CEO CFO

FPRT Bio

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A Clinical Stage Company, FPRT Bio is Focused on XPro1595, a Protein Therapeutic Drug Development Program, for the Treatment of Neurodegenerative Diseases such as Parkinson's Disease, Alzheimer's Disease and ALS

Healthcare
Biotech

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Mark Hamblin
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BIO: Spent a decade as a transplant surgeon (kidney, liver, pancreas and intestinal) before joining SangStat Medical Corporation (SANG: NASDAQ) as part of the leadership team. At SangStat, he played an integral role in developing SangStat's product portfolio and commercial success before the company was acquired by Genzyme Corporation for more than $600M USD in 2004. Dr. Tesi then became Chief Medical Officer of Cellerant Therapeutics – a company focused on stem cell therapies targeted at the treatment of autoimmune diseases and cancer. Most recently, Dr. Tesi was the founding CEO of Coronado Biosciences (CNDO:NASDAQ), an immunotherapy company with novel products to treat autoimmune diseases and cancer. Many ask why a successful transplant surgeon would move to biotech. In Dr. Tesi's mind, he had no choice, "…I love being on the cutting edge of medicine. When I started in transplant, it was the cutting edge of medicine. Ten years later, organ transplantation was part of main stream medicine – I got restless. Start-up companies like FPRT Bio deal with the most important problems in medicine. These problems and their treatments define the future of medicine. I must be part of it! Dr. Tesi received his medical degree from Washington University in St. Louis.

About FPRT Bio

FPRT Bio was formed for the development of XPro1595 in the treatment of neurodegenerative diseases. FPRT Bio is a clinical stage company seeking Series A financing to support clinical trials with XPro1595 in ALS and Parkinson's Disease (PD). Expansion into other neurodegenerative and neuroinflammatory diseases such as Alzheimer's disease, Multiple Sclerosis, autism and depression will depend on resources.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Tesi, FPRT Bio is a development stage company. What is your focus and concept?

Dr. Tesi: FPRT Bio is focused on the development of XPro1595 for the treatment of neurodegenerative diseases - a group of neurologic diseases with both chronic neuroinflammation and nerve cell death. The list includes ALS, Parkinson's disease, Alzheimer's disease, MS and Huntington's disease. Almost everyone knows someone suffering from one of these devastating diseases. In general, neurodegenerative diseases are not well served by current therapeutics. Parkinson's and Alzheimer's disease have important implications to our society because of the tsunami of baby boomers that are entering their at-risk years. These two diseases have the potential to bankrupt any healthcare system that must pay for the care of patients.

CEOCFO: What is XPro1595?

Dr. Tesi: XPro1595 is more than a simple TNF inhibitor. First, a bit of background. TNF is a key cytokine involved in inflammation that became famous as the therapeutic target for rheumatoid arthritis and Crohn's disease. The anti-TNF therapy drug category is the largest pharmaceutical franchise on the planet; over twenty three million dollars per year. However, those TNF inhibitors are not the same as XPro1595. XPro1595 is a selective inhibitor of soluble TNF and only soluble TNF. What does that mean? The biology of TNF is quite complicated. There are two types of TNF. Soluble TNF is the 'bad guy' that causes inflammation. Trans-membrane TNF is the "good guy" that has positive effects on the immune and central nervous system. All currently approved anti-TNF drugs are non-selective inhibitors that block both soluble and trans-membrane TNF. XPro1595 is different - it only inhibits soluble TNF. That is, XPro1595 is a targeted, specific, highly selective protein therapeutic that neutralizes soluble TNF and allows trans-membrane TNF to work normally. This

difference has important therapeutic implications. XPro1595 is as effective as the non-selective drugs in blocking inflammation, but provides benefits of normally functioning trans-membrane TNF. In the brain, trans-membrane TNF is a beneficial cytokine that is neuroprotective, promotes remyelination and improves neural plasticity. The non-selective inhibitors are contra indicated in patients with neurologic diseases. Because of the unique biology, FPRT Bio is focused on neurologic diseases for our development efforts. XPro1595 is the perfect drug for the treatment of neuroinflammatory diseases.

CEOCFO: What actually happens when the drug gets to the cell or to its target?

