CEO CFO

Issue:
June 26, 2009

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Pro-Pharmaceuticals Has Shown In Phase I And II With Late Stage Colorectal Patients That Their DAVANAT® Technology Added To Standard Chemotherapies Can Enhance The Effectiveness Of The Drug, While Reducing Side-Effects – Thereby Improving Quality Of Life

Healthcare
Drugs – Target Delivery
(PRWP-OTC: BB)

Pro-Pharmaceuticals, Inc.

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Dr. Theodore D. Zucconi, Ph.D.
President and CEO, Director

BIO:
Theodore D. Zucconi, Ph.D., is Chief Executive Officer and President of the Company. Dr. Zucconi is presently a Director of the Company, and was President of the Company since October 2007. Formerly, since 2002, Dr. Zucconi was President of Implementation Edge, a management consulting firm that specializes in organizational performance improvement. From 1994 until 2002, Dr. Zucconi served in various capacities at Motorola, including Director of Motorola University. Prior to Motorola, Dr. Zucconi held technical, operational, and scientific positions at Nortel and IBM. Dr. Zucconi received his Ph.D. in analytical chemistry from State University of New York in 1977. Dr. Zucconi also received a Master's Certificate in international management from Thunderbird University and is a Stanford Certified Project Manager.

Company Profile:
Pro-Pharmaceuticals is a clinical stage bio-pharmaceutical company engaged in the discovery, development and commercialization of carbohydrate-based, target therapeutic compounds for advanced treatment of cancer and fibrosis. The Company's initial focus is the development of carbohydrate polymers to treat cancer patients. DAVANAT®, the Company's lead product candidate, is a polysaccharide drug whose mechanism of action is based upon binding to lectins on the cell surface of tumors. This form of targeted therapy may allow for higher doses of chemotherapy administration with no increase in toxicity. The Company's technology also is being developed into new chemical entities to treat serious diseases such as liver and kidney fibrosis. The Company is headquartered in Newton, Mass.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Dr. Zucconi, you have taken on the CEO role recently, what has changed under your leadership?
Dr. Zucconi: "We are less focused on research and development and more focused on commercializing our lead product DAVANAT® for oncology. Therefore, this fits perfectly with my background, because although I have a Ph.D. in chemistry, for the past 20 or 25 years I have been taking products to market and I have been running successful commercial organizations."

CEOCFO: What is happening with DAVANAT?
Dr. Zucconi: "Great things are happening. The first product from our technology platform, DAVANAT, is focused on oncology. It is a drug that is used with chemotherapy to improve the efficacy of the chemo and reduce the side-effects. We recently issued a press release discussing the lack of mucositis with the use of DAVANAT. Mucositis is a serious and common side-effect of chemotherapy. We have completed our Phase I and II trials and we now are designing our Phase III trial to submit to the FDA in the next few months. It will be a relatively small trial, less than three hundred people because our results have been excellent. Statistically, the better the results, the fewer the patients you need. We are working right now to submit the trial to the FDA in the next few months, and possibly even finish the first part of the Phase III trial early next year."

CEOCFO: Would you explain what DAVANAT does, and the effect it has on Mucositis?
Dr. Zucconi: "When people get diagnosed with cancer it is devastating enough, but then they have to make a choice with the doctor of the type of treatment to have. Of course, different kinds of cancer have different treatments, but the most general treatment, especially for solid tumors is chemotherapy. They may have an operation first, but in general, most of the patients for colorectal cancer, breast cancer, lung cancer, will wind up with chemotherapy. Chemotherapy works. One drug called 5-FU, has been used for forty years and is well known. It definitely kills cancer cells. Unfortunately, most of these treatments also kill healthy cells, so while you are

starting to shrink the tumor you also wind up with side effects because you are effecting healthy cells. The typical side-effects are nausea, vomiting, drastic reduction of blood count. One of those side-effects which happens frequently is called mucositis. That is where the chemotherapy actually attacks the mucous membrane lining in your mouth and possibly all the way through your stomach and into your intestines. It can cause ulceration, which can have serious consequences such as bleeding, getting bacteria into your colon. Sometimes the effects so severe that the people can hardly chew food or talk from the pain. The worse part of it is that they cannot absorb nutrients. Therefore, you will see people be treated on chemo losing weight. They don't look healthy because they are having a hard time absorbing nutrients. Some of them will have to have intravenous feedings because the side-effects have their ability to chew and digest food."

CEOCFO: What is DAVANAT?

