CEO CFO

SironRX THERAPEUTICS

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SironRX Therapeutic's JVS-100 is currently in Clinical Studies to Demonstrate Safety and to Show it is Capable of Reducing the Rate of Time Wounds Need to Heal and that it Has a Positive Cosmetic Impact on Scar Reduction Using the Body's Natural Tissue Repair Mechanism

Healthcare
Wound Care
(Private)

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Evan Facher, Ph.D.
President and CEO

BIO:
Evan A. Facher, Ph.D. joined SironRX as its President and CEO in May of 2012. He came to SironRX after spending approximately 8 years at MEDRAD. Inc., part of Bayer AG's Medical Device organization. During his time at MEDRAD/Bayer, Dr. Facher was involved with leading business development, corporate strategy, M&A and product development. His most recent appointment there was as General Manager of MEDRAD/Bayer's global cardiovascular fluid delivery business. Before MEDRAD/Bayer, Dr. Facher worked at Athersys, Inc., a Cleveland based biotechnology company, where he was focused on business development, strategy and fundraising. Dr. Facher has earned an MBA from Case Western Reserve's Weatherhead School of Management, a Ph.D. in Human Genetics from the University of Pittsburgh and a B.S. in Biology from the University of Miami.

Company Profile:
SironRX is a venture-backed biotechnology company developing novel regenerative medicine therapies that promote wound repair and prevent scarring of dermal wounds. The company's lead product, JVS100 is a clinically tested product that encodes Stromal cell-Derived Factor-1 (SDF-1). SDF-1 is produced by the body in response to tissue injury and activates natural repair processes to prevent cell death and recruit stem cells to the damaged organ.

SironRX has a double-blind, placebo-controlled, randomized clinical trial underway evaluating the safety and efficacy of JVS-100 treatment in 48 patients receiving surgical sternotomy incisions following open-chest surgery. The goal of the study is to demonstrate product safety and assess the impact of JVS-100 on wound healing rates and scar formation. Previous clinical studies with JVS-100 have demonstrated the drug is well tolerated and safe.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Dr. Facher, would you give a little background on how SironRX Therapeutics came to be?

Dr. Facher: SironRX was actually spun out from technology developed at the Cleveland Clinic and an early-stage company called Juventas Therapeutics. Juventas Therapeutics had rights to a method of use for a specific protein and related drug product that was initially focused on conditions within the heart and realized that this factor had many applications beyond just this organ system. The idea was to create a new entity that would focus purely on the use of the factor and the drug in the application of skin wounds and bone repair, so that is how the company was formed back in December of 2010.

CEOCFO: What is special about the drug that does not exist elsewhere?
Dr. Facher: It is actually a form of non-viral gene therapy encoding a protein called Stromal cell Derived Factor 1 (SDF-1), which has been known in the literature for over a decade to be involved with tissue repair. Specifically, it is the main factor involved with attracting internal stem cells from the bone marrow or from the organs themselves to home to the site of injuries and induce localized tissue repair. SDF-1 has also been found to reduce localized inflammation and reduce cell death. The drug we are using is called JVS-100 and it produces SDF-1 within the cells it is injected into. JVS-100 is actually a form of regenerative medicine as we are regenerating the body's natural tissue by increasing the therapeutic window for the body's own natural response to tissue injury. As such, we are approaching wound repair in a way that other products really do not. We are helping the body to repair it-

self as it naturally would versus adding other products that are more palliative. We are applying SDF-1 in a way that it was meant to be used as far as triggering the body to repair itself thus enhancing the rate of wound healing and reducing scar formation.

CEOCFO: How is this drug able to achieve natural repair?
Dr. Facher: SDF-1, the protein that is expressed by JVS-100, is upregulated naturally in response to tissue injury triggering the native tissue repair process; we are just spiking the levels of this protein, to allow it to be expressed for longer than it would under normal conditions. Typically, this protein is only around for a handful of days, but with our therapy, we are allowing this normally expressed protein to be around for several weeks and therefor are extending the therapeutic window for repair longer than it would be during a regular tissue injury.

CEOCFO: Does it matter what type of wound or does it work across the board?
Dr. Facher: From the work that we have done and the work Juventas has done (Juventas is focused on tissue injury in the heart and critical limb ischemia) both pre-clinically and clinically we have a good amount of data showing that it works well on many types of wounds. From a dermal wound only perspective, in addition to our work, there are other laboratories that have looked at wounds caused in the skin as a result of diabetic ulcers and burns and have demonstrated the presence of SDF-1 and its therapeutic capabilities. I mentioned the cardiac injuries Juventas is focusing on and there is also a great deal of literature out there that shows it is up-regulated in a host of different organ systems as a result of injury to that organ tissue.

CEOCFO: Is there any reason why you would not want to use the therapy?
Dr. Facher: We have done a very large number of animal studies to date and we have not seen any safety issues. Furthermore, the drug – JVS-100 - has been through a Phase 1 human study for heart failure and in those patients we have not seen any safety related issues. The product is currently in Phase 2 studies for critical limb ischemia and to date have likewise seen no safety concerns. So in all the historic information in humans and in a significant number of animal studies, we have not seen any safety related issues.

