Issue:
September 9, 2013

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

Developing a Device that specifically Removes Harmful Substances from a Mother's Blood using a Targeted Apheresis Method, Advanced Prenatal Therapeutics is offering hope in Treating Preeclampsia which is a Leading Cause of Maternal and Fetal Death

Healthcare
Medical Device

Advanced Prenatal Therapeutics
27071 Cabot Rd #104
Laguna Hills, CA 92653
949-340-7261
www.advancedprenatal.com

James Smith
CEO

BIO:
Dr. Smith has over fifteen years of experience in regulatory affairs and the development of novel technologies from concept through commercialization. He is experienced in all aspects of regulatory affairs, quality and data management systems, supervision of R&D, development of new product specifications, and with evaluating and registering medical drug and device product lines. Dr. Smith obtained his Ph.D. in Pharmacology and Toxicology from the University of California, Irvine.

About
Advanced Prenatal Therapeutics:
Advanced Prenatal Therapeutics, Inc. (APT) is developing a novel therapeutic device for treating preeclampsia. The device specifically removes harmful substances from the mother's blood using a targeted apheresis method. Removal of these substances may help alleviate the symptoms associated with preeclampsia and delay premature birth.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Dr. Smith, would you tell us about the goal at Advanced Prenatal Therapeutics?
Dr. Smith: Our goal at APT is to develop a therapy that will help patients suffering from preeclampsia deliver healthier babies. We are developing a targeted apheresis column that will remove harmful substances related to the symptoms of preeclampsia. This will be the first medical device specifically designed to treat preeclampsia, and will be designed for use with commercially-available apheresis machines currently used in healthcare facilities.

CEOCFO: Would you explain what preeclampsia is and how many are affected by it?
Dr. Smith: Preeclampsia is a disease marked by very high blood pressure and proteinuria during pregnancy. About 5-8% of all pregnant women develop preeclampsia – around 300,000 women in the United States. Of those that develop preeclampsia, about 25% are serious enough to require in-patient care. If left untreated, the condition can lead to maternal organ failure and/or life-threatening seizures. Preeclampsia is life threatening, and it is a leading cause of maternal death, fetal death, and fetal prematurity. Preeclampsia is regarded as a "disease of theories" as it is not clear what the cause is. There is a lot of research exploring different biological mechanisms, however the leading theories involve circulating factors, produced by the placenta, that affect blood vessel growth and the timing of development of the placenta. When these mechanisms are dysregulated, the mother develops high blood pressure and other symptoms of preeclampsia.

CEOCFO: What, if any, is the current treatment?
Dr. Smith: The most common treatment is monitoring and bed rest. There are some medications for controlling blood pressure, but they are limited due to the pregnancy risks. The only real cure for preeclampsia is premature delivery of the infant. When the mother's blood pressure reaches dangerous levels, or if it remains dangerously elevated, the doctor typically recommends removal of the fetus. If this occurs very early on, the pregnancy is likely to be terminated. After week 25 the child may be able to survive in a Neonatal Intensive Care Unit; however, the likelihood of negative, long-term developmental impacts for the child increases the earlier the baby is delivered.

CEOCFO: Would you tell us about what you have already developed?
Dr. Smith: Our technology is based off an idea discovered around 1997. It was observed that high levels of a circulating receptor called sFlt-1 were associated with the incidence of preeclampsia. sFlt-1 receptors, which are normally attached to the placenta, bind to vascular endothelial growth factor (VEGF) and placental growth factor (PlGF) circulating in the blood –

factors that are involved in the development of the placenta and regulation of blood pressure. In preeclampsia, the sFlt-1 receptors break off from the placenta, enter the blood stream, and bind to the circulating VEGF and PlGF before they can reach their target organs. The proper signaling mechanism is thereby inhibited, which leads to impaired development and poor regulation of blood pressure. We are developing an antibody-based apheresis column that can very specifically remove sFlt-1 and other circulating factors from the blood. The apheresis process, which is similar to dialysis, involves removing blood from the patient through the arm and passing it through a machine that separates the plasma from the blood cells. The plasma fraction is then passed through a column that contains antibodies for specific factors. The column acts like a reverse coffee maker: whereas the coffee water would pick up color and flavor from the coffee beans as it passes through the coffee filter, our device instead removes disease-causing factors from the plasma as it passes through the antibodies in the column.

