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A Biotechnology Company Developing a Biologic Therapy through Oncolytic Viruses for the Treatment of Aggressive Cancer Forms, the Lead Product of DNAtrix Inc., DNX-2401 Represents an Important New Weapon for Fighting Cancer

Healthcare
Oncolytic Virus Development

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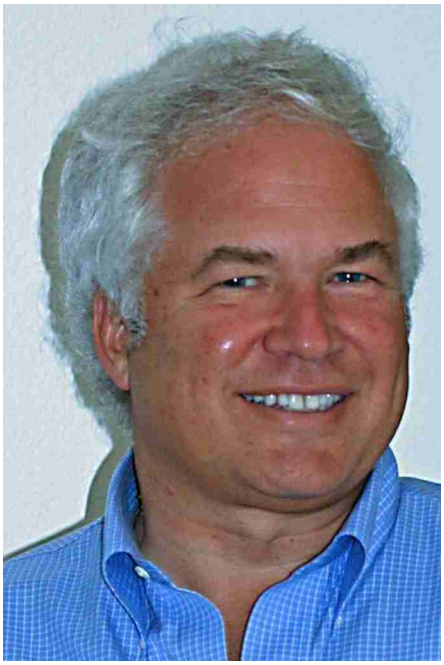

Frank Tufaro
CEO

BIO:
Frank Tufaro has extensive experience with the founding, financing, and operation of biotechnology firms. Prior to DNAtrix, Frank was part of the founding team of Neurovir, Inc., a Vancouver-based biotech company with a mission to develop herpes-simplex virus oncolytic vectors for treating cancer. Frank was instrumental in raising venture financing that established NeuroVir as a major player in the field of viral oncology. Frank also co-founded Nurel Therapeutics (Pittsburgh) a gene therapy company later sold to Diamyd Medical AB (Sweden), and Allera Health Products, Inc. (St. Petersburg, FL). From 1987-2002, Frank was a Professor of Microbiology at the University of British Columbia, wherein his laboratory worked on herpes simplex virus and cancer. Frank received his BSc in Cell and Molecular Biology, a PhD in Developmental Biology from McGill University in Montreal, Canada and was a postdoctoral fellow with Dr. Steve McKnight, at the Fred Hutchinson Cancer Center (Seattle, WA) and the Carnegie Institution of Washington (Baltimore, MD).

About DNAtrix Inc.:
DNAtrix is a biotechnology company developing oncolytic viruses for the treatment of the most aggressive forms of cancer. The company's initial focus is on glioblastoma, a devastating brain tumor that is currently incurable. DNAtrix scientists have harnessed this ability by modifying a common cold virus so that it targets and kills cancer cells selectively. More than 35 patients have been treated with the cancer-killing virus, called DNX-2401, with excellent early results. The Company's lead product, DNX-2401, is the culmination of more than a decade of scientific and clinical research and appears to be the most potent and effective oncolytic virus ever used to destroy human brain tumors. DNAtrix is also working to expand its platform technology for treating other cancers, including brain metastases, ovarian and pancreatic cancer. Targeted cancer-killing viruses such as DNX-2401 represent an important new weapon in the fight against cancer.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Tufaro, what is the concept at DNAtrix?
Dr. Tufaro: DNAtrix is developing a product based on a biologic therapy that has been tested for nearly twenty years, but is now actually beginning to work in the clinic. It is called oncolytic virus therapy. It starts with a virus that causes, for example in our case, the common cold, and transforms it into something that can kill cancer cells specifically. The company is testing this product in clinical trials for treating incurable brain tumors.

CEOCFO: Why use virus cells to kill cancer cells?
Dr. Tufaro: Scientists have always studied viruses because they can cause many important diseases in animals and humans. However, scientists also realized that viruses can be modified genetically such that they can safely target and kill tumor cells. In fact, these modified viruses have an almost amazing ability to destroy tumor cells selectively. Consequently, scientists have now harnessed this ability for cancer therapy. In our case, this project has taken over ten years, resulting in a clinical trial at the MD Anderson Cancer Center for treating brain tumors.

