preferred stock issuance	-	-	-	-	-	-	-	-	(5,500)	-	(5,500)
Registered offering of common stock [1]	-	-	-	-	807,759	80	-	-	15,723,828	-	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)	-	-	-	500	-	-	-	-	-	-
Shares issued as consideration for extension of lock-up period	-	-	-	-	86,976	9	-	-	1,156,769	-	1,156,778
Treasury stock acquired, at cost	-	-	-	-	-	-	(62)	(7,168)	-	-	(7,168)
Warrant modification	-	-	-	-	-	-	-	-	181,891	-	181,891
Exercise of pre-funded warrants	-	-	-	-	2,555,565	256	-	-	870	-	1,126
Warrant inducement offer - exercise proceeds [2]	-	-	-	-	203,463	20	-	-	757,627	-	757,647
Round up share adjustment due to reverse split	-	-	-	-	33,801	4	-	-	(4)	-	-
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	4,052,119	$ 405	(62)	$ (7,168)	$114,300,484	$(103,219,124)	$ 11,074,598

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

	For the Period from January 1, 2022 through December 12, 2022						
	Series A Preferred Stock		Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Deficiency
Predecessor							
Balance - January 1, 2022	-	-	24,167,257	242	40,065,109	(52,896,817)	(12,831,466)
Issuance of preferred stock in private placement [3]	625,639	6	-	-	1,865,378	-	1,865,384
Conversion of convertible notes payable into preferred stock [4]	1,802,193	18	-	-	5,658,870	-	5,658,888
Conversion of preferred stock into common stock	(2,427,832)	(24)	6,406,210	64	(40)	-	-
Conversion of convertible notes payable into common stock [5]	-	-	2,940,537	29	5,838,180	-	5,838,209
Stock-based compensation	-	-	-	-	3,524,801	-	3,524,801
Net loss	-	-	-	-	-	(14,047,607)	(14,047,607)
Balance - December 12, 2022	-	$ 0	33,514,004	$ 335	$56,952,298	$ (66,944,424)	$ (9,991,791)

[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 $1,964,524 less issuance costs of $99,140

[4] Includes principal of $5,230,000 and accrued interest of $428,888

[5] Includes principal of $3,961,000, accrued interest of $709,608 and derivative liability of $1,167,601

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

ZYVERSA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF CASHFLOWS

	Successor		Predecessor
	For the Year Ended December 31, 2023	For the period December 13 through December 31, 2022	For the period January 1 through December 12, 2022
Cash Flows From Operating Activities:			
Net loss	$ (98,297,946)	$ (75,018)	$ (14,047,607)
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	1,192,963	56,333	3,524,801
Issuance of common stock pursuant to vendor agreements	671,620	-	-
Shares issued as consideration for extension of lock-up period	1,156,778	-	-
Amortization of debt discount	-	-	39,492
Change in fair value of derivative liability	-	-	607,001
Depreciation of fixed assets	10,400	532	9,868
Non-cash rent expense	90,532	4,443	79,918
Deferred tax benefit	(9,479,069)	(745,050)	-
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	56,547	36,606	73,675
Vendor deposits	136,524	125,645	255,627
Accounts payable	2,405,938	(2,076,863)	6,617,064
Operating lease liability	(100,100)	(4,786)	(86,100)
Accrued expenses and other current liabilities	101,535	(715,730)	1,431,620
Net Cash Used In Operating Activities	(8,720,819)	(3,393,888)	(1,494,641)
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	(2,417,095)	-	-
Redemption of Series A Preferred Stock	(10,695,611)	-	-
Proceeds from issuance of preferred stock in private placement	-	-	1,964,524
Purchase of treasury stock	(7,168)	-	-
Exercise of pre-funded warrants	1,126	-	-
Warrant inducement offer - exercise proceeds	966,349	-	-
Registration and issuance costs associated with preferred stock issuance	(5,500)	-	(99,140)
Net Cash Provided By Financing Activities	5,956,294	-	1,865,384
Net (Decrease) Increase in Cash	(2,764,525)	(3,393,888)	370,743
Cash - Beginning of Year	5,902,199	699,324	328,581
Cash - End of Year	$ 3,137,674	$ 5,902,199	$ 699,324
Supplemental Disclosures of Cash Flow Information:			
Conversion of convertible notes payable and accrued interest into preferred stock	$ -	$ -	$ 5,658,888
Conversion of convertible notes payable and accrued interest into common stock	$ -	$ -	$ 5,838,209
Reclassification of formerly redeemable common stock	$ 331,331	$ -	$ -
Recognition of ROU asset and lease liability upon adoption of ASC 842	$ -	$ -	$ 182,732
Accounts payable for deferred offering costs	$ 44,892	$ 240,691	$ 667,224
Warrant modification - incremental value	$ 181,891	$ -	$ -
Warrant inducement offer - incremental value	$ 134,591	$ -	$ -

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

ZYVERSA THERAPEUTICS, INC.
NOTES TO 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 (see Note 4 – Business Combination for additional details) 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

The Company has incurred losses each year since its inception and has a net working capital deficiency as of December 31, 2023. Subsequent to December 31, 2023, the Company received proceeds of $2.7 million upon the exercise of certain warrants (see Note 10 – Subsequent Events – Stock Warrants for further discussion). 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. As a result of the Business Combination, for accounting purposes, Larkspur Health Acquisition Corp. was the acquirer and ZyVersa Therapeutics, Inc. was the acquiree and accounting predecessor. Therefore, the financial statement presentation includes the financial statements of the Predecessor for the periods prior to December 13, 2022 and the Successor for the periods including and after December 13, 2022, including the consolidation of ZyVersa Therapeutics Operating, Inc. 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 "Reverse Split"). Upon the effectiveness of the 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 Reverse Split. Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively for the successor periods, where applicable, to reflect the 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.

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.

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, 2023 and 2022, 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 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.

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. As of December 31, 2023 and 2022, equipment consisted of $52,000 of medical equipment, placed in service on September 1, 2019, less accumulated depreciation of $45,067 and $34,667 as of December 31, 2023 and 2022, respectively. During the year ended December 31, 2023, the Successor recognized depreciation expense of $10,400. For the period from December 13, 2022 through December 31, 2022 the Successor recognized depreciation expense of $532. During the period ended December 12, 2022, the Predecessor recognized depreciation expense of $9,868. Depreciation expense was included in general and administrative expenses in the statements of operations for all periods.

Financing Costs

Debt issuance costs, which primarily consist of direct, incremental professional fees incurred in connection with a debt financing, are reported as a direct deduction from the face amount of the notes payable and are amortized over the contractual term of the underlying notes payable using the effective interest method.

Convertible Promissory Notes

The Company evaluates its convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with Topic 815 "Derivatives and Hedging" ("ASC 815") of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC"). The accounting treatment of derivative financial instruments requires that the Company record any bifurcated embedded features at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded in earnings each period as non-operating, non-cash income or expense. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. Bifurcated embedded features are recorded at their initial fair values which create additional debt discount to the host instrument.

