CEO CFO

Juventas THERAPEUTICS

Issue:
December 17, 2012

CEOCFO Magazine - The Most Powerful Name In Corporate News and Information

With their JVS-100 Product now in Phase II Clinical Trials for Late-Stage Heart Failure and Critical Limb Ischemia, Juventas has shown that they can Protect and Repair Tissue by Activating Natural Stem Cell Based Repair Pathways using Non Cell-Based Regenerative Therapies

Biotechnology
Regenerative Therapies

Juventas Therapeutics
3615 Superior Avenue East #4403C
Cleveland, OH 44114
216-273-4000
www.juventasinc.com

Rahul Aras
CEO

BIO:
Rahul Aras, Ph.D. (President and Chief Executive Officer) is the founding CEO for Juventas. He is also a co-founder of SironRX Therapeutics, a company focused on novel regenerative therapies in the dermal and cosmetic fields. For these companies he has raised more than $35 million in venture capital and grant funding to transition both companies from concept into mid-stage clinical trials. Prior to Juventas, Rahul was the Director of Life Science Commercialization at Cleveland Clinic Innovations (CCI) where he is managed commercialization of all biotechnology and pharmaceutical related technologies. He has extensive experience negotiating licensing deals and strategic partnerships ranging from top 10 pharmaceutical companies to newly formed start-ups. He received a B.S. from Tufts University and a Ph.D. in biomedical research from New York University. He has held research positions at Vanderbilt University Medical Center and Massachusetts General Hospital and has published articles in several leading scientific journals.

About Juventas Therapeutics:
Juventas Therapeutics is a privately-held clinical-stage biotechnology company developing a pipeline of factor-based regenerative therapies to treat life-threatening diseases. The company's lead product, JVS-100 encodes Stromal cell-Derived Factor-1 (SDF-1) which has been shown to protect and repair tissue following ischemic injury by recruiting the body's own stem cells to the damaged tissue, preventing cell death and promoting new blood vessel growth. Through activating natural stem cell based repair pathways within the patient, we overcome the cost and complexity associated with current cellular therapies. Juventas is currently enrolling multiple Phase II clinical trials to test therapy efficacy in heart failure and critical limb ischemia patients.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Mr. Aras, what is the focus at Juventas?
Dr. Aras: Juventas is developing non cell-based regenerative therapies for cardiovascular disease. Our lead product is JVS-100, is currently in Phase II clinical trials for late-stage heart failure and critical limb ischemia.

CEOCFO: What is the science you are developing? How is your concept different?
Dr. Aras: If you look historically of how people have developed therapies, it has been an effort to alleviate symptoms or lesson the workload of failing organs. There is a whole field of regenerative medicine that is now looking at how the body's own stem cells can help repair organs and improve function. This provides the potential to halt or reverse disease progression by getting down to a root cause of what is causing the disease. The challenge of regenerative medicine for the most part has been that we need to use a patient's cells as therapeutic. That could either be the patient's own cells or those from a donor. In either case there are several challenges associated with the logistics in delivering cellular therapy and the expense of scaling this to a level that is actually going to be accessible. That said, scientifically and clinically the regenerative medicine field looks like it is moving forward and providing benefits. That is where we step in. About ten or twelve years ago, our scientific founder and Chief Medical Officer, Marc Penn, MD, PhD,, discovered that a factor called Stromal cell-Derived Factor-1 (SDF-1) plays

an important role in signaling stem cells to the heart following a heart attack. That is somewhat like a beacon or a lighthouse providing a guide as to where stem cells can go to help repair the disease. The challenge being that in a natural setting, the SDF-1 signal is to short lived to promote significant repair. At Juventas, we are delivering SDF-1 at a time remote from injury, basically tricking the body into thinking it was just injured. By doing so we activate the body's natural stem cell based repair pathways and are able to get benefits associated with regenerative medicine without having to extract and redeliver the cells. We believe our factor-based strategy is more cost effective and easily accessible therapeutic alternative to cell therapy.

CEOCFO: What do you have to do to 'trick' the cells?

Dr. Aras: SDF-1 attracts cells and when we deliver it to the heart; its presence literally serves as a beacon. We all have circulating stem cells; the problem is they just do not know where to go. When the SDF-1 is present in the heart, it provides them a map as to where there is damage. Our founder puts it nicely in a couple of different ways, if you think of the stem cells as the orchestra and the SDF-1 is the conductor and it is telling them where to go and what to do. The other is we think of SDF-1 as somewhat of a startup pistol and when it fires, it really catalyzes the process of stem cell based repair. Then a number of things go into motion where the cells actually come in and provide benefits. The nice thing is that the mechanisms through which SDF-1 works in the heart are also proving true in other organ systems – for example the peripheral vasculature.

CEOCFO: Why did you make the decision to start with the heart?

