

ZyVersa Therapeutics Inc.: Developing Innovative Drug Therapies for Patients with Inflammatory and Renal Diseases



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CEOCFO: *Mr. Glover, the first thing I see on the ZyVersa Therapeutics, Inc site is, “Restoring Health, Transforming Lives through Innovation.” What does that mean for ZyVersa?*

Mr. Glover: At ZyVersa, we are focused on developing innovative drug therapies for patients with significant unmet medical needs, who are desperate for effective, well tolerated, and safe treatment options. We are currently focused in two key therapeutic areas, chronic kidney diseases and chronic inflammatory diseases. Our kidney disease initiatives will give you context around our goal to restore health and transform lives. Fourteen percent of the U.S. population suffers from chronic kidney disease, yet there are no approved drugs that specifically address this progressive disease that leads to kidney failure and the need for dialysis and ultimately transplant. This not only results in poor quality of life, but has significant economic consequences, with around 18% of the Medicare/Medicaid budget used to treat chronic kidney disease. Our lead renal drug candidate has potential to protect against kidney damage and maintain kidney function.

Our anti-inflammatory development program is also focusing on patient populations with limited effective treatment options, such as primary progressive MS and NASH.

CEOCFO: *Are these two areas because you came upon technology or because you identified the need?*

Mr. Glover: I have been in the industry for over thirty plus years. My early career focused on renal diseases when I was at Amgen and inflammatory diseases when I was at Roche. It has been a passion of mine to develop and commercialize effective treatments in these areas. As my career progressed to starting new companies, this is my third, I have always kept an eye toward the progress, or quite frankly, the lack of progress in these disease areas, and this continues to be my focus.

As part of my work here in South Florida, I have been working with the University of Miami and their Innovation Group. Both of our current product platforms came out of the University of Miami since they are focused in the areas where my passions align and where there are substantial unmet medical needs.

CEOCFO: *What are you working on now?*

Mr. Glover: As a company we are working on two platform technologies. As mentioned earlier, those technologies are in the areas of kidney and inflammatory diseases. Our lead renal candidate is a compound that we refer to as VAR 200, in development for three potential indications. Two of the indications, focal segmental glomerulosclerosis, which we refer to as FSGS, and Alport syndrome, are progressive orphan renal diseases. The third indication is diabetic kidney disease, which affects about fifteen million people in the United States alone.

Our anti-inflammatory program takes a really unique approach to addressing chronic inflammatory diseases by targeting the innate immune response. We have a novel compound that we refer to as IC 100, which is an inflammasome inhibitor. IC 100 has potential to block initiation of the inflammatory cascade and to stop perpetuation of the intense, damaging inflammation associated with chronic inflammatory diseases. Approximately fifty diseases have been associated with chronic inflammation. We are initially targeting primary progressive multiple sclerosis, lupus nephritis, NASH and diabetic kidney disease. However, IC 100 has potential to treat many other inflammatory conditions, such as Alzheimer's disease, atherosclerosis, and spinal cord injuries.

CEOCFO: *What is it? How does it work? Why does it work? Would you give us a little more of the science?*

Mr. Glover: Absolutely. If you look at our lead candidate that is going into Phase II-A clinical trials, VAR 200 for treatment of FSGS, it has a very unique and differentiated mechanism of action. It literally targets the underlying pathophysiology of the disease, accumulation of excess lipids in the kidneys' filtration system resulting from impaired transport out of the cell. The excess lipids damage the structure of the filtration system, resulting in protein leakage into the urine rather than reabsorption back into the bloodstream. VAR 200 works by directly removing excess intracellular lipids from the kidneys and by mediating up-regulation of lipid transporters to remove the excess lipids. VAR 200 is expected to be a disease-modifying treatment.

There are no other compounds on the market or in development that address the impaired lipid transport out of kidney cells. Although kidney damage from excess intracellular lipids has been identified as a problem for decades, until development of VAR 200, nobody has found a way to address the issue.

Moving on to our inflammatory program, targeting inflammasomes is actually one of the hottest areas in the industry right now, and our approach is radically different than that of others developing products in this space.

Our product, IC 100, really has a differentiated mechanism of action. It is expected to block initiation of the inflammatory cascade and attenuate perpetuation of the intense, damaging inflammation that is pathogenic in inflammatory diseases. It does this by targeting a component of the

inflammasome called ASC. What is unique about this is that ASC is a component of multiple types of inflammasomes. As numerous inflammatory diseases are associated with activation of more than one type of inflammasome, IC 100 has potential to target a broad range of inflammatory diseases. Other inflammasome inhibitors in development are targeting the sensor molecule component. Given that each type of inflammasome has one unique sensor molecule, it is likely that their therapeutic efficacy will be limited to inflammatory diseases associated with activation of only one type of inflammasome.