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.

Leases

See Note 3 - Summary of Significant Accounting Policies – Recently Adopted Accounting Pronouncements for further details on the adoption of ASC 842.

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. Successor common stock is being valued using the market approach using the trading prices of the common stock on the Nasdaq Capital Market. During 2022, the fair value of the Predecessor common stock was determined using a market approach based on the status of the business combination agreement arm's length discussions with the acquirer at each valuation date and which agreement was ultimately entered into on July 20, 2022 with a Predecessor valuation of $85 million. 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.

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:

	Successor		Predecessor
	December 31,		
	2023	2022	December 12, 2022
Predecessor warrants [1]	-	-	8,560,561
Successor warrants [1]	9,032,739	246,534[2]	-
Predecessor options	-		10,039,348
Successor options	101,752	56,950	-
Successor Series A Convertible Preferred Stock	714	24,671[3]	-
Successor Series B Convertible Preferred Stock	20,664	14,465[4]	-
Predecessor Series A Convertible Preferred Stock	-	-	6,406,210
Total potentially dilutive shares	9,155,869	342,620	25,006,119

[1] As part of the InflamaCORE, LLC license agreement, warrants to purchase 3,404 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.

[2] Does not include an additional 98,686 shares if the Successor Series A warrant exercise price resets to its floor price.

[3] Does not include an additional 98,686 shares if the Successor Series A Convertible Preferred Stock conversion price resets to its floor price.

[4] Does not include an additional 6,199 shares if the Successor Series B Convertible Preferred Stock conversion price resets to its floor price.

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 December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes," which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. ASU 2019-12 is effective for fiscal years beginning after December 15, 2021. This standard was adopted on January 1, 2022 and did not have a material impact on the Company's consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options. This new standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Companies should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. This standard was adopted on January 1, 2022 and did not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)." ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. This amendment will be effective for private companies and emerging growth companies for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The FASB issued ASU No. 2018-10 "Codification Improvements to Topic 842, Leases" and ASU No. 2018-11 "Leases (Topic 842) Targeted Improvements" in July 2018, and ASU No. 2018-20 "Leases (Topic 842) - Narrow Scope Improvements for Lessors" in December 2018. ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company adopted ASU 2016-02 on December 31, 2022, effective January 1, 2022 and the adoption of this ASU resulted in the recording of right-of-use assets and lease liabilities for the Company's operating leases in the approximate amounts of $182,732 and $199,642 and derecognizing deferred rent in the approximate amount of $16,910.

Note 4 – Business Combination

On July 20, 2022, the Operating Company entered into a Business Combination Agreement, (the "Business Combination Agreement"), with Larkspur, Larkspur Merger Sub Inc. ("Merger Sub" a wholly owned subsidiary of Larkspur) and Stephen Glover, in his capacity as the representative of the shareholders of the Operating Company. Larkspur was a blank-check special purpose acquisition company ("SPAC") that became a public company as a result of completing its initial public offering on December 23, 2021 and it was formed for the purpose of effecting a combination with a private company business that could benefit by gaining access to the capital that can be raised because its shares are publicly traded on Nasdaq.

On December 12, 2022, the Business Combination was consummated following a special meeting of stockholders on December 8, 2022, where the stockholders of Larkspur, considered and approved, among other matters, a proposal to adopt the Business Combination Agreement. Further information regarding the Business Combination is set forth in (i) the proxy statement / prospectus included in the registration statement on Form S-4 (File No. 333-266838), as amended and supplemented, originally filed with the SEC on August 12, 2022 and declared effective by the SEC on November 14, 2022; and (ii) the Current Report on Form 8-K filed with the SEC on July 22, 2022.

The Business Combination included the following transactions:

- The Operating Company merged into Merger Sub with the result that the Operating Company was the surviving entity and incorporated in Delaware.
- The Operating Company's common stockholders exchanged their 33,845,335 shares of Predecessor common stock (includes 33,514,004 permanent equity shares and 331,331 temporary equity shares) for 191,992 shares of the Successor's common stock based on the established exchange ratio of 176.28. Those Predecessor common stock shares were canceled and the New Parent only owns one share of the Operating Company. Accordingly, the Operating Company became a wholly-owned subsidiary of the New Parent.
- The 10,039,348 outstanding Predecessor options were exchanged for 56,950 outstanding Successor options. The number of Successor options issued to Predecessor option holders was determined after giving effect to an exchange ratio of 176.28. The exercise price of each of the corresponding options was also adjusted by the exchange ratio.
- The 8,560,561 outstanding Predecessor warrants were exchanged for 48,561 outstanding Successor warrants. The number of Successor warrants issued to Predecessor warrant holders was determined after giving effect to an exchange ratio of 176.28. The exercise price of each of the corresponding warrants was also adjusted by the exchange ratio.

Given the non-recurring nature of Larkspur's activities as a SPAC, pro forma financial data combining the pre-Business Combination results of both Larkspur and the Operating Company would not be meaningful and have not been presented.

The Company accounted for the Business Combination as a forward acquisition of the Operating Company as it was determined that the Operating Company was a variable interest entity as of the date of the Business Combination. The New Parent is the primary beneficiary as its ownership provides the power to direct the activities of the Operating Company and the obligation to absorb the losses and/or receive the benefits of the Operating Company.

Purchase Price Allocation

The Business Combination was recorded using the acquisition method of accounting and the initial purchase price allocation was based on the Company's preliminary assessment of the fair value of the purchase consideration and the fair value of the Operating Company's tangible and intangible assets acquired and liabilities assumed at the date of acquisition. As of December 31, 2022, the purchase price allocation was not complete due to the proximity of the acquisition date to the calendar year end.

As of June 30, 2023, the preliminary estimates of the acquisition-date fair value of the purchase consideration and the preliminary estimates of the purchase price allocation were confirmed, do not require measurement period adjustments, and are now considered final. The acquisition-date fair value of the elements of the purchase consideration were estimated using a market approach with Level 1 inputs (observable inputs) in the case of the fair value of the Successor's common stock and Level 3 inputs (unobservable inputs) in the case of the fair value attributed to the Successor warrants and options. The acquiror was obligated to replace the Operating Company's existing warrants and options pursuant to the Business Combination Agreement. Accordingly, it was necessary to allocate the fair value of the replacement warrants and options between purchase consideration (the fair value attributable to pre-combination services) and compensation for post-combination services. The fair value of the replacement warrants and options attributable to post-combination services was $584,260 and $1,731,237, respectively.