CEOCFO: What are you specifically doing at DNAtrix? How is the compa-

ny taking this concept and working on it?

Dr. Tufaro: Our virus product called DNX-2401 has been developed, manufactured and tested for human clinical studied. It was then tested on 37 patients suffering from glioblastoma, a devastating brain tumor with a median survival of about 15 months. It is directly injected into brain tumors during a biopsy. We inject only a single dose into the patient and then follow the patient to see if the tumor is destroyed, leading to longer survival. The patient comes into the clinic every month or two for an MRI brain scan. The tumor is visible on the scan and physicians determine if it is growing or shrinking. If it is growing then you have failed and patiets are treated with other therapies. In the first study of DNX-2401, about fifty percent of the patients showed a "clinical benefit". In some patients, the tumors were partially or fully destroyed, their symptoms were reduced or absent and some of them are now long-term survivors. Therefore, we are quite encouraged by these results. DNX-2401 is undergoing additional clinical testing in an attempt to gain FDA approval.

CEOCFO: What specifically does the virus do that allows the results?

Dr. Tufaro: Most viruses have the ability to kill cells. Think of the cold sore that arises from a herpes simplex virus infection. A cold sore forms because the herpesvirus kills cells and spreads from cell to cell, causing a "mounts an immune response so that you do not get a giant cold sore or other serious problems. In fact, the virus could kill you if you did not have an immune system. However, our bodies are typically in balance with the virus. It can make a cold sore, but then your body can take over and make sure that it does not go any further. We harnessed the same type of properties with a common cold virus called adenovirus. Our first product, DNX-2401 is an adenovirus that has two genetic changes that make if suitable for killing tumors. After it is injected into a tumor, it infects cancer cells, produces thousands of copies of itself, and then spreads from cell to cell in a kind of chain reaction. Then your body senses that you have an infection in your brain tumor and it sends immune cells to the rescue to try to "destroy" the virus. We now believe that these immune cells also see the tumor and try to kill the tumor at the same time. We have evidence from several patients that shows virus replication in the tumor and complete tumor destruction, which is the ultimate goal. These are exciting results and we are hopeful that this therapy can be extended to the large number of patients who need it. There are over 25,000 patients per year in the US and Europe who present with this disease.

CEOCFO: Are there many companies working in this same area? Are they working with different viruses or different formulations? Where does DNAtrix fit in?

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- Frank Tufaro

Dr. Tufaro: That is a good question. There are several companies working in this area; I would say that there are four or five main companies. DNAtrix is one of them. Another company is working on a retrovirus, similar to an HIV virus that has been modified to deliver certain chemotherapy enhancing genes to cancer cells. Another company is testing poxvirus, like a modified smallpox virus, for killing liver cancer. There are different "flavors" of viruses that all have slightly different properties that can be exploited for treating different cancers. However, the major property that they have in common is that they have been engineered to be safe for delivery. The trick is to make them as potent as you possibly can as well. I just attended a meeting in Quebec City that is held every two years called the Oncolytic Virus Meeting. There were hundreds or people, scientists and physicians there talking about new ways to exploit viruses for cancer therapy. It has become a very exciting possibility.

CEOCFO: Why do you feel that your offering is ahead of the others? Is it better or is it just another form?

Dr. Tufaro: We think that in brain tumors, our first product, DNX-2401 is showing remarkable activity. We have these data in hand now. We see a very clear example in multiple patients where if you inject the virus you can actually follow it and you can see the virus spread in the tumor, kill it and then over a period of months the tumor can basically disappear and the patient improves. We have one patient who is alive nearly forty months after treatment with no signs of tumor re-emerging. One expects a five to seven month median survival in this patient population, who have already failed current standard therapy. These patients have already undergone surgery, radiotherapy and chemotherapy. They have what is called recurrent disease or relapsed disease. Once they fail, then we can treat them with DNX-2401. It is rewarding that about half of our patients are achieving meaningful benefit. Again, we think these data show that our product is active. We have already met with the FDA and we are planning our next clinical trial, called a Phase II trial, to start later this year to test the product on more patients with recurrent disease.