CEOCFO: Where are you with your first patients and what is the timetable going forward?
Dr. Facher: Our IND was just approved in April of this year. Our Phase 1 study is in the process of getting ready to dose patients. In the very near future, we expect our first patient to be treated with JVS-100, the same drug that Juventas has used in their completed Phase 1 heart failure study and the critical limb ischemia study they are currently in Phase II for. In regards to our approved study, the three sites that we are using have all been activated, they all currently have drug and they are all screening for patients to be entered into the trial.

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CEOCFO: What enhancements typically can be used today as far as bone repair and tissue repair? What is the competing technology?
Dr. Facher: There is an already existing, large wound repair market which addresses acute injuries such as surgical incisions, trauma, cosmetic procedures and chromic wounds such as diabetic foot ulcers and pressure ulcers. On an annual basis, there are tens of millions of dermal wounds found in each of these segments. Between the 20 million plus surgeries in the US annually or the millions of yearly diabetic foot ulcer cases there is an overall market in excess of fifteen billion dollars. Today most of the therapies that are out there to close wounds or help wounds are described largely as goops and gauzes, which are placed on the wound to help clean it out to make sure that the wound remains moist, and provide for a localized environment that allows the body to naturally heal itself - so they are more palliative in nature. Our product is more of an active therapy to treat the wound to improve its rate of healing and help it so it looks better once healed. Our product has been shown, through the animal studies we have conducted, that it can get healing rates which are quicker than would otherwise occur and just as importantly, we can get to significantly reduced formation of scars, a dramatic cosmetic benefit. Our products are focused on improving the rate of healing and just as importantly to reducing any of the tissue challenges that you would get from scar formation as well. We are enhancing the body's natural response to repair and really letting it occur over a longer period of time than it naturally would. This is one of the main reasons why our Phase 1 study is focused on median sternotomies, where folks may get the repair that the cardiothoracic surgeon provides but they are also typically left with large scars. There are risks around infection of a wound of that size, so our focus is to show our therapy can enable the wound to heal more rapidly and just as importantly show the cosmetic benefit by having a reduction in the formation of scar.

CEOCFO: Has the medical community been paying attention or is it too early?
Dr. Facher: They actually have been paying attention and much of it is because the factor we are using - SDF1 - has been studied in the literature for years now. It has been well described across many laboratories throughout the world. It has been the subject of Phase 1 human studies and it is in Phase II for a couple of different indications so folks out there know about it and what it is used for. The attention has also increased as the field of regenerative medicine has become more established over the last few years and we have a regenerative therapy drug that has been studied in animal models as well as humans. A good indication of that from a financing perspective is that we closed a

round of $3.5 million of funding in August of 2011. In the middle of last year, we also received a $1 million grant from the State of Ohio to continue our work. Our sister company Juventas just closed a $22 million round of financing to continue their focus in the cardiovascular side of the world. Between the fundraising side and the different groups we have been talking with from a strategic partnership side outside of the financial markets, we are getting a decent amount of attention from organizations interested to learn more and they certainly are following where our clinical studies are going.

CEOCFO: How far will that funding take SironRX Therapeutics?
Dr. Facher: Currently we have more than enough funding to get through our Phase 1 studies and beyond, so we are in pretty decent shape based on our current trajectory and run rate.

CEOCFO: That is rather unusual for drug development companies today!
Dr. Facher: One of the main advantages we have is the drug we are using has a well understood mechanism of action and has also been examined in human studies. As I mentioned, it is the exact same drug Juventas has completed Phase 1 studies on and is using in its Phase 2 work – the only difference is we are delivering it in a bit of a different manner owing to the indication we are examining. As a result, our development work has a lower risk profile. A typical drug development company would be starting from the beginning and identifying what is the potential factor it could use and then would perform all the research/mechanism of action work, then all the drug development work, and then eventually move to the preclinical and clinical work. We have been able to move through much of that process relatively quickly because we are using a drug that has been used in humans before and has been in front of the FDA. We had a dossier composed of a significant amount of data, performed detailed animal studies on our indication and that allowed us to quickly move into human clinical trials rather than spending a lot of our resources focused on the R&D side. From our founding in December of 2010 to where we are now in 2012, we have gone from an organization with very little funding just being started, to one now where we are in a 48-patient double-blind, randomized, dose escalation clinical study with funding to get us all the way through this effort.

CEOCFO: Why should investors pay attention to SironRX Therapeutics today?
Dr. Facher: People should pay attention because we have a novel therapy that has been shown to do things from a wound healing and scar reduction perspective in a way that other therapies have not. We are in a very large market with a significant unmet need where no product really helps to cure the condition. We believe our therapy can reduce the rate of the time wounds need to heal and will have a significant, positive cosmetic impact on scar reduction by using the body's natural tissue repair mechanism. All this is being done with a drug that has Phase 1 human data and is in Phase II with another indication, so we are moving into a large market with unmet need with a product that has clinical validation from safety and efficacy perspectives. If you put all of these things together, we offer a unique opportunity for folks in the investment community that are trying to get into an early-stage opportunity that has some reduced risk and significant upside. I think that is an attractive target for lots of folks.

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