The final estimates of the acquisition-date fair value of the purchase consideration were as follows:

Successor common stock	$	67,197,300
Successor warrants		12,190,015
Successor options		11,864,556
Total fair value of the purchase consideration	$	91,251,871

The final acquisition-date fair values of the assets acquired and liabilities assumed (see the table below) were determined by management, with the assistance of a third-party valuation expert specifically for the in-process research and development ("IPR&D"). The estimated fair value of the IPR&D assets were determined using the "income approach" which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life using Level 3 inputs. Some of the more significant assumptions utilized in the valuations include the estimated net cash flows for each year for each asset, the appropriate discount rate necessary to measure the risk inherent in the future cash flows, the life cycle of each asset, the potential regulatory and commercial success risk, royalties on net sales, as well as other factors. There are inherent uncertainties related to these factors and management's judgment in applying them to arrive at the estimated fair values. The excess of the purchase price over the estimated fair values of the identifiable net assets acquired was recorded as goodwill, which management believes is attributable to the assembled workforce and other intangible assets that don't qualify for separate recognition.

Current assets, including cash of $699,324	$	1,093,223
In-process research and development		100,086,329
Goodwill		11,895,033
Other non-current assets		64,523
Total assets acquired		113,139,108
Current liabilities		10,818,204
Deferred tax liabilities		11,069,033
Total assumed liabilities		21,887,237
Net assets acquired	$	91,251,871

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. Because the acquisition was structured as a stock sale, the IPR&D and the goodwill do not have any tax basis and will not be deductible for tax purposes.

Impairment

While management did not identify any unfavorable developments directly related to its IPR&D assets through December 31, 2023, management did determine that it was more likely than not that the Company's single reporting unit's fair value was below its carrying amount, due to a significant and sustained decline in the Company's market capitalization through December 31, 2023.

The Company's estimated market capitalization included an estimated implied control premium of approximately 100%. The Company's determination of a reasonable control premium that an investor would pay, over and above the market capitalization for a control position, included a number of factors:

- Market control premium; The identification of recent public market information of comparable peer acquisition transactions. The selection of comparable peer acquisition transactions is subject to judgment and uncertainty.
- Impact of low public float and limited trading activity on market capitalization: A significant portion of the Company's common shares are owned by a concentrated number of investors. The public float of the Company's common shares, calculated as the percentage of common shares freely traded by public investors divided by the Company's total shares outstanding, is significantly lower than that of the Company's publicly traded peers. Based on the Company's evaluation of third-party market data, we believe there is an inherent discount impacting the Company's share price due to the low public float and limited trading volume, thus impacting the Company's market capitalization.

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.

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.

Note 6 – Accrued Expenses and Other Current Liabilities

As of December 31, 2023 and 2022, accrued expenses and other current liabilities consisted of the following:

	For the Years Ended December 31,	
	2023	2022
L&F milestone payment liability	$ 500,000	$ 1,500,000
L&F Note [1]	-	(351,579)
L&F, net	500,000	1,148,421
Payroll accrual	668,803	584,226
Other accrued expenses	41,969	214,229
Federal income tax payable	-	106,683
Bonus accrual	536,500	-
Registration delay liability [2]	7,261	-
Total accrued expenses and other current liabilities	$ 1,754,533	$ 2,053,559

[1] See Note 5 – "Note Receivable" and Note 8 – "Commitments and Contingencies" for details of the forgiveness of the L&F Note.

[2] 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:

	Successor		Predecessor
	For the Year Ended December 31, 2023	For the Period December 13 Through December 31, 2022	For the Period January 1 Through December 12, 2022
Current tax benefit:			
Federal	$ -	$ -	$ -
State	23,240	-	-
	23,240	-	-
Deferred tax benefit:			
Federal	(19,104,800)	(151,625)	(2,191,344)
State	(4,468,170)	(34,844)	(482,283)
	(23,572,970)	(186,469)	(2,673,627)
Change in valuation allowance	14,093,900	(558,581)	2,673,627
Provision for income taxes	$ (9,455,830)	$ (745,050)	$ -

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

	Successor		Predecessor
	For the Year Ended December 31, 2023	For the Period December 13 Through December 31, 2022	For the Period January 1 Through December 12, 2022
Federal statutory rate	21.0%	21.0%	21.0%
State tax rate, net of federal benefit	3.8%	3.6%	3.6%
Permanent items	(2.8)%	(1.9%)	(5.4)%
Nondeductible basis difference	0.0%	0.0%	0.0%
Effect of change in state rate	(0.1)%	0.0%	(0.1)%
Prior period adjustments and other	0.0%	0.0%	(0.1)%
Change in valuation allowance	(13.1)%	68.1%	(19.0)%
Effective income tax rate	8.8%	90.8%	0.0%

Deferred tax assets and liabilities consist of the following:

	Successor		Predecessor
	December 31,		
	2023	2022	December 12, 2022
Net operating loss carryforwards	$ 9,974,075	$ 6,671,907	$ 6,639,882
Stock-based compensation expense	3,258,463	2,936,945	4,084,595
Capitalized research and development costs	2,182,104	2,421,390	2,362,939
Capitalized start-up costs	1,033,504	1,121,802	565,530
Capitalized licensing costs	647,489	687,926	689,820
Capitalized patents	351,721	288,123	273,682
Warrants	134,341	133,203	238,768
Accrued payroll	299,487	71,830	-
Contributions carryforward	2,857	2,833	2,833
Operating lease liability	2,151	26,794	-
Deferred tax assets	17,886,192	14,362,753	14,858,049
Valuation allowance	(14,093,900)	-	(14,853,648)
	3,792,292	14,362,753	4,401
Operating lease right-of-use asset	(1,948)	(24,236)	-
In-process research and development	(4,633,535)	(24,658,231)	-
Fixed assets	(1,723)	(4,270)	(4,401)
Deferred tax liabilities	(4,637,206)	(24,686,737)	(4,401)
Deferred tax assets, net	$ (844,914)	$ (10,323,984)	$ -

On December 31, 2023 and 2022, the Successor had approximately $40,807,990 and $27,515,427 Federal net operating loss ("NOL") carryforwards, respectively, and $32,322,138 and 20,567,703 of State NOLs, respectively. On December 12, 2022, the Predecessor had approximately $27,385,445 Federal net operating loss ("NOL") carryforwards and $20,458,902 of State NOLs that may be available to offset future Federal and State taxable income. Such NOL carryforwards do not expire. However, their use to offset future taxable income may be subject to limitations under Section 382 of the Internal Revenue Code and similar state statutes as a result of ownership changes.

The Company has assessed the likelihood that deferred tax assets will be realized and considers all available positive and negative evidence, including the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. A valuation allowance is established when it is "more likely than not" that all, or a portion of, deferred tax assets will not be realized. After the performance of such a review as of December 12, 2022, management believed that uncertainty existed with respect to future realization of the Predecessor deferred tax assets and therefore, established a full valuation allowance as of that date. Thus, the Predecessor recorded an increase in the valuation allowance of $2,673,627 in connection with the tax provision for the period from January 1, 2022 through December 12, 2022.