The technology behind IC 100 was developed at the University of Miami by leading experts and pioneers in the field of inflammasomes. We have been working with this group for the last five years, and through an exclusive worldwide license of the technology, we are progressing development into the clinic over the next 18 months. IC 100 has preclinical data in MS, spinal cord injury, acute lung injury, and traumatic brain injury. As I mentioned earlier, it has potential for many other inflammatory diseases, such as Alzheimer's disease, atherosclerosis and NASH. These are major diseases with limited or no efficacious treatment options.

CEOCFO: *What have you learned so far that may have surprised you?*

Mr. Glover: This is always hard! I joke about that. I think what is interesting is that as we progress development of our pipeline candidates, we are beginning to understand the breadth of potential that our products actually have. It is like every development initiative that you undertake. You begin work focused on one or two indications, but as you gain a greater understanding of how these products actually work, you see more and more potential for label extensions in different therapeutic areas.

CEOCFO: *Why the change of name from Variant?*

Mr. Glover: When we initially started this company back in 2015, as with most start-up biotechs, we had one lead compound in the renal therapeutic area. As we advanced that program and built out the company over the first couple of years, we started to build relationships beyond the U.S., in Europe and in Asia. Then we brought on some very experienced and versatile team members. When we added the inflammasome program, we began asking ourselves if the branding of company still matches our vision and mission. The name, ZyVersa, really came about as a result of that. It is a play on the word, versatility. We have a highly experienced and versatile team, and with addition of our inflammasome inhibitor platform, we have a more versatile pipeline. We decided the time was right to rebrand ourselves as we prepare to go into the public marketplace.

CEOCFO: *Are you seeking funding, partnerships or investment? Where do you stand right now?*

Mr. Glover: Yes. As with all biotech companies, we are always looking to raise capital, obviously to move our programs forward. In general, as a company, we are at what I call the transition phase - we are getting ready to go into the clinic with our lead renal compound. We are involved with some major banks in the United States, looking at the ideal process, targeted for the middle of 2020. We are also heavily involved in discussions with major pharmaceutical companies, and we are looking at the public markets as an option as well.

CEOCFO: *Does the investment community understand what you are doing?*

Mr. Glover: I think there are select groups within the investment community that understand what we are doing, particularly in the inflammasome area, which is an evolving science. I think it will be interesting to see if our transitional phase will last two years. There have actually been acquisitions of some early stage inflammasome companies by major pharmaceutical companies such as BMS (Bristol-Myers Squibb Company), Genentech, Inc., and Novartis International AG, that has brought the spotlight from other investor communities onto the area. There is a higher understanding today than there was two years ago, which is a positive for the industry. I think there are several other companies within the industry that continue to try to come up to speed as well. This is one of the challenges facing an innovative company like ourselves.

CEOCFO: *What about the scientific community? What has been the response to your novel approaches?*

Mr. Glover: One of my favorite stories, actually, is when the investigators and researchers at the University of Miami started their work in the inflammasome space almost fifteen years ago, there were only three publications on the topic.

Today, there are well over fifteen hundred publications from research conducted by the academic community, the NIH, or the pharmaceutical industry. There is an evolving understanding of inflammasomes, but there is still a lot of academic work and insights, that need to be generated.

CEOCFO: *What, if anything, might people miss, either from the medical side or the investment side, when they first take a look at ZyVersa?*

Mr. Glover: We are at the beginning of an evolution in the inflammasome space. There are several pioneer companies developing inflammasome inhibitors or agonists. The investor groups have to understand the science, which takes time since it is so new. What much of the investment community continues to miss early on is the significance of the research. I think they miss the breadth of the potential opportunity, with fifty to one hundred diseases that could benefit from inflammasome-targeted therapies. I think it literally takes a group that has several different disciplines to understand this.

CEOCFO: *Why take an interest at ZyVersa right now?*

Mr. Glover: I think what we are doing is important. Every one of us has a family member or friend that has been affected by chronic renal or inflammatory diseases.

When you look at ZyVersa you have to look at us as a group of experienced people with demonstrated success in the industry, who are focused on developing innovative drug therapies for patients who are desperate for effective, well tolerated, and safe treatment options. A key focus is assuring that our development efforts serve the needs of all our stakeholders: patients, health care providers, payors, and our investors.

Our mission is to restore health and transform lives through innovation. If we accomplish this, we will provide significant value to all our stakeholders.