

Novel Treatment Development for Oncology and Neurology Disease



George Farmer, Ph.D.
CEO

CEOCFO: Dr. Farmer, what is the idea behind Cortice Biosciences?

Dr. Farmer: Cortice is a biotechnology company that is devoted to the development of novel treatments for oncology and neurology disease indications with significant unmet medical needs.

CEOCFO: You are certainly in an area where there is a great deal of attention and research. What is your approach?

Dr. Farmer: Our lead anti-cancer drug, TPI 287, has the unique ability of being able to get into the brain while working very similar to an existing class drugs that has been widely used to treat a variety of cancer indications. Targeted indications include glioblastoma, which is a highly aggressive brain tumor, as well as tumors that spread to the brain from other organs, such as those originating from lung and breast.

CEOCFO: What is the action that we are looking to have happen and please explain how what you have developed can get this action?

Dr. Farmer: TPI 287 has special modifications to its outer core that enables passive penetration into the brain without being pumped out. This enables the drug to accumulate in the brain and exert its anti-cancer activity.

CEOCFO: Are there any potential negatives so far?

Dr. Farmer: There are always negatives when developing treatments for cancers, because most are associated with undesirable side effects. However, with all marketed cancer drugs, these side effects can be manageable, which is so far the case with TPI 287. We see side effects such as myelo suppression, which is a reduction of immune cells. We also see some finger and toe tingling called peripheral neuropathy, which can be annoying and even debilitating as seen with other drugs, but can so far be managed in our clinical trials. Other than that, this is a pretty run of the mill cancer drug as far as a side affect profile is concerned.

CEOCFO: What else are you working on now?

Dr. Farmer: We are also using TPI 287 to treat neurodegenerative disease. We have evidence in animal models that using the drug at doses far lower than those designed to kill cancer cells may actually restore the function of neurons that are dying as a consequence of dysfunctional tau protein. These diseases include small orphan indications which resemble Alzheimer's disease, Parkinson's disease and other CNS diseases, but they have very distinct pathologies. Importantly, there are no standards of care for treating these diseases. We are also looking at Alzheimer's disease as well, which is a very complex disease, but there is good rational for why this drug could potentially work.

CEOCFO: What gave you the idea that the drug that was working and killing cancer would be good in the other application?

Dr. Farmer: There is precedent for similar drugs that do the same thing as our drug does in certain animal models of neurodegenerative disease. We know that TPI 287 gets into the brain really well, so it made sense to test in the same animal models. Indeed, we do see the same effects in animals with these particular types of diseases. We can improve the cognitive performance of mice and we also show a reduction in a critical biomarker that correlates with disease severity.

CEOCFO: Will there be applications even further in other areas?

Dr. Farmer: There could be and we may find out next year. With an investigator at a major university here in the United States, there are ongoing clinical trials that are enrolling both patients with Alzheimer's disease and also patients with these rare disease tauopathies.

CEOCFO: *Has the medical community been paying attention or is it too early?*

Dr. Farmer: Last November we presented data from a glioblastoma clinical trial evaluating TPI 287 at the annual meeting of the Society for Neuro-Oncology. There, in thirteen patients, we showed that TPI 287 in combination with standard-of-care shrank tumors in over half the patients evaluable for response. Actually, two of those patients had a complete reduction of tumor loss and the responses have appeared to last for a meaningful length of time. We need to see some longer follow up data for sure, but the results that we presented were regarded as very encouraging.

CEOCFO: *You have been CEO since the beginning of the year and do have considerable experience in finance, academia as well as bio. Why take on the role at Cortice now?*

Dr. Farmer: I am extremely excited about where the company is at this point in time. This is also a great time for our industry, where the overall capital markets are recognizing that biotech is an important part of the United States economy. Some very important and successful discoveries have come out of biotech over the past two decades, and many people believe that this wave will continue to grow. I believe Cortice is going to be riding the top of that wave, along with a number of other companies with as good ideas as ours.

CEOCFO: *What have you learned from some of your previous experience that has been and will continue to be most helpful in Cortice?*

Dr. Farmer: Great question! This is my first role as a CEO, but in my prior life for over a decade I was a biotechnology analyst. I got to know management teams from hundreds of companies. I have seen many successes and I have seen many failures. I would not say that I necessarily know how to be a CEO after watching these companies, but I certainly know how *not* to be a CEO. I've learned that transparency and being very open with the investment community and medical communities is extremely important for building a credible company. Just show the data as it is, convey your enthusiasm and allow the sophisticated healthcare investment community to make up their own decisions as to the validity of what you are presenting. The rest will follow.

“We see lots of interesting, highly valued inflection points coming up over the next couple of years. This is a great time to be involved with the company.” - George Farmer, Ph.D.

CEOCFO: *What surprised you in the past year, related to the company or the industry?*

Dr. Farmer: I am surprised at some of the enthusiasm over other much earlier stage biotechnology companies than Cortice that are missing the clinical validation that would have been required, say, just three to five years ago. I am not saying that this is a bad thing, because capital is certainly required to realize the promise of some of these discoveries and inventions at the various companies, and investors can do well getting in at the early stage. Nevertheless, I am surprised at the degree of risk that investors are willing to take now than they were willing to take in the past.

CEOCFO: *What is the timetable for Cortice?*

Dr. Farmer: In 2015 we are going to have further read outs from our glioblastoma trials with TPI 287. We also have another trial with an investigator here in the US that is looking at our drug in combination with radiation for treating secondary brain metastases. Data from the neurological disease trials could be coming as well. Then we have another drug, known as CRT 001, which is at an earlier stage of development and has potential for treating cognitive impairment associated with diseases like Alzheimer's disease. We know, based on the fact that CRT 001 had been approved for an unrelated indication in Europe, that it is very safe, which is a key factor in developing any drug for a neurological indication. Therefore, based on the safety profile and the very encouraging preclinical data that we have seen, we are excited to get CRT 001 moving forward into the clinic, which we think should happen sometime next year.

CEOCFO: *Are you able to use that data? Do you have to prove the safety over again or are you able to use some or all of that data when you are getting to the FDA now?*

Dr. Farmer: The safety data compiled so far will support our clinical trial plan. However, we are still going to have to get FDA approval prior to moving forward in any clinical trials.

CEOCFO: *Would you make the case for Cortice Biosciences?*

Dr. Farmer: Cortice is at a great inflection point right now. We have a novel pipeline designed to treat challenging disease indications, but could provide enormous benefits to patients. We see lots of interesting, highly valued inflection points coming up over the next couple of years. This is a great time to be involved with the company.

CEOFO: *How do you deal with the frustration of the time it takes to go from concept to potentially a product when you have something that obviously can change so many lives?*

Dr. Farmer: We are working with compounds that are already supported by a deep amount of clinical trial experience. Therefore, much of the risk and uncertainty that is associated with moving a compound from preclinical stage to clinical stage has been mitigated. TPI 287 was previously evaluated in almost two hundred cancer patients, so we were very familiar with the safety profile of this drug and its ease of administration. Likewise, for CRT 001, the drug has been in thousands of patients prior to us in-licensing the rights to this molecule. We think that that can help cut down significantly on the development time frame.

Interview conducted by: Lynn Fosse, Senior Editor, CEOFO Magazine



Cortice Biosciences

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