As a result of the December 12, 2022 Business Combination and the availability of new deferred tax liabilities (a) the Predecessor released its $14,853,648 valuation allowance as part of the acquisition accounting. During the 2022 Successor period, the New Parent released its $558,581 valuation allowance as an income tax benefit, separate from the Business Combination.

However, due to the impairment of the IPR&D and the corresponding reduction in the related deferred tax liabilities during the year ended December 31, 2023, the Company established a $14,093,900 valuation allowance as of December 31, 2023.

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, 2023 and 2022. 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, 2023 and 2022 and no tax related interest or penalties were incurred during those years. The Company's tax returns beginning with the year ended December 31, 2020 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.

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 Predecessor warrants to purchase an aggregate of 878,947 shares of Predecessor common stock at an exercise price of $1.00 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 Predecessor warrant to purchase 351,579 shares of Predecessor 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; the Company will recognize expense associated with the remaining warrants when it is probable that the associated performance conditions will be achieved; a Predecessor warrant to purchase 175,789 shares of Predecessor 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; Predecessor warrants to purchase 351,578 shares of Predecessor common stock were not exercisable as of December 31, 2022 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 Predecessor 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 Predecessor 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 Predecessor warrants to purchase an aggregate of 1,000,000 shares of Predecessor common stock, of which, a Predecessor warrant to purchase 400,000 shares of Predecessor common stock (equivalent to 2,270 shares of Successor 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 $2.30 per share (or $405.30 per share of Successor common stock) and the remaining Predecessor warrants to purchase 600,000 shares of Predecessor common stock are to be issued at a price per share equal to the fair value of the Predecessor's 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 200,000 shares of Predecessor 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, 2023, the Successor did not pay or owe any royalties, the performance milestones associated with the cash payments and issuance of Successor warrants were not achieved and the Company did not accrue for any payments or issue the remaining Successor warrants associated with the license agreement.

Operating Leases

On January 18, 2019, the Predecessor 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 Predecessor's share of taxes and operating costs, was approximately $89,000 for the first year and increases 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.

The Successor recognized rent expense in connection with its operating lease for the year ended December 31, 2023 of $154,841 and the Successor and Predecessor recognized $7,795 and $148,881, respectively, for the period ending December 31, 2022 and December 12, 2022, respectively.

See Note 3 – Summary of Significant Accounting Policies – Recently Adopted Accounting Pronouncements for information related to the Company's adoption of the new lease accounting standard and the recognition of a right-of-use asset and operating lease liability.

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

	Successor		Predecessor
	For the Year Ended December 31, 2023	For the Period December 13 Through December 31, 2022	For the Period January 1, 2022 Through December 12, 2022
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash flows used in operating activities	$ 100,099	$ 4,786	$ 86,100
Right-of-use assets obtained in exchange for lease obligations			
Operating leases	$ -	$ -	$ -
Weighted Average Remaining Lease Term			
Operating leases	0.08 Years	1.08 Years	1.08 Years
Weighted Average Discount Rate			
Operating leases	6.5%	6.5%	6.5%

Future minimum payments under these operating lease agreements are as follows:

	Amount
For the year ended December 31, 2024	$ 8,703
Less: amount representing imputed interest.....	(48)
Total	$ 8,656

Note 9 – Stockholders' Permanent and Temporary Equity

Authorized Capital

The Predecessor was authorized to issue 75,000,000 shares of Predecessor common stock, par value of $0.00001 per share, and 5,000,000 shares of Predecessor preferred stock, par value of $0.00001 per share. The holders of the Predecessor's common stock were entitled to one vote per share.

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

Effective November 30, 2023, the Company amended its certificate of incorporation to increase the authorized number of shares of the Company's capital stock from 111,000,000 to 251,000,000 and the number of authorized shares of common stock from 110,000,000 to 250,000,000.

Equity Incentive Plans

Predecessor 2014 Equity Incentive Plan

The Predecessor was authorized to issue awards under its 2014 Equity Incentive Plan (the "2014 Plan"), as amended on October 9, 2018, February 2, 2019 and February 2, 2021. Under the 2014 Plan, 102,651 shares of Predecessor common stock of the Company are authorized for issuance as of December 12, 2022. The number of shares of common stock available for issuance under the 2014 Plan shall automatically increase on the first trading day of January each calendar year during the term of the 2014 Plan, beginning with calendar year 2019, by an amount equal to five percent (5%) of the total number of shares of common stock outstanding on the last trading day in December of the immediately preceding calendar year. The 2014 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 2014 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, 2023, there were no shares available for future issuance under the 2014 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.

Successor 2022 Omnibus Equity Incentive Plan

The Successor is authorized to issue awards under the 2022 Omnibus Equity Incentive Plan (the "2022 Plan"). Under the 2022 Plan, 31,138 shares of Successor common stock were initially authorized for issuance. The number of shares of Successor 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 Successor common stock outstanding on the last trading day in December of the immediately preceding calendar year. On January 1, 2023 the shares automatically increased to 41,523. On September 8, 2023, the Company's Board of Directors approved the Company's Amended and Restated 2022 Omnibus Equity Incentive Plan (the "A&R Plan"), which the stockholders approved on October 31, 2023. The restated plan increases the number of shares of the Company's Successor common stock reserved for issuance by 114,286 shares to 155,809. 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 Successor common stock on the date of grant. As of December 31, 2023, there were 114,286 Successor shares available for future issuance under the 2022 Plan.

Successor Common Stock

On December 12, 2022, the Company closed on the Business Combination (see Note 4 – Business Combination) which met the legal definition of a reverse merger with a publicly traded company (albeit for accounting purposes it was a forward merger). Accordingly, such Business Combination met the definition of a Qualified Offering and, as such, the $3,961,000 of Predecessor convertible notes principal, $709,608 of related accrued interest and $1,167,601 of derivative liabilities, were automatically converted into 2,940,537 shares of Predecessor common stock, which in turn were exchanged for 16,681 shares of Successor common stock. The automatic conversion was pursuant to the share-settled redemption feature included in the original terms of the Predecessor convertible notes which resulted in a conversion price of $1.58835 (80% of the $1.98542 fair value per share of the Predecessor common stock which was determined using the Business Combination exchange ratio of 176.28). The automatic conversion of Predecessor convertible notes pursuant to a share-settled redemption feature is accounted for as an extinguishment, but this automatic conversion didn't result in the recognition of an extinguishment loss because the redemption feature (derivative liability) was marked to the market on the date of the Business Combination, prior to the derecognition of the carrying value of the Predecessor convertible notes principal, accrued interest and derivative liability, and those aggregate amounts are allocated to common stock (par value) and additional paid-in-capital.

