

Pluristem Therapeutics Inc. (PSTI)



DR. WILLIAM R. PRATHER, Senior Vice President, Corporate Development at Pluristem Therapeutics, Inc., is a Registered Pharmacist as well as a Board Certified Internist and Geriatrician. He received his BS in Pharmacy and Medical degree from the University of Missouri. He practiced internal medicine in the Kansas City, Missouri, and Vail, Colorado, areas until leaving internal medicine in 1987 to pursue a Fellowship in Geriatric Medicine at Harvard University. He completed this fellowship in 1989. In 1992, Dr. Prather left the practice of medicine to pursue a career in the financial industry where he has held senior healthcare research positions for a variety of investment banks. Dr. Prather co-founded Panacos, Inc., a public pharmaceutical company. Additionally, he has been on the Boards of several public and private companies, including Boston Biomedica Inc. (a public medical diagnostics company), PriMed (a private medical device company), MdBio (a Maryland healthcare venture firm), and he sat on the Advisory Board of MDS Capital Management, a Canadian venture firm.

SECTOR – BIOTECHNOLOGY

(AKY602) TWST: May we start with a short history and overview of your company?

Dr. Prather: Pluristem Therapeutics is a NASDAQ-traded public company that actually first came into being as a public company in 2003 via a reverse merger. The company's technology came from a co-collaboration between Technion and the Weizmann Institute, both in Israel. So the company's manufacturing facilities and administrative offices are all in Haifa, Israel. We do have offices in the United States and that's where I am located, in Colorado. The company initially was on the OTC Bulletin Board and then approximately a year ago, I believe, we came to NASDAQ.

TWST: What are your products? What is the technology behind those products?

Dr. Prather: What Pluristem is doing is taking stem cells — and these are non-controversial adult stem cells, they are not embryonic — and we extract these cells from the tissue of the placenta. The placenta or the afterbirth is an organ that has traditionally been thrown away as medical waste. So everyone is appreciative of our technology because we are taking a non-controversial stem cell from a plentiful source that is non-controversial — the placentas are currently being donated to us. We then take those cells and grow them or expand them in a very proprietary way in a three-dimensional bioreactor. This is compared to taking and growing stem cells on the rungs of a jungle gym, you might say, versus the traditional way of growing them in a petri dish. We add no adulterants of any kind, no growth factors, we simply use sugar and water to grow these cells. So in that respect, we're really just farmers. The cells that come out of this three-dimensional growth process are called PLX cells or PLacental eXpanded cells, and PLX cells have been found in several animal models of different disease states to have potential efficacy, and so that's really the basis for the company and the technology.

Our first product is called PLX-PAD. The PAD stands for Peripheral Artery Disease and we will begin clinical trials after the first of the year in two locations in Europe, as well as two locations here in the United States for the treatment of patients with a decrease in blood flow to their lower extremities. This is a very common problem, actually a huge market aggravated by diabetes, high blood pressure, smoking, etc. This would be a Phase I trial that proves the safety of the cells in those patients who really have no alternative except amputation.

We have other animal models proving potential efficacy in other disease state, such as inflammatory bowel disease, which includes Crohn's disease and ulcerative colitis, and that's called PLX-IBD for inflammatory bowel disease. We also have PLX-MS, which is documented to be efficacious in multiple sclerosis animal models, as well PLX-STROKE in animal models of stroke. The cells have also been proven to be useful as an alternative to bone marrow transplantation where they can enhance the engraftment or the expansion of blood-forming stem cells that come from cord blood when you use them together with cord blood and this product is called PLX-BMT. So there are a variety of animal models that we've used and we're continuing to add more, but our first product will be PLX-PAD.

TWST: With all the options available to you to pursue so many targets, why was PLX-PAD taken as the first choice?

