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Q&A with Shlomo Sadoun, CEO of TrioxBio Inc. developing their MTR-107 now with Fast Track and Orphan Drug FDA Designation for preventing the enhanced manufacturing of Nitric Oxide during Dialysis in the Treatment of Intradialytic Hypotension

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CEOCFO: ***Mr. Sadoun, what is the concept behind TrioxBio?***
Mr. Sadoun: TrioxBio is a company focusing on the inhibition of Nitric Oxide Synthase (NOS). The company mission is to explore different pathologies where overproduction of Nitric Oxide plays a major negative role and inhibit the production with our unique inhibitor, to actually prevent those unwanted events. That is the core values of the company.

CEOCFO: ***What is Nitric Oxide? How is it created?***
Mr. Sadoun: Nitric Oxide is a signal molecule that is being created naturally by the body. In different pathologies, nitric oxide might be produce in an uncontrolled way and cause various morbidities and enhance mortality. For instance in (IDH) intradyalitic patients on hemodialysis patients Nitric Oxide production is out of control and causes vasodilatation. The overproduction of (NO) nitric oxide ignites different systems in the body that can harm or create significant damage over time. TrioxBio mission is to try and control the NO production and balance it.

CEOCFO: ***What has been done in the past about Nitric Oxide? Have there been attempts to control it?***
Mr. Sadoun: The invetors that discovered Nitric Oxide back in the year 2000 was actually awarded the Nobel Prize. Once they discovered this molecule they thought they were going to cure all of the diseases in the world, because it was a signaling molecule that played a role in many diseases. This is information that you can retrieve online. Basically, Nitric Oxide inhibitors were explored in sepsis and migraine. The facts are that nobody to date could deliver a Nitric Oxide inhibitor which was well defined and controlled. We believe that our unique molecule can be adequate for the mission.

CEOCFO: ***What is your inhibitor called?***
Mr. Sadoun: Our drug is called Raviten (MTR-107). It is an injectable solution that will be furnished previous to dialysis. We have several indications. The main leading indication is the treatment and prevention of intradialytic hypotension. Intradialytic hypotension is a severe hypotension that happens during dialysis with very high morbidity and mortality. It is

an unmet medical need without approved treatment as of this date. Our drug, will be furnish just before the dialysis starts and by doing that we are preventing the enhanced manufacturing of Nitric Oxide from being produced. By that we are eliminating an incident that is called intradialytic hypotension that is basically a very severe hypotension that happens during dialysis.

CEOCFO: ***How does it work?***
Mr. Sadoun: The way it works is that our molecule is actually binding to the production site of Nitric Oxide in the body. By doing that it stops Nitric Oxide from being produced. Nitric Oxide knows to cause vasodilatation. Once you have an excessive amount of Nitric Oxide the patient starts to suffer from severe vasodilatation, which causes hypotension. By actually inhibiting Nitric Oxide we prevent the vasodilatation consequentially we are preventing the incidence of IDH.

CEOCFO: ***Why does it work?***
Mr. Sadoun: Raviten is a small molecule. It is a new chemical entity formed as an injectable solution mixed with sterile water and furnish as an IV. As you probably know a dialysis patient already hold an intravenous access, and no additional specific preparation need to take place before the process. We hold a significant human proof of concept with very encouraging results.

CEOCFO: ***Where are you in the development and testing process right now?***
Mr. Sadoun: We are currently in Phase II of the clinical trials. We are going to start the Phase IIb clinical trials in the end of Q4 this year. We have already produced the material and feel very confidence with the results. Right now we are working very closely with the DaVita Healthcare on the phase IIb protocol, which is almost ready. We are planning to initiate the Phase II clinical trials in DaVita Healthcare in two centers. One in Minneapolis and the other one is in Denver. It will include seventy two patients, and we look to finish around the middle of next year: Q2, Q3 of 2019.

"Knowledge is power and gaining the right up to date knowledge and translating it into the right actions can lead to great success… If you try to go down into the numbers you will see that we are talking about ten to twenty thousand people that are dying from IDH a year."- Shlomo Sadoun

CEOCFO: ***What have you learned in Phase I? What have you learned that may have surprised you during the initial trials?***
Mr. Sadoun: In Phase I we saw that the safety profile was really promising, and safety come first. There was a slight alleviation of blood pressure. That was expected because that is what the drug is actually intended to do. Phase I trial results helped us with dose determination. We also saw the expected side effects. However, overall we felt very comfortable with the molecule. It taught us a lot of how exactly we would like to position ourselves towards Phase II.

CEOCFO: ***Did the FDA grant you Fast Track designation recently?***
Mr. Sadoun: It is important to say that in 2016 we were also granted with orphan designation for this specific indication. On top of that, I am also happy to announce that in the end of May 2018 the FDA granted us with Fast Track designation. Therefore, we currently have Fast Frack and Orphan Drug designation for this molecule. Raviten is the only product in the dialysis space as of date that was designated with both designations by the FDA.