On June 5, 2023, the Company issued 86,976 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 56,507 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 two vendors in which the Company issued an aggregate of 104,571 shares of common stock and cash in exchange for marketing services. The $671,620 fair value of the common stock was established as a prepaid expense and the Company is recognizing the expense over the terms of the contracts.

Successor Equity Offerings

On April 28, 2023, the Company completed an offering of 314,729 shares of common stock and warrants to purchase 314,729 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 $35.00 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 of 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 public offering of 93,030 shares of common stock, pre-funded warrants (the "July 2023 Pre-Funded Warrants") to purchase 270,565 shares of common stock and common warrants (the "July 2023 Warrants") to purchase 363,636 shares of common stock at a combined public offering price of $5.78 per share (less $0.0035 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 $0.0035 per share. The July 2023 Warrants are exercisable immediately for a term of five years and have an exercise price of $5.78 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 public offering of 400,000 shares of common stock, pre-funded warrants (the "December 2023 Pre-Funded Warrants") to purchase 3,600,000 shares of common stock, Series A common warrants (the "December 2023 Series A Warrants") to purchase 4,000,000 shares of common stock, and Series B common warrants (the "December 2023 Series B Warrants") to purchase 4,000,000 shares of common stock at a combined public offering price of $1.25 per share (less $0.0001 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 $0.0001 per share. The December 2023 Series A Warrants are exercisable immediately for a term of five years and have an exercise price of $1.25 per share. The December 2023 Series B Warrants are exercisable immediately for a term of 18-months and have an exercise price of $1.25 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.

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 (see Note 4 – Business Combination) whereby the 331,331 shares of Predecessor common stock subject to the Put Option were exchanged for 1,880 shares of Successor common stock at a price of $176.28 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 1,880 shares of Successor common stock and $331,331 classified as temporary equity to permanent equity.

Predecessor Series A Preferred Stock

*Predecessor Series A Preferred Stock Financing*s

On March 31, 2022, the Predecessor sold 133,541 shares of Series A Preferred Stock to investors at a price of $3.14 per share for net proceeds of $392,301, of which $100,000 was from related parties.

The Predecessor Series A Preferred Stock is convertible, at the option of the holder, at any time into shares of Predecessor common stock on a one-to-one basis, subject to standard antidilution adjustments. In addition, in the event of any non-exempt issuances by the Company for less than the in-force conversion price, the Predecessor Series A Preferred Stock conversion price shall be reduced on a weighted average basis. Each share of Predecessor Series A Preferred Stock shall automatically be converted into shares of Predecessor common stock at the then effective conversion price concurrently with (i) the closing of a Public Transaction or (ii) the date specified by written consent or agreement of the holders of a majority of the then outstanding shares of Predecessor Series A Preferred stock. A Public Transaction represents either (a) a firm commitment underwritten public offering; or (b) the closing of a transaction with a special purpose acquisition company ("SPAC") listed on the Nasdaq Stock Market in which the Company would become a wholly owned subsidiary of the SPAC.

The Predecessor Series A Preferred stockholders shall vote together with the Predecessor common stockholders on an as-converted basis and dividends will only be paid on an as-converted basis when, and if paid to Predecessor common stockholders. In the event of any liquidation, dissolution or winding up of the Predecessor or upon a Deemed Liquidation Event, the Predecessor Series A Preferred stockholders will be entitled to be paid, out of the assets of the Predecessor available for distribution before any payments are made to Predecessor common stockholders, one times the original purchase price, plus declared and unpaid dividends on each share of Predecessor Series A Preferred Stock or, if greater, the amount that the Predecessor Series A Preferred Stock holders would receive on an as-converted basis. The balance of any proceeds shall be distributed pro rata to the Predecessor common stockholders. Deemed Liquidation Events include (a) a merger or consolidation in which the Predecessor or a subsidiary thereof is a constituent party which results in a change-of-control (a "Merger Event"); or (b) the sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Predecessor (a "Disposition Event").

The Predecessor Series A Preferred Stock is not mandatorily redeemable and therefore it is not subject to classification as a liability. The Predecessor determined that the Deemed Liquidation Events were within the control of the Predecessor and, therefore, the Predecessor Series A Preferred Stock should be classified as permanent equity. Specifically, Merger Events and Disposition Events require the approval of the board of directors pursuant to state law and the Predecessor preferred stockholders are unable to control the vote of the board of directors. The Predecessor 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 Predecessor will need to assess the accounting for the price reset. Due to the Predecessor'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 July 8, 2022, the Predecessor sold an additional 94,393 shares of Predecessor Series A Preferred Stock to investors at a price of $3.14 per share of Predecessor Series A Preferred Stock, generating $296,400 in gross proceeds. Placement agent fees of $21,200 were recorded as a reduction of additional paid-in capital.

On September 16, 2022, the Predecessor sold an additional 222,929 shares of Predecessor Series A Preferred Stock to investors at a price of $3.14 per share of Predecessor Series A Preferred Stock, generating $700,000 in gross proceeds. Placement agent fees of $16,000 were recorded as a reduction of additional paid-in-capital.

On December 6, 2022, the Predecessor sold an additional 174,776 shares of Predecessor Series A Preferred Stock to investors at a price of $3.14 per share of Predecessor Series A Preferred Stock, generating $548,805 in gross proceeds. Placement agent fees of $2,000 were recorded as a reduction of additional paid-in capital.

Amendment of Predecessor Series A Preferred Stock Designation

On May 10, 2022, the Predecessor obtained the requisite approvals to (a) amend the Predecessor Series A Preferred Stock Designation within the Predecessor's Certificate of Incorporation to reduce the effective conversion price of the Predecessor Series A Preferred Stock from $3.14 per share of Predecessor common stock to $2.78 per share of Predecessor common stock; and (b) and added 100% warrant coverage, such that, for each share of Predecessor common stock issued at conversion, the holder will also receive a Predecessor warrant to purchase one share of Predecessor common stock. These Predecessor warrants are exercisable at an initial exercise price of $3.20 per share of Predecessor common stock (subject to reduction upon completion of a Public Transaction, if the deemed offering price is less than the current exercise price) and expire in five years (the "Predecessor Series A Warrants") or upon an earlier change of control that doesn't meet the definition of a Public Transaction. The Predecessor determined that (a) the Predecessor Series A Warrants qualified to be equity-classified upon issuance, without subsequent remeasurement and (b) the contingently issuable nature of the Predecessor Series A Warrants doesn't alter the Predecessor's conclusion 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. The Predecessor also determined that the reduction of the Predecessor Series A Preferred Stock conversion price, combined with adding 100% warrant coverage at conversion, represented a significant change of the Predecessor Series A Preferred Stock terms requiring the application of extinguishment accounting. Accordingly, it was necessary to record the $331,200 incremental fair value of the amended Predecessor Series A Preferred Stock and the new Predecessor Series A Warrants (as compared to the carrying value of the Series A Preferred Stock) as a deemed dividend for the purpose of calculating loss per share.