Dr. Tesi: The understanding of TNF biology in the brain has evolved dramatically in the last decade. There are two sources of soluble TNF in the brain - a circulating pool from peripheral inflammation and a local pool produced by nerve cells, especially microglial cells. TNF from the circulating pool crosses the blood brain barrier by active transport and causes microglia cell activation – the trigger to the destructive inflammatory response in the brain. Soluble TNF is the master cytokine that initiates and potentiates this destructive inflammatory cascade. Chronic neuroinflammation causes death of nerve cells. The local pool of TNF is produced by glial cells in response to local conditions including dead nerve cells. You can imagine how the vicious cycle of neuroinflammation causing nerve cell death causing more neuroinflammation is started. As nerve cells die, patients get worse. Current therapies do not target chronic neuroinflammation. XPro1595 targets neuroinflammation by eliminating soluble TNF. XPro1595 neutralizes soluble TNF in a unique way by using dominant negative technology to prevent soluble TNF from binding TNF receptor. What does that mean? Human soluble TNF exists as a homotrimer of three identical monomers. That homotrimer binds to TNF receptor to cause the biologic effect. XPro1595 is an engineered protein that has six amino acid substitutions - sort of an "identical twin" except for a beauty mark on its cheek. This 'identical twin' can easily replace one or two of the monomers in the soluble TNF homotrimer. The trimer with an XPro1595 substitution becomes an inactive heterotrimer that cannot bind the TNF receptor. The formation of the heterotrimer completely eliminates soluble TNF function without affecting the normal function of trans-membrane TNF and TNF receptors. In the brain, XPro1595 eliminates destructive chronic neuroinflammation caused by soluble TNF activated microglial cells and polarizes TNF biology to reparative trans-membrane TNF effects. XPro1595 is a unique therapeutic agent for the brain that stops destructive pathology and promotes reparative biology.

CEOCFO: Where are you in the process?

"With XPro1595, investors are getting, for quite a for a very modest investment, a de-risked protein therapeutic drug development program, that is addressing very large, underserved markets. XPro1595 will make a difference at the bedside while it rewards investors."- Mark Hamblin

Dr. Tesi: This drug was in-licensed from Xencor, Inc. a very innovative protein engineering company in Southern California. Historically, they had two product platforms – the DN-TNF technology platform that spawned XPro1595 and their antibody engineering platform. Today, they are focused exclusively on their antibody engineering platform with five antibodies in the clinic; many with big pharma/biotech partners. Although XPro1595 was no longer their focus, they recognized its potential and decided to out-license the drug. FPRT Bio was lucky, we in-licensed a drug that had completed IND enabling safety toxicology, pharmacology and manufacturing scale-up. XPro1595 is an IND ready drug that is ready for Phase I clinical trials. At a Type B pre-IND meeting, the FDA encouraged us to field a Phase I program in ALS. Our second disease target is Parkinson's disease. We have developed a relationship with the Michael J Fox Foundation. Currently, we are raising a Series A to complete the Phase I programs in these two devastating neurodegenerative disease.

CEOCFO: Certainly, Alzheimer's and other diseases that you are talking about are in the news quite a bit. However, different diseases are in favor with the investment community at different points of time. Are you in a "hot area" for the investment community? Have you been able to generate interest?

Dr. Tesi: That is a very good question. From where I sit, cancer still remains the "hot area" in biotech investing for reasons I do not understand. It isn't market size – there are fewer patients with breast, colon or lung cancer than Parkinson's disease. Fewer patients have acute leukemia than ALS. The neurodegenerative disease markets a very large, the needs are great, the opportunity is gigantic. Investors also love orphan diseases where a company can succeed with a very small patient population. Part of attraction to orphan diseases is the clear and simple regulatory and clinical paths. This is in contrast to the large and interesting neurosciences markets where regulatory pathways are more complex and clinical trials more difficult. FPRT Bio has a development strategy that depends on biomarkers and, in ALS, attacking a lethal orphan disease. Our development program look very similar to a cancer program that attacks an orphan indication using biomarkers that will quickly allow early evidence of efficacy. Personally, I think stealing a page out of the cancer development play-book is a great idea! It helps us communicate to an investment community that has been badly burned by neuroscience drug development programs, especially in Alzheimer's disease where some very big bets have gone awry. We are focused on two diseases. ALS is a desperate orphan indication with a six month development path that allows the use of biomarkers to select a subset of ALS patients that are going

to respond to XPro1595. Similarly, Parkinson's disease, a disease of aging with more than one million patients has imperfect therapies that will benefit from a focused therapeutic strategy directed by easily tested biomarkers. I have given you a long answer to the question. Yes, everyone is well aware of the weak pipelines of neurology products. However, many investors are very cautious about investing because of the rich history of failures. We have decreased that risk with a biomarker directed development strategy. All we need is the money to proceed.