Dr. Prather: PLX-PAD was taken as the first choice because the administration of the cells for the patient will be an intramuscular injection and the hurdle at the FDA is going to be less versus giving the cells, for example, intravenously. In addition, the formatting of the clinical trial has been done by others before us although they've used autologous cells, but the prototype for the study is kind of already there and we're not really bringing anything super new to the FDA.

TWST: Do you have an assessment of the market size that you will be addressing?

Dr. Prather: We consider the market size for PLX-PAD to be about a \$4 billion market, and these are patients who are afflicted with vascular disease of the lower extremities where the decrease in blood flow to their legs is so severe that they are beginning to get ulcers and gangrene. They've potentially been through a variety of medical and surgical interventions without much help. The disease is aggravated by patients who are smokers, have high blood pressure or high cholesterol, diabetics, etc. So it's actually a very common disorder, and these patients will have no alternative except amputation, so we see that the trial should have fairly rapid enrollment to prove safety and hopefully get a trend toward efficacy as well.

"We are taking non-controversial stem cells from an organ that has been traditionally thrown away and developing products that are soon to go into clinic. These cells are grown in a unique, proprietary way with only sugar and water and have the properties of being one-size-fits-all and off-the-shelf. So we are not focusing on personalized medicine, but on the kind of medicine that large pharmaceutical companies are used to dealing with and will want to collaborate with as they get into cellular medicine."

TWST: In the past, your lead candidate was PLX-1 for the treatment of hematological diseases. What is the status of PLX-1?

Dr. Prather: PLX-1 is still viable. We now call that PLX-BMT for bone marrow transplantation, and we decided to replace PLX-PAD as our primary indication or primary disease for the cells at this point because PLX-BMT is going to be needed to be used intravenously with the co-administration of cord blood. We don't have control of cord blood at this particular point in time. We don't own a cord blood bank, for example. Until we do have a relationship with a cord blood bank as far as being able to monitor and assess the quality of the cord blood, we'll keep that on the back burner. We believe the indication is a phenomenal indication that certainly has unmet need.

I personally believe that bone marrow transplantations will be a thing of the past and that patients who need blood forming stem cells will be turning toward cord blood. We think that we have the answer to expand those blood forming stem cells found in cord blood as right now there is no technology for that. However, we could have the best quality PLX cells and we could combine them with cord blood that's not good and our study would fail. So we need to do some additional work in getting control of the quality of cord blood before we go further with that indication.

TWST: Has your company formed any alliances or partnerships?

Dr. Prather: We have an alliance with Charite of Germany; it's kind of the Mayo clinic of Europe, the largest clinical

research facility in Germany. They have been doing some of our pre-clinical work in animals, and they are also going to be one site for our Phase I PLX-PAD trials. We also have collaborations with Technion and the Weizmann Institute. We actually purchased the patent for the 3D expansion technology from them approximately about a year ago, and they reinvested the proceeds from the sale back into Pluristem.

TWST: How does the balance sheet look to you and what is your current burn rate?

Dr. Prather: As of our last Q, we have assets of about \$4 million with cash of about \$1.5 million. We have a burn rate of only \$450,000 a month. We have zero liabilities. Shares outstanding are about 9.3 million at this point.

TWST: Given the conditions for credit at this point, how optimistic are you that you will continue to raise additional funds to keep the research going?

Dr. Prather: Because of where these cells come from and how they are grown, which is very unique, we have proven that these cells can be used allogeneically. In other words, our PLX cells will be off-the-shelf where one size fits all with no matching needed. Essentially you can take them down, unfreeze them and use them. We've been approached by a variety of large pharmaceutical companies that are interested in the stem cells with these kinds of properties. There is a possibility that we might be able to get into a collaboration with one or more pharmaceutical companies that would help us financially, as well as with our clinical trials. In addition, we have been awarded a grant from the Israeli Minister of Health, which is pending. When it arrives, it would certainly help us so that we may not have to raise money for the rest of the Phase I clinical trial for the PLX-PAD clinical trial that I was just describing to you.

TWST: Are there any products commercialized using stem cells?