CEOCFO: ***Why was intradialytic hypotension the first condition you went after?***
Mr. Sadoun: The company was looking for a condition where over production of Nitric Oxide played a major negative role and it might serve an unmet medical need with no approved treatment. That's how we came across with IDH that unfortunately a very severe and debilitating disease with high morbidity and mortality. We really wanted to make a change. We had various indications like migraines and cluster headaches, which are also known to be caused by the over production of Nitric Oxide. However, we really wanted to make a serious impact on patients' lives. I see it as a personal mission to develop drug for intradialytic hypotension patients that are dying because of lack of available treatment. About 10,000 patients die a year from IDH complications and I feel proud and dedicate in the mission of bringing a solution for this debilitating disease.

CEOCFO: ***Do the results vary depending on the patient, age, sex or physical condition or does it seem to be pretty much across the board that what you are giving them will help?***
Mr. Sadoun: We are working very closely with a strict inclusion criteria and we make sure that the inclusion criteria will be adequate to the patient population. The drug indicated to treat an orphan disease, as a result we selectively choose the right patients that can respond to the trial. We believe that our inclusion criteria focus mainly on the patients that are Nitric

Oxide related. Therefore, they can be older or younger, but the criteria are actually being set by the clinical trial structure. You work closely with the nephrology community and the dialysis clinics in order to make the trials as accurate and effective as possible.

CEOCFO: ***Are you funded for the trial and your next steps? Are you seeking partnerships?***
Mr. Sadoun: No. Right now we are actually seeking to close the round. We are in the middle of a private round of between fifteen to twenty million with closing date of end of Q3 2018. I am currently in New York for a bunch of meetings and we do have a lead investor in place. I am quite positive that we are going to close it quite soon.

CEOCFO: ***What is the interest from the medical community that are aware of what you are working on?***
Mr. Sadoun: I think that they are really exciting and interesting in our product and program. The reasons are that we have Fast Track designation in addition to Orphan Drug designation. That means that Raviten serve an unmet medical need, and is also addressing a serious condition of the disease. The dialysis space in general are suffering from lack of innovation. The ones that really know the space and understand that the US government is actually covering one hundred percent of all the dialysis expenses are very bullish on the company. I can elaborate more on the reimbursement, making long story short, our drug can have a full reimbursement not restricted to the dialysis bundle, which is very unique. I believe that we have a full reimbursement plan in place, we have an indication which is an unmet medical and we got the FDA back up with the Orphan Drug designation and Fast Track. That means that this is really valuable to program for the FDA and have meaningful potential impact for patients.

CEOCFO: ***You personally have led over one hundred drug launches. What do you understand from having done this before? What is important in getting this through the whole process?***
Mr. Sadoun: First of all, I have to say and to be really precise; I led over one hundred generic drugs or hybrid generic drugs, not innovative drugs. This is, I would say, a different journey, but it is a journey that I learn a lot from, amd leveraged many process and knowledge from my past experience towards the innovative space. Some examples can be drug production and CMC. I believe I did it very efficient in a short period of time in the production of Raviten. I learned that the regulatory pathway of innovative drugs is a bit different than generic, although if you have logic and rationale behind what you are doing and you deliver the message in a proper way, the FDA will support you, that was exactly what I saw. I was really happy from the regulatory results and the similarity in the agencies correspondents and registration pathways. Knowledge is power and gaining the right up to date knowledge and translating it into the right actions can lead to great success.

CEOCFO: ***How did you learn about the molecule? What was the basis for the founding of the company?***
Mr. Sadoun: I am the founder of SK-Pharma Group, which is a group of companies dealing mainly with generics. After a wide experience I had in the generic field, I thought that it was the right time to move to the next level, which is innovation. We were exploring over four hundred different projects where I had well defined the criteria of what I am looking for and that is how I got to this asset. The asset was licensed from an Israeli company where TrioxBio is holding an exclusive global license. I took the asset, worked on the regulatory, manufacturing and clinical strategy and pick the indication to start with and took it in relatively short amount of time two years to where it is right now.

CEOCFO: ***There are many new ideas in health and many new drugs. Why pay attention to TrioxBio? What sets the company apart?***
Mr. Sadoun: The company led by young and dynamic team that are really hungry for success, not only materialistic wise but also as a self-fulfillment of bringing value to the world. Gratefully, I already did quite a journey and I have the privilege to actually run this company as part of a mission, not only for financial reasons. More than that, I would say that the indication that we chose is really unique in the sense that we can really save people lives. If you try to go down into the numbers you will see that we are talking about ten to twenty thousand people that are dying from IDH a year. This is quite substantial. TrioxBio is led by a young successful group of people from SK-Pharma. We led many products into the market, we know how to do it, we know how to work lean in order to get results. We are driven by results and we can see the Fast Track and the Orphan Drug and the unique indication that we choose. No one to date got Fast Track or Orphan Drug designation for intradialytic hypotension It is clear that we know how to communicate with the FDA which is a valuable asset moving forward with our mission. Our core benefits don't lay only on the clinical aspect, but also on the economical aspect. We have a full reimbursement strategy in place which is going to be funded by the US government. We know how to position ourselves, outside of the dialysis bundle which is a key from a price position. I believe that this is only the beginning. We have several other indications in the pipeline and we believe that we hold the best Nitric Oxide inhibitor, which can result in multiple indications, which are quite interesting. We can leverage the first approval, hopefully with intradialytic hypotension, towards additional approvals as 505(b)(2), with other indications in a shorter period of time, with less risk and less investment.