CEOCFO: Where are you in the development process?

r. Smith: We had the idea of targeting sFlt-1 for the treatment of preeclampsia back in 2005. In recent years, we have seen that research in this area has progressed, so we have moved forward with developing our technology. We are currently in full development of the prototype column and proprietary antibodies for use within that column, and we think that over the next year and a half we will have completed all of the basic preclinical requirements in order to enable a clinical study to be initiated.

CEOCFO: Has the medical community paid attention, or is it too early for them?

Dr. Smith: There has been a lot of interest in preeclampsia in general, but there is very little translational work being done that gets academic knowledge into either a device or a drug model. Despite this, we believe that the medical community will be responsive to the idea. Apheresis is currently used to treat HELLP syndrome, a complication associated with severe preeclampsia, and apheresis is also used during pregnancy for the treatment of other chronic diseases such as familial hypercholesterolemia. Because of the very specific removal of harmful factors, I think that there would be few, if any, barriers to our targeted apheresis treatment once we demonstrate the ability to remove the biomarker properly.

CEOCFO: It sounds to me like there cannot be any harm.

Dr. Smith: Pregnancy is a fragile and dynamic state. Most companies haven't focused on drug and device research in pregnant women because it is traditionally very high risk and a very complicated system. However, our targeted apheresis process is anticipated to be a very low-risk process, and even a modest benefit would have a profound impact in the clinical setting because there is currently no other direct treatment for this problem. We hope to delay delivery by a few days or weeks, and we might be able to do as much as a month or more. Optimistically, we hope to have babies born healthy and on time. That is a very big deal, for patients to go from no treatment options to something that may alleviate the problem entirely. We anticipate that APT's low-risk apheresis procedure will be easily acceptable when weighed against the potential benefits of treatment.

"Preeclampsia is a completely unmet need. It is a leading cause of maternal and fetal death, and we think Advanced Prenatal Therapeutics has one of the first truly viable, low-risk therapeutic interventions. Even a modest positive result will make this an indispensible therapy option for preeclampsia."- James Smith

CEOCFO: Would you explain where the idea came from, and is your father the co-inventor?

Dr. Smith: My father, Henry, and I co-developed many of our technologies. Henry received a PhD in immunology and I received a PhD in pharmacology and toxicology. Our past work has involved looking at novel targeting mechanisms for cancer, rheumatoid arthritis, inflammation, and other chronic diseases. In our research exploring targeting antibodies and circulating factors, we came across literature related to preeclampsia and circulating sFlt-1. We thought that it was a poor candidate for a drug product, but an excellent candidate for an extracorporeal therapy. At the time, we thought this was interesting but it was not our focus. We filed off the IP for future use, and as we saw the popularity of the general idea of using sFlt-1 as a therapeutic target take hold in the industry, we decided to move forward with it.

CEOCFO: Funding and development is always expensive, and this seems to be a complicated project. Are you funded to continue now, or will you be seeking more funding or partnerships?

Dr. Smith: We have had some fantastic angel investors that have put in funding to get us going. We started the company formally last July. On very modest funding we set up our infrastructure, developed and implemented an ISO-certified quality system for medical device development, and launched formal development efforts. We think that we will be able to advance very rapidly on a reasonable budget, and we are currently seeking additional funding and partnership opportunities.

CEOCFO: Why should people in the business and investment community pay attention to Advanced Prenatal Therapeutics?

Dr. Smith: Preeclampsia is a completely unmet need. It is a leading cause of maternal and fetal death, and we think Advanced Prenatal Therapeutics has one of the first truly viable, low-risk therapeutic interventions. Even a modest positive result will make this an indispensible therapy option for preeclampsia. We are using a technology with minimal risk, which facilitates the process of getting to the clinical stage. We think this is a phenomenal opportunity, and it is exactly why it makes such a great story.