CEOCFO: Aside from people that may know you personally, does your history of having been involved with successful companies before help when you are looking for funding or is it really what the drug has to offer right now?

Dr. Tesi: Clearly, if you are a superstar, biotech CEO, people throw money at you and ask questions later. I am not. I have a solid history. People appreciate what I have done, but the product drives the investment. Investors understand that I know how to get from point A to point B quickly and efficiently. XPro1595 is the star in this company. That is a good thing because it is a very good drug.

CEOCFO: As a transplant surgeon what do you take from that experience to the table at a company like the one that you are at now or when you are working on the business side?

Dr. Tesi: That is a good question. I think there are two things that are important. First of all, it is "patients first". My experience is that every company that takes that perspective; will be successful. If you are not focused on, or your drug does not make a difference at the bedside; your company will struggle. This business is very simple, it is all about developing technology that helps patients get better and improve their lives. I am driven by making a difference at the bedside. That is what I did as a clinician and what I strive for as a CEO. I have developed the business knowledge to be successful, but at the end of the day, I am a clinician first. I am proud of that and I think it is the reason for my success. When I started my career in transplant, we were the cutting edge of medicine. That experience gave me a unique perspective to the drug development process. Therefore, my strength is how to get a drug through proof-of-concept clinical trials in a way that is low risk and cost effective. You hear these huge numbers thrown the cost of drug development. There is no question that it can be a "king's sport", but it does not have to be that way. Large, well-served therapeutic areas require big expensive trials because of the tyranny of statistics; it is hard to improve on good outcomes. In the fields that interest me, a good drug that makes a difference at the bedside does not need large trials, just well-done trials. There are many ways to make to get it wrong. We believe we are good at getting it right. I was lucky when I joined the business world. Because I was not struggling with the medical side of the business, I was able to focus on the business side of biotech. I learn by "sitting at the knee" of the experienced biotech executives. For instance, I spent four years I working very closely with JJ Bienamie, who is the CEO of Biomarin. JJ is a talented CEO who I consider a mentor and a friend. I have a fortunate blend of clinical and business experience that is ideal for running a fledgling biotech. Our future is bright!

CEOCFO: Why should investors and people in the business community pay attention to FPRT?

Dr. Tesi: That's easy! We have a therapeutic strategy that treats large markets with an important unmet medical need. ALS is a lethal disease with no cure Parkinson's disease has only symptomatic therapies do little to change the outcome; the patient ends up dependent on others for their day-to-day care. Alzheimer's disease and dementia affect an important segment of the population - it is a condition people fear as much as cancer. FPRT will treat these diseases with a new therapeutic strategy. We will attack neuroinflammation; a strategy that has not been done. FPRT Bio is a classic biotech play with a twist. We are at the forefront of the science and a bit ahead of clinical thinking. The clinicians are catching up with us. We will give them a tool to make a difference in these devastating diseases. The second advantage is the twist. We have wrung much of the risk out of the drug development process. Drug development has three classic risks in the trip from the bench-to-bedside. The first risk is safety. Is it going to do something unexpected in the pharm/tox study? We have completed the pharm/tox studies – the safety risk has been wrung out of the equation. The second risk, and it is a risk that is especially acute for small companies with protein therapeutics like XPro1595, is manufacturing risk. Producing a bit of drug at "test tube" scale is one thing; it is something else to make enough for clinical trials. Manufacturing scale-up is a difficult and expensive process for any company, but it can cripple a small company. Our scale-up was done as part of the IND submitted in 2006. We have eliminated the manufacturing risk. What remains is efficacy risk. Does it work? Quite honestly, that puts us in the same place as Amgen, Roche or GSK when they start their Phase I trials. They have a drug that has completed safety trials and know how to make. Now they must prove that it works by doing a clinical trial. With XPro1595, investors are getting, for quite a for a very modest investment, a de-risked protein therapeutic drug development program, that is addressing very large, underserved markets. XPro1595 will make a difference at the bedside while it rewards investors.

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