Dr. Prather: Osiris is a NASDAQ company that's out of Baltimore. They use allogeneic, mesenchymal stem cells, similar to ours, but their stem cells come from the bone marrow instead of from the placenta. We believe it's easier to get cells from an organ that is being thrown away versus having to perform a surgical procedure to get cells. But Osiris has a product in the orthopedic area that they've developed, but I think they have sold that product line.

TWST: Would you sketch a realistic picture of your company, let's say, 12 to 24 months down the road?

Dr. Prather: In 12 to 24 months we would have completed our Phase I trial hopefully and have then entered into pivotal efficacy trials for PLX-PAD. We would be also in probably a Phase I trial using PLX cells for another indication, and I would think that we would potentially have collaborated with a partner for the development of PLX cells.

TWST: Do you have the management team in place to take the company to your goals?

Dr. Prather: I believe we do. I believe we have an excellent management team and scientific advisory board. We have about 30 employees at this point and somewhere around seven or eight PhDs. I am an MD. I believe we'll grow this base with expert scientists and business people going forward.

TWST: What keeps you occupied on a day-to-day basis?

Dr. Prather: I wear a variety of hats for Pluristem. I'm responsible for most of the IR work, responding to investor questions, etc., and presenting at conferences. We are focused on our clinical trials at this point and don't have an IR firm or PR firm at this time — we feel that probably is a waste of money until we get into humans and get the trials finished. So, until then, we really don't have the tools to be able to give to an IR firm or PR firm. So I take care of most of that kind of work. For example we're going to Rodman & Rodman in November but that conference is of no charge to us.

I also speak at academic institutions. I was at the University of Missouri, Kansas City, School of Pharmacy, speaking to the pharmacy students not necessarily about Pluristem per se, but more about stem cells. I think that, unfortunately, when the general public hears the term "stem cells" or "stem cell research," they think of embryonic stem cells and they think of the destruction of human life and all the ethical issues that surround that. It's unfortunate, but people don't seem to realize that there is another whole class of cells that are non-embryonic, the so-called adult stem cells that, in my, opinion will yield commercial, FDA-approved products long before embryonic stem cells yield products, if they ever do.

I can go on and on about this, but one reason I don't think embryonic stem cells will ever yield a product that's commercially available to patients is because in order to be defined an embryonic stem cell, they have to form tumors upon injection and that's a difficult hurdle to get past the FDA when you try to work with a product that is forming tumors in animals. But I think we will see products over the near term come from adult stem cells like our PLX cells.

In addition to handling Pluristem's IR work, I also am involved in coordinating the clinical trials here in the US as well as collaboration and other corporate development work.

TWST: Are there any misconceptions that you encounter when you are speaking with shareholders?

Dr. Prather: I think it's related to the fact that people think that you can put a stem cell in a petri dish, for example, and you're going to grow an organ such as a heart or a liver, and that's just simply not the case, even with embryonic stem cells. In order for those kinds of things to happen, those cells have to be manipulated, genetically engineered if you will, and that's a long ways off with all the hurdles that come with the manipulation of these cells.

Again, we use only sugar and water to grow our PLX cells. We don't mess with the cells at all once they're expanded or grown. We believe that probably the primary mechanism of action for our cells is that they secrete immune modulators at the right time, at the right place, in the right amount to help the injured or diseased tissue, so they are kind of mega anti-inflammatory cells, if you will.

TWST: What would you like readers to come away with from this interview?

Dr. Prather: I want readers to realize that we are taking non-controversial stem cells from an organ that has been traditionally thrown away and developing products that are soon to go into clinic. That these cells are grown in a unique, proprietary way with only sugar and water and have the properties of being one-size-fits-all and off-the-shelf. So we are not focusing on personalized medicine, but on the kind of medicine that large pharmaceutical companies are used to dealing with and will want to collaborate with as they get into cellular medicine. This is the kind of product that they'll want to partner with.

TWST: Thank you. (WT)

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