CEOCFO: Has the medical community been paying attention or is it still a bit early?

Dr. Tufaro: Again, that is a great question. We cannot introduce a new drug that no one wants to administer. Physicians have to be able to use it. DNX-2401 is a drug that is delivered by direct injection into a tumor, so you would have a neurosurgeon do the procedure. Brain tumors are treated, virtually one hundred percent, by a neurosurgeon first. They perform surgery to remove the tumor or to do a biopsy, for example. DNX-2401 is perfectly compatible with this workflow. I would say that over the last two or three years there has been a greatly heightened awareness of this field.

Physicians and patients are looking for answers. There are newly emerging drugs called biologics; antibodies and viruses that are used for treating disease. Therefore, I think the idea of oncolytic virus therapy is becoming more accepted and mainstream. I do not foresee any problem with physician acceptance. Amgen is already developing a herpes simplex virus product for melanoma treatment. They bought the program about three years ago, I believe, for about one billion dollars. This could become a major new therapy and we are encouraged by that.

CEOCFO: How far will your current funding take you?
Dr. Tufaro: We have very good investor support. We are mostly venture funded. We can progress through our next two clinical trials with the funding that we are currently raising. We are a very lean operation. We really focus on the clinic; therefore we are able to do things less expensively than some other companies. The other factor is the virus that we use; the adenovirus. It has been tested by many other companies over the past fifteen years for a variety of treatments. The FDA is very comfortable with it. It is also one of the easiest to manufacture, fortunately. Therefore, we kind of lucked out in that regard. Some of those costs, such as manufacturing, are much less for our company than they are for others. Therefore, to answer your question, we can progress through our large Phase II study and show proof of content in the clinic, as well as conduct another small study that we are initiating in Spain in the next month or two.

CEOCFO: What is the timetable for you, assuming that everything works the way that you anticipate?
Dr. Tufaro: If everything works the way that we anticipate, we believe that within two years we would have the data from the Phase II to be able to approach the FDA again to discuss with them the final data that we would need to provide to gain regulatory approval. Again, recurrent glioblastoma is a disease for which there is essentially no standard of care. When you have a recurrent disease there is very little available. The FDA is aware of this and they are willing to perhaps grant something like accelerated approval where you can start to offer it to patients while continuing with clinical development. Therefore, we believe we are on a two year horizon towards that point.

CEOCFO: You personally have extensive history; funding, financing and being involved with biotech companies. What have you learned in previous ventures that has been most applicable for you here at DNAtrix?
Dr. Tufaro: I used to be a university professor and a herpes virologist and worked on cancer as well, so I have both the science and I learned the business aspects after that for the past fifteen years. The single most important thing that I learned and applied to DNAtrix is that you cannot beat good, early clinical data. You need to wait until you obtain strong clinical data before you build a large, very expensive company. DNAtrix made sure that it had some patients that were responding well before hiring many people. Too many times companies build and then wait for data. That is a very expensive proposition and you can run out of money quickly. Without good data you are just not going to be able to get funded. Early on, spend as little as you can to get as much clinical data as you can.

CEOCFO: Why should DNAtrix stand out for investors and people in the business community?
Mr. Tufaro: DNAtrix stands out because we are a very lean company with experienced management. My former company, Neurovir, was the first company to test herpes simplex virus in the clinic for brain tumors. We have a very good core group of investors who continue to support us. I think the quality of the clinical data that was generated by the MD Anderson Cancer Center is just second to none. We work with excellent advisors who look at our data critically. We maintain an excellent product focus on one disease that we think we can get approval for. Clearly, glioblastoma is a disease for which there is a high, unmet medical need. I think we have been very fortunate to see early efficacy in the clinic and that has really allowed us to move this quickly. We are hoping to be able to offer the product to these patients who have very few options. That is very rewarding for the company.

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