Second Amendment of Predecessor Series A Preferred Stock Designation

On August 31, 2022, the Predecessor filed with the Florida Department of State a second amendment to the Predecessor Series A Preferred Stock Designation within the Predecessor's Certificate of Incorporation, which reduced the conversion price of the Predecessor Series A Preferred Stock from $2.78 per share of Predecessor common stock and Predecessor Series A Warrant to $1.19 per share of Predecessor common stock and Predecessor Series A Warrant. In addition, the Predecessor reduced the exercise price of the Predecessor Series A Warrants issuable at conversion from $3.20 per share to $1.37 per share.

The Predecessor determined that the reduction of the Predecessor Series A Preferred Stock conversion price, combined with the revised terms associated with the Predecessor Series A Warrants (collectively the "Second Amendment Securities") issuable at conversion, represented a significant change requiring the application of extinguishment accounting. Accordingly, it was necessary to record the $9,684,637 incremental fair value of the amended Predecessor Series A Preferred Stock and the amended Predecessor Series A Warrants (as compared to the carrying value of the Series A Preferred Stock and the pre-Second Amendment fair value of the Predecessor Series A Warrants) as a deemed dividend for the purpose of calculating loss per share.

Automatic Conversion of Predecessor Series A Preferred Stock

On December 12, 2022, in connection with the Business Combination, all outstanding 2,427,832 shares of Predecessor Series A Preferred Stock automatically converted into 6,406,210 shares of Predecessor common stock and five-year Predecessor Series A Warrants to purchase 6,406,210 shares of Predecessor common stock, which were then exchanged for 36,340 shares of Successor common stock and five-year warrants to purchase 36,340 shares of Successor common stock at an exercise price of $241.50 per share. The conversion of equity classified preferred stock that converts pursuant to the original terms of the preferred stock, results in the derecognition of the carrying value of the preferred stock and the allocation of that amount to common stock (par value) and additional paid-in-capital, without the recognition of a gain or loss.

Successor Preferred Stock

Successor Series A Preferred Stock Financing

In connection with the Business Combination, the Successor sold 8,635 shares of Series A Preferred Stock and five-year warrants to purchase 24,671 shares of Successor common stock at an exercise price of $402.50 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 Successor Series A Preferred Stock is convertible, at the option of the holder, at any time into a number of shares of Successor common stock equal to the face value divided by the conversion price then in effect (initially $350.00). In addition, for five years following the issuance of the Successor Series A Preferred Stock, the conversion price is automatically adjusted to the greater of (a) $70.00; 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 Successor Series A Preferred Stock (each a "Commencement Date") to the greater of (a) $70.00; and (b) 85% of the lowest of the ten consecutive daily volume-weighted average prices commencing on, and including, each Commencement Date.

The Successor Series A Preferred stockholders have no voting rights and dividends will only be paid on an as-converted basis when, and if paid to Successor common stockholders. In the event of any liquidation, dissolution or winding up of the Successor, each Successor 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 Successor Series A Preferred stockholders on an as-converted basis *pari passu* with Successor common stockholders.

The Successor 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 Successor Series A Preferred Stock anytime at 120% of the face value. The Successor 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 Successor'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 2,465 shares of common stock at an exercise price of $2.00 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 24,671 shares of common stock at an exercise price of $402.50 per share that were issued to participants in the original PIPE financing had the exercise price reset to its floor price of $70.00 per share, while becoming exercisable for 141,861 shares of common stock (which resulted in the recognition of a $1.4 million deemed dividend); (b) the remaining 235 shares of Series A Preferred Stock had their $350.00 original conversion price reset to the floor conversion price of $70.00 per share of common stock (which resulted in the recognition of a $37,000 deemed dividend); and (c) the $350.00 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 $245.00 per share of common stock (which resulted in the recognition of a $0.1 million deemed dividend).

Following the triggering of the down round provision, the holders of 35 shares of Series A Preferred Stock converted into 500 shares of common stock at the new conversion price of $70.00 per share.

Successor Preferred Series B Issuance

In connection with the Business Combination, the Successor 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 Successor Series B Preferred Stock is convertible, at the option of the holder, at any time into a number of shares of Successor common stock equal to the face value divided by the conversion price then in effect (initially $350.00). In addition, for five years following the issuance of the Successor Series B Preferred Stock, the conversion price is automatically adjusted to the greater of (a) $245.00; 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 Successor Series B Preferred Stock (each a "Commencement Date") to the greater of (a) $245.00; and (b) the lowest of the five consecutive daily volume-weighted average prices commencing on, and including, the Commencement Date.

The Successor Series B Preferred stockholders have no voting rights and dividends will only be paid on an as-converted basis when, and if paid to Successor common stockholders. In the event of any liquidation, dissolution or winding up of the Successor each Successor 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 Successor Series B Preferred stockholders on an as-converted basis *pari passu* with Successor common stockholders.

The Successor Series B Preferred Stock is not redeemable and, therefore, it is classified as permanent equity. The Successor 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 Successor will need to assess the accounting for the price reset. Due to the Successor'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.

Stock-Based Compensation

For the year ended December 31, 2023, the Successor 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. As of December 31, 2023, there was $1,027,460 of unrecognized stock-based compensation expense, which the Company expects to recognize over a weighted average period of 1.7 years.

For the period December 13, 2022 through December 31, 2022, the Successor recorded stock-based compensation expense of $56,333 (of which, $7,808 was included in research and development and $48,525 was included in general and administrative expense) related to options issued to employees and consultants. For the period ended December 12, 2022, the Predecessor recorded stock-based compensation expense of $3,524,801 (of which, $673,160 was included in research and development and $2,851,641 was included in general and administrative expense) related to options issued to employees and consultants. As of December 31, 2022, there was $2,957,047 of unrecognized stock-based compensation expense, which the Company expects to recognize over a weighted average period of 1.6 years.

Stock Options

On January 27, 2023, the Company granted ten-year stock options to purchase 2,858 shares of Successor common stock, with an aggregate grant date value of $184,426 to its newly appointed Chief Medical Officer and Senior Vice President of Medical Affairs as inducement for entering into employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4) under the 2022 Omnibus Equity Incentive Plan (the "2022 Plan"). The stock options vest annually over three years and have an exercise price of $73.85 per share.

On March 10, 2023, the Company granted ten-year stock options to purchase 372 shares of Successor common stock to employees of the Company under the 2022 Plan. The stock options have an aggregate grant date value of $23,770, vest annually over three years and have an exercise price of $79.10 per share. Of the 372 shares, 143 shares were issued to the son of an executive officer of the Company.

On May 24, 2023, the Company granted ten-year stock options to purchase 41,523 shares of Successor common stock to employees and directors of the Company under the 2022 Plan. The stock options have an aggregate grant date value of $555,004, of which $499,660 vest annually over three years and $55,344 vest immediately and have an exercise price of $15.25 per share.

