

With Capillary Leak Syndrome that is Caused by Major Trauma, Massive Infection or Chemotherapy Agents Being a Major Concern with No Current Safe Therapy Available, ADS Biotechnology, Ltd. is Focused on Changing the Way Critical Care Medicine is Done with their ADS4203 that Effectively Treats Hypovolemia

**Healthcare
Biotechnology
(Privately Held)**

ADS Biotechnology, Ltd.

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**Todd Davies
Chief Executive Officer**

BIO:

Dr. Todd Davies is the CEO of ADS Biotechnology and has over 15 years of experience in bioscience. He received his Ph.D. in Medical Science from the University of Toledo Medical Center. Dr. Davies also served as the Commissioner of Economic Development for the City of Toledo and led the Bioscience activity of Rocket Ventures Pre-Seed Fund where he assisted in the creation and develop-

ment of 22 medical technology start-up companies before joining ADS Biotechnology.

Company Profile:

ADS Biotechnology, Ltd. is an early-stage biomedical company founded in January 2008 to pursue the commercial development of ADS4203. The three founders, Ragheb Assaly, PhD, David Dignam, PhD, and Joseph Shapiro, MD, invented ADS4203 in response to the tragic death of a patient of Drs. Assaly and Shapiro, whose uncontrollable hypovolemia led to fatal multiorgan dysfunction. The founders thus perfected an original technology to develop ADS4203 initially as a treatment for hypovolemia, but quickly realized the broader application for any condition that triggers capillary leak syndrome (CLS).

ADS Biotechnology's purpose is to save lives and reduce treatment costs that otherwise result from hypovolemia and hypovolemic conditions. Its business is to improve outcomes in hypovolemic patients by commercializing effective blood colloid technologies.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Dr. Davies, would you tell us about the events that lead you to starting at ADS Biotechnology and what is your role as CEO?

Dr. Davies: I was working at a pre-seed company (Rocket Ventures in Northwest Ohio). ADS Biotechnology was a client of ours and it got to the

point where the company needed investment and we were looking for leadership. I had a good relationship with the founders, and we had a lot of confidence in each other. The founders of this company are some scientists with very high levels of integrity and this is a product that I really believe in. It is pegylated albumin and we are developing it so that we can solve a problem with capillary leak syndrome in critical care patients. This is the kind of technology that will change the way medicine is done, and it is really quite humbling to be part of that kind of product.

CEOCFO: What is the vision for ADS Biotechnology today as it relates to ADS4203, the treatment for hypovolemia and the broader application for any condition that triggers capillary leak syndrome (CLS)?

Dr. Davies: There are a number of conditions that cause capillary leak syndrome, such as any major stress to the body, whether it be a major trauma, or a massive infection like a sepsis. Even a lot of chemotherapy agents actually cause capillary leak syndrome. That is a condition where pores open up in the capillary beds and fluid from the vasculature will leak out. In many cases, so much will leak out that the patient will develop what is called hypovolemia, which is low blood pressure. It just means there is not enough fluid in your vasculature. These patients have to be given some sort of volume expansion and right now the only volume expansion they can give are deleterious under the best circumstances. Whether it be saline or albumin, you can get various kinds of what are

called crystalloids or basically molecules that cause expansion in the fluid. There are starch molecules, but those can be very dangerous in these situations even though they expand the volume. Every one of the current solutions causes more leakage. There is an increase in edema, which is fluid building up in the surrounding tissues and organs. In a remarkably high percentage of patients, actually the fluid itself that you get with these volume expanders causes multi-organ failure and death. What our ADS4203 does is we are able to get the volume expansion without the fluid, so it allows chemotherapies to be more effective, it allows surgeries to be more effective, and antibiotics in the case of sepsis. All of them become more effective because we control the hypovolemic issue. So by doing that we really are going to change the way critical care medicine is done. Once we control the capillary leak syndrome, not only are these patients not dying, they are no longer dying slowly at an enormous cost of the overall healthcare system. Therefore, even at a higher price for our product, we end up saving the healthcare system an enormous amount of money.

CEOCFO: Would you tell us about your ADS4203 technology and how it works or affects hypovolemia and CLS?

Dr. Davies: It is actually very simple. The component parts of the product are ones that have been proven to be very safe. We take a molecule that is designed to coordinate well with the systems that are already in the vasculature, but it is made in such a way that it does not leak through these capillary pores. Therefore, it is maintained for a long period of time within the vasculature. By doing that, it will actually draw fluid from the surrounding tissues and organs back into the blood. Not only do we prevent this edema and this fluid accumulation, but we reverse it. Hence, we pull the cytokines that cause inflammation in these areas, back into the vasculature.

CEOCFO: Have you started clinical trials for ADS4203?

Dr. Davies: We have yet to start clinical trials.

CEOCFO: Have you looked at potential side effects?

Dr. Davies: We have. The toxic effects that we do see are all based on efficacy. It is such an effective volume expander. In the study that we have done we have seen no toxicity at all, other than what you would expect from volume expansion. It is actually quite remarkable. We have seen no affect on the kidneys, none of the platelet or coagulation effects that you would see with a starch molecule, and the major drawbacks to the other

Clearly, the market is large enough where whatever the investment size you are going to get a large, a respectable return on investment. In order to get us to clinical proof of concept from our current stage, we are looking for a little over \$16 million, which is a pretty low threshold. That will get us all the way through our Phase II trial, because we are going to be utilizing an orphan indication for our first market entry. Therefore, we have a product that is acute in its treatment and it has a great profile in terms of risk both in the clinic and in other areas. So it is a relatively modest amount to get to a point where a return could be acquired at a pretty descent percentage.

- Todd Davies

volume expanders in terms of saline and other collagen crystalloids, in the edema we have actually designed a molecule to reverse that. We expect it to prove to be incredibly safe.

CEOCFO: Would you tell us about any alliances or collaborations you may have or will need to bring ADS4203 forward?

Dr. Davies: We are actually in negotiations with a number of potential partners right now. The only true collaboration we have had going forward is with The University of Toledo where the technology was originally developed. They have been remarkably forward thinking in terms of how they interact with a spin-off company like ours where, we have taken and licensed their technology developed at The University of Toledo. They are

very entrepreneurial on their thinking and have made it very easy on us.

CEOCFO: What is the potential market for your ADS4203?

Dr. Davies: If you take an aggregation of all the patients with conditions where capillary leak is a prominent issue, it is about 2.6 million patients in the US annually. These are conditions where they do not change based on nationality, so in Europe or in Japan, you are going to get about the same number. In China, you are going to get that number increased relative to the patient population and then you are looking at a product price for this around \$8,000 for a three-day treatment. So you can do the math from there.

CEOCFO: What is the goal for ADS Biotechnology; will you remain as a development company or try to someday bring drugs to the market?

Dr. Davies: Our first and highest priority is to get ADS4203 to the market, because we really believe we are going to save a lot of lives with this product. That is our primary goal. How we accomplish that is that we are prepared to grow and build as a singular company. However, if it makes sense to partner and grow this through an M&A activity, that is acceptable too.

CEOCFO: Do you utilize your website to reach potential investors or provide information on the technology?

Dr. Davies: Right now, our website is just more informational about the technology giving a good basis. We do not use it as effectively as I would like to, but that will change in the coming months. Certainly, it is nice as a tool to use for updating folks and keeping people abreast of the coming technology.

CEOCFO: Are you focused on reaching out to the investment community, going out on road shows and making presentations?

Dr. Davies: Absolutely! Sure that is part of the start-up game.

CEOCFO: In closing, why should investors and venture capitalists consider ADS Biotechnology?

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