Dr. Aras: At the end of the day, heart failure is probably one of the most significant, if not the most significant unmet clinical need in our country. We have reached the limit of what we can do with devices. When SDF-1 and its role in tissue repair was first discovered by our founder it was found in the setting of an acute heart attack and the natural biology in the heart became well defined through his work and several other researchers in the field. Being able to halt or reverse heart disease is a meaningful opportunity for which we can design reasonable clinical trials and pursue meaningful regulatory approvals and reimbursement. There are a number of different areas, in which the SDF-1 biology seems prominent. The second place we went to was critical vascular disease. Here the outcome is within a year of diagnosis there is, I believe, a 50% chance they are either going to die or have a major amputation. The medicine is delivered to the limbs of these patients for the ability to restore blood flow and hopefully preserve the limbs. Beyond that, there are a number of different areas where the SDF-1 biology is starting to show promise including the brain and dermal wound repair.

"We have a strong therapeutic platform, which is built on a very strong foundation of mechanistically-driven science. The clinical indications, after which we are going, represent large market opportunities for which there is limited competition or existing therapeutic solutions. You add to that the fact that we have a unique therapeutic approach that can be delivered in a very cost effective fashion and I think you have the formula for success." - Rahul Aras, Ph.D.

CEOCFO: Has the medical community been paying attention?

Dr. Aras: It has, and more so, as we progress through mid-stage clinical trials. It is encouraging to watch the regenerative medicine field grow over the last decade. The field started several years ago as an academic exercise of "have-cell will inject". It has now started to mature into an industry. People are trying to understand how to transition regenerative medicine into viable therapies. Along with that have come more substantial clinical trial activity and more meaningful results. The clinical results are what will drive the most interest. If you look at the indications that we are pursuing, they are ones in which physicians and patients are desperately looking for novel therapies to help improve outcomes. When we talk with our investigators they tell us that patients are calling them and asking them what available regenerative medicines they have in clinical trials. I think as the field has matured, there are a number companies with technologies and products that are becoming better defined. Specific to SDF-1, what people really like about the strategy is that there is no need to manipulate a patient's own stem cells. Our drug is produced at a cGMP manufacturing plant; it is highly scalable, has at least a two-year shelf life at least and can sit in the fridge at the pharmacy. This takes a lot of complexity out of the cell therapy model.

CEOCFO: Where are you in the development process?

Dr. Aras: We are in the middle of two Phase-II clinical trials. We should have data from both of them sometime in second-half of 2013. Last year we completed a Phase 1 trial in patients with late-stage heart failure. While the primary endpoint of the trial was safety, which was met, we also were able to see some encouraging signs of efficacy within these patients, which helped us with Phase II. We're also running a Phase II a study in patients with critical limb ischemia. We started in 2007 so we moved from concept to two Phase II trials in a relatively reasonable amount of time and without significant cash expenditure. We recently raised $22 million, which is sufficient to take us through the ongoing trials. At that point, we will have a nice data set that hopefully will allow us to start thinking about how we might take this into late-stage approval trials.

CEOCFO: Do you see the potential changes in healthcare having an effect on interest?

Dr. Aras: Absolutely! Everyone has become painfully aware that we no longer live in a society where it is "build it, and they will come". When we are developing our platform and

selecting indications in which to introduce our therapies, cost implications are major consideration, specifically, how will this be reimbursed, what will it cost and how will that play into the evolving healthcare system. For us it is an advantage. If you look at one of the largest challenges for cell therapy, it is the cost of delivering therapy. By nature, because of the way that you have to harvest and redeliver cells, it is destined to be a relatively expensive therapy. We are cheaper to manufacture, cheaper to deliver. From my experience it is a leading question now with a lot of investors and companies. It is not just about the science, it is about the science and how you can do this in a cost effective way.

CEOCFO: What has surprised you as you have been developing the drug?
Dr. Aras: If you look at it from a company perspective, the whole field of biotechnology has shifted drastically to the right. Investors need more data, companies need more data and we as a start-up biotechnology companies have really started to push the envelope on the size and magnitude in the trials we are doing. In the long-term, that benefits everyone. People are not buying into fifteen-person Phase 1 trials anymore and writing checks for that. What surprised me scientifically is how long it has taken industry to get an appreciation for the way regenerative medicine is going to play a role into our future. Cell therapy has been around for a while. We are now starting to hit a point where large companies know it is important but they are still trying to understand how it plays into their existing systems. I understand why to some level, many of these companies are used to making a drug - we always say is drugs are products and cell therapy is a process. Juventas is actually developing a drug, so it has been nice that potential downstream partners have been able to gain comfort with this approach.

CEOCFO: Why should the business and investment communities pay attention to Juventas Therapeutics?
Dr. Aras: The primary reason is we have a strong therapeutic platform, which is built on a very strong foundation of mechanistically-driven science. The clinical indications, after which we are going, represent large market opportunities for which there is limited competition or existing therapeutic solutions. You add to that the fact that we have a unique therapeutic approach that can be delivered in a very cost effective fashion and I think you have the formula for success. We are in the process of proving this out in a clinical sense. As we start getting our clinical data and assuming it is positive, I think that will help convince a lot of people here that we have the ability to make a very significant impact and clinical indication at a reasonable cost.

Juventas
THERAPEUTICS

Juventas Therapeutics
3615 Superior Avenue East #4403C
Cleveland, OH 44114
216-273-4000
www.juventasinc.com