The grant date fair value of stock options granted during the Successor year ended December 31, 2023 and the period from December 13, 2022 through December 31, 2022 for the Successor and the period from January 1, 2022 through December 12, 2022 for the Predecessor was determined using the Black Scholes method, with the following assumptions used:

	Successor		Predecessor
	For the Year ended December 31, 2023	For the Period December 13 through December 31, 2022	For the Period January 1 through December 12, 2022
Fair value of common stock on date of grant	$15.26 - $78.05	n/a	$2.27 - $3.00
Risk free interest rate	3.53% - 4.27 %	n/a	1.68% - 3.01%
Expected term (years)	5.00 - 6.00	n/a	3.53 - 6.00
Expected volatility	120% - 123%	n/a	111% - 119%
Expected dividends	0.00%	n/a	0.00%

During the period ended December 12, 2022, the fair value of the Predecessor's common stock was determined using a market approach based on the status of the business combination agreement arm's length discussions with the acquirer at each valuation date and which agreement was ultimately entered into on July 20, 2022 with a Company valuation of $85 million. The options granted during the period ended December 12, 2022 had a contractual term between seven and ten years and a requisite vesting period of zero to three years.

A summary of the option activity for the year ended December 31, 2023 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2023	56,999	$ 366.29		
Granted	44,753	19.52		
Exercised	-	-		
Forfeited	-	-		
Outstanding, December 31, 2023	101,752	$ 220.65	6.3	$ -
Exercisable, December 31, 2023	56,284	$ 333.65	5.0	$ -

The following table presents information related to stock options as of December 31, 2023:

Options Outstanding			Options Exercisable	
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$ 15.25	41,523	9	4,286
$ 73.85	2,858	-	-
$ 79.10	372	-	-
$ 176.05	18,952	2.1	18,952
$ 396.55	351	8.5	351
$ 405.30	20,819	5.3	20,819
$ 572.60	16,877	7.4	11,876
	101,752	5.0	56,284

Stock Warrants

On July 26, 2023, in connection with the July 2023 Offering (see Successor Equity Offerings above), the Company amended the exercise price of certain warrants to purchase 39,372 shares of common stock for three investors from $35.00 to $5.78 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 270,565 shares of common stock at an exercise price of $0.0035 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 $4.75 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 $4.75 per share. The new warrants are not exercisable for the first six months. Under the program, warrants to purchase an aggregate of 203,463 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.

A summary of the warrant activity for the year ended December 31, 2023 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, Janaury 1, 2023	246,594	$ 376.11		
Issued [4]	8,881,859	2.71		
Exercised [5]	(203,463)	4.75		
Forfeited	(9,447)	32.47		
Repriced - Old [1]	(24,672)	402.50		
Repriced - New [1]	141,868	70.00		
Repriced - Old [2]	(39,372)	35.00		
Repriced - New [2]	39,372	5.78		
Repriced - Old [3]	(203,463)	5.78		
Repriced - New [3]	203,463	4.75		
Outstanding, December 31, 2023	9,032,739	$ 12.34	3.2	$ -
Exercisable, December 31, 2023	8,827,273	$ 12.48	3.3	$ -

[1] Warrants represent the reset of the exercise price of the PIPE Warrants to purchase 24,672 shares of common stock to their floor price of $70.00 per share.

[2] Warrants represent the reset of the exercise price of certain April 28, 2023 offering warrants to purchase 39,372 shares of common stock to a price of $5.78 per share.

[3] Warrants represent the reset of the exercise price of certain July 26, 2023 offering warrants to purchase 203,463 shares of common stock to a price of $4.75 per share.

[4] Warrants issued exclude 270,565 July Pre-Funded Warrants with an exercise price of $0.0035 and 3,600,000 December 2023 Pre-Funded Warrants with an exercise price of $0.0001.

[5] Warrants exercised exclude 270,565 July 2023 Pre-Funded Warrants exercised with an exercise price of $0.0035 and 2,285,000 December 2023 Pre-Funded Warrants exercised with an exercise price of $0.0001.

The following table presents information related to stock warrants as of December 31, 2023:

Warrants Outstanding [1]		Warrants Exercisable [1]	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$ 1.25	8,000,000	3.2	8,000,000
$ 4.75	203,464	n/a	-
$ 5.78	199,555	4.5	199,555
$ 35.00	275,378	4.3	275,378
$ 70.00	139,403	4.0	139,403
$ 176.05	2,994	1.1	998
$ 241.50	36,363	3.9	36,363
$ 402.50	173,306	4.0	173,306
$ 405.30	2,270	0.3	2,270
	9,032,733	3.3	8,827,273

[1] Warrants outstanding and exercisable exclude 1,315,000 Pre-Funded Warrants with an exercise price of $0.0001.

Effectiveness Failure

In connection with the Business Combination, the Company conducted the Successor 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 Successor 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 Successor Series A Preferred Stock (see Successor Series A Preferred Stock Financing above). As of December 31, 2023, the Company has accrued additional Registration Delay Payments of approximately $7,261 in the aggregate.

Note 10 – Subsequent Events

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

License Agreements

On January 30, 2024, the Company paid $500,000 of cash to L&F, thus meeting the conditions of Waiver B (see Note 8 – Commitments and Contingencies – License Agreements).

Common Stock

On January 2, 2024, the Company entered into a marketing agreement with a vendor in which the Company issued an aggregate of 90,000 shares of common stock in exchange for marketing services. The $79,200 fair value of the common stock was established as a prepaid expense and the Company will recognize the expense over the term of the contract.

Stock Warrants

Subsequent to December 31, 2023, investors of the December 2023 Offering exercised warrants to purchase 2,138,000 shares of common stock at an exercise price of $1.25 per share for total proceeds of $2,672,500.

Between January 17 and February 23, 2024, a December 2023 Offering investor exercised 1,315,000 pre-funded warrants on a cashless basis to purchase 1,314,806 shares of common stock at an exercise price of $0.0001 per share.

Successor 2022 Omnibus Equity Incentive Plan

On January 1, 2024, the total number of shares under the Successor 2022 Omnibus Equity Incentive Plan automatically increased to 317,891.

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

FORM 10-K/A
Amendment No. 1

(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, 2023
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, 2023, 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 $8.61 for such shares on the Nasdaq Global Market on June 30, 2023) was approximately $5.6 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 in Part III, Item 12 of our Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on March 25, 2024.

As of May 10, 2024, the number of shares outstanding of the registrant's common stock, $0.0001 par value per share, was 834,896.

Auditor Name	Auditor Location	Auditor Firm ID
Marcum LLP	New York, NY	688

DOCUMENTS INCORPORATED BY REFERENCE

None.

Explanatory Note

ZyVersa Therapeutics, Inc. (the "Company," "ZyVersa," "we," "us" and "our") is filing this Amendment No. 1 on Form 10-K/A (this "Form 10-K/A") to amend the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "2023 10-K"), which was originally filed with the Securities and Exchange Commission (the "SEC") on March 25, 2024. This Form 10-K/A amends and restates in its entirety Item 9A of Part II and Item 15 of Part IV of the 2023 10-K in order to clarify its existing language. The cover page of the 2023 10-K is also amended to update the number of outstanding shares of common stock as of May 10, 2024. Also, Exhibit 97.1 was appended to this Form 10-K/A.

Pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), this Form 10-K/A amends Item 15 of Part IV of the 2023 10-K solely to update the exhibit list to include new certifications by our principal executive officer and principal financial officer under Section 302 of the Sarbanes-Oxley Act of 2002. Because no financial statements have been included in this Form 10-K/A, paragraph 3 of these certifications has been omitted. Similarly, because no financial statements have been included in this Form 10-K/A, certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 have been omitted.

Except as described above, no other changes have been made to the 2023 10-K, and this Form 10-K/A does not modify, amend or update in any way any of the financial or other information contained in the 2023 10-K. This Form 10-K/A does not reflect events occurring after the date of the filing of the 2023 10-K, nor does it amend, modify or otherwise update any other information in the 2023 10-K. Accordingly, this Form 10-K/A should be read in conjunction with the 2023 10-K and with the Company's filings with the SEC subsequent to the filing of the 2023 10-K.

Emerging Growth Company—Scaled Disclosure

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), enacted in April 2012. We intend to take advantage of certain exemptions under the JOBS Act from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. We will remain an emerging growth company until the earliest of the last day of the fiscal year in which we have total annual gross revenues of approximately $1.07 billion or more; the last day of the fiscal year following the fifth anniversary of the date of the completion of the closing of our IPO, which is December 23, 2026; the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

ZYVERSA THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K/A
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2023
TABLE OF CONTENTS

PART II

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, 2023. Based upon their evaluation and due to the material weakness cited below, 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, is 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, 2023, 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, our principal executive officer and principal financial officer have concluded that our internal control over financial reporting was not effective as of December 31, 2023, as a result of the material weakness described below.

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

Remediation Plan

Our management is committed to taking further action and implementing necessary enhancements or improvements, including those actions already taken to address the material weakness related to design and implementation of effective controls over the accounting for significant and complex non-routine transactions cited in the Company's December 31, 2022 Form 10-K, and the material weakness identified as of December 31, 2023. Management expects to complete the development and implementation of its remediation plan, during 2024.

Inherent Limitations of the Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

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

Attestation Report of Registered Public Accounting Firm

This Form 10-K/A does not contain an attestation report of our independent registered public accounting firm related to internal control over financial reporting because the rules for emerging growth companies provide an exemption from the attestation requirement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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	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).
3.3	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).
3.4	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).
3.5	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 8K filed with the SEC on November 30, 2023).
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**	Description of the Company's Securities.
4.9	Form of Warrant (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement filed with the SEC on April 24, 2023).
4.10	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).
4.11	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).
4.12	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).
4.13	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).
4.14	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).
4.15	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).
4.16	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).

4.17	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).
10.1	Amended and Restated Registration Rights Agreement, dated as of December 12, 2022, by and among the Company and each of the purchasers identified on the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.2	Form of Shareholder Support Agreement, dated as of July 20, 2022, by and among Larkspur Health Acquisition Corp., ZyVersa Therapeutics, Inc. and certain of the stockholders of ZyVersa Therapeutics, Inc., identified on the signature pages thereto (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed with the SEC on July 22, 2022).
10.3	Form of Lock-Up Agreement, dated as of July 20, 2022, by and among the Company and the parties listed on Schedule A thereto (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on July 22, 2022).
10.4	Registration Rights Agreement, relating to Series A Preferred Stock, dated as of December 12, 2022, by and among the Larkspur Health Acquisition Corp. and each of the PIPE Investors (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.5	Registration Rights Agreement, relating to Series B Preferred Stock, dated as of December 12, 2022, by and among the Company and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
10.6	Business Combination Advisor Agreement, dated December 20, 2021, by and between the Company and A.G.P (incorporated by reference to Exhibit 1.2 to the Company's Current Report on Form 8-K filed with the SEC on December 23, 2021).
10.7+†	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).
10.8+†	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).
10.8.1	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).
10.8.2	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).
10.9+†	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).
10.10#	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).
10.11#	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).
10.12#	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).
10.13#	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).
10.14#	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).
10.15#	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).
10.16#	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).
10.17#	Executive Employment Agreement, by and between the Company and Nicholas A. LaBella (incorporated by reference to Exhibit 10.17 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).

10.18#	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).
10.19#	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).
10.21#	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).
10.22#	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).
10.23	Form of Placement Agency Agreement (incorporated by reference to Exhibit 1.1 to Company's Registration Statement on Form S-1 filed with the SEC on April 24, 2023).
10.24	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.22 to Company's Registration Statement on Form S-1 filed with the SEC on April 24, 2023).
10.25	Form of Escrow Agreement (incorporated by reference to Exhibit 10.23 to Company's Registration Statement on Form S-1 filed with the SEC on April 24, 2023).
10.26	Placement Agency Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 26, 2023).
10.27	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.24 to the Company's Registration Statement on Form S-1/A filed with the SEC on July 7, 2023).
10.28	Form of Inducement Letter (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on September 14, 2023).
10.29	Form of Securities Purchase Agreement, dated as of December 6, 2023, between the Company and each purchaser named in the signature pages thereto (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on December 11, 2023).
10.30	Placement Agency Agreement, dated as of December 6, 2023, between the Company and A.G.P (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on December 11, 2023).
16.1	Letter dated December 22, 2023 from Ernst & Young LLP to the U.S. Securities and Exchange Commission (incorporated by reference to Exhibit 16.1 to the Company's Form 8-K filed with the SEC on December 22, 2023).
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
23.2**	Consent of Ernst & Young 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).
31.3*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a).
31.4*	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.
99.1	Securities Purchase Agreement, dated as of July 20, 2022, by and among Larkspur Health Acquisition Corp. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
99.2	Securities Purchase Agreement, dated as of December 12, 2022, by and among Larkspur Health Acquisition Corp. and each purchaser identified on the signature pages thereto (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K filed with the SEC on December 13, 2022).
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.

** Incorporated by reference to the Company's December 31, 2023 Form 10-K that was filed with the SEC on March 25, 2024.

SIGNATURES

Pursuant to the requirements of Section 13 and 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Amendment No. 1 to the report to be signed on its behalf by the undersigned thereunto duly authorized.

ZYVERSA THERAPEUTICS, INC.

Date: May 15, 2024

/s/ Stephen C. Glover

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

Date: May 15, 2024

/s/ Peter Wolfe

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