Dr. Zucconi: "DAVANAT is a natural product that is modified. It is a carbohydrate. We all try to avoid carbohydrates because we know that the body loves carbohydrates and uses them very efficiently to produce fat or stored energy. The body is very specific and understands very well how to use carbohydrates. It is well known that cancer tumors grow faster than normal cells and of course, they need energy to do that, so they love carbohydrates. What DAVANAT® does is interact with the receptors on the surface of the tumor. It interferes with the how the receptors control the tumor activity; how it absorbs the nutrients out of the body, how fast it grows blood vessels, how quickly the cells grow in the tumor and how they metastasize. There is a large body of evidence in the literature describing this from many well-known researchers. We also have published two books on the subject; one on carbohydrate drug design, and one on Galectins. The Galectins are the receptors on the surface of the tumor that specifically interact with one type of sugar, which is a building block of our carbohydrate. Because they love sugar, our carbohydrate attaches or interacts in some way, we are not sure exactly how, with these Galectins on the surface and then interfere with how the tumor does its work. We have shown through animal trials with radioactive tests that the tumor, in the presence of DAVANAT®, increases the amount of chemotherapy taken into the tumor and keeps it in the bloodstream longer. So when the DAVANAT® is administered with the chemo, the chemo stays in the tumor in the bloodstream longer, that would be devastating if you didn't have something to reduce the potential serious side-effects. That is what the data indicates, even though we are not sure how DAVANAT® does this."

"We have shown toxicity improvement of chemotherapies by adding DAVANANT®, reduction of side effects, and we have shown efficacy through increased longevity of those patients in Phase II. What really is important for the patient is the quality of life. We can help them live longer and while they are living longer, we are reducing the side effects of the chemotherapy, so they are really getting a double benefit. The third benefit is that DAVANANT® is a relatively inexpensive treatment compared to some of the standard chemotherapy. So it may add a cost to the chemotherapy, but in essence it is a cost reduction because we reduce the side-effects, reduce the medicine needed to treat the side-effects, and we also may reduce unexpected hospitalization."

- Dr. Theodore D. Zucconi, Ph.D.

CEOCFO: Is there anything now addressing mucositis?

Dr. Zucconi: "People are working on oral rinses that are available as a prophylactic treatment to keep it from happening or from becoming severe. You can treat it in the mouth, but when it is in the throat and down through the digestive system, it is very hard to get a drug in to treat it. That is why it can be devastating to the patient because once you have a serious Mucositis event, it is extremely difficult to treat from your stomach through your intestines."

CEOCFO: You were in Phase II with late stage colorectal patients; why that particular area?

Dr. Zucconi: "The FDA requires new drugs to be tested initially in Phase I or II on late-stage patients because the disease had are already advanced, they have failed previous treatments and they don't have many choices for treatment, if any. The Phase I and II trial that we completed were end-stage patients, in other words they had tried and failed just about every standard chemotherapy. They had all previously failed the chemotherapy drug 5-FU and 70% of them had failed the newer monoclonal antibody drugs. Also, they had all failed multiple chemotherapy regimens before they entered into our trial. Usually when you fail a specific chemotherapy, the doctor doesn't put you back on it because for some reason it has become ineffective. When we add DAVANAT® to the 5-FU, the data shows that not only do they now respond to 5-FU, but we also can reduce the side-effects that they would have been expected to get when they were treated.

When you go for approval of a drug, there are multiple claims you can make. You can claim for example reducing side effects, which would be a safety and toxicity issue. We have shown in animal trials and early-stage trials with humans using a dose escalation protocol, that there is no toxicity of DAVANAT® by itself, and no dose-limiting toxicity level that we have reached. On the other hand it does not have anti-cancer activity until you administer is in combination with the chemotherapy. You can a claim safety improvement, or you can claim efficacy, which is an improvement of the therapeutic effect of the drug or improvement over the standard therapy. This is a requirement to get an approval. In our case, we happened to do both, which is significant. We have shown toxicity improvement of chemotherapies by adding DAVANANT®, reduction of side effects, and we have shown efficacy through increased longevity of those patients in

Phase II. What really is important for the patient is the quality of life. We can help them live longer and while they are living longer, we are reducing the side effects of the chemotherapy, so they are really getting a double benefit. The third benefit is that DAVANANT® is a relatively inexpensive treatment compared to some of the standard chemotherapy. So it may add a cost to the chemotherapy, but in essence it is a cost reduction because we reduce the side-effects, reduce the medicine needed to treat the side-effects, and we also may reduce unexpected hospitalization."

CEOCFO: What are your plans as you go forward in terms of marketing; will you be doing partnerships, pending approval of course?

Dr. Zucconi: "Actually we have a dual strategy. We are talking to partners in the United States, which would be for the US, Europe and Canada. We may try to market it ourselves in the US. We are also pursuing partnerships outside the US. We have a letter of intent with a company that is an established distributor in the Middle East and North Africa. We are talking to companies in Turkey, in Asia, and we are working on a South American initiative. Our goal is to be registered in one country within a year."

CEOCFO: You are working on many levels!

Dr. Zucconi: "These days it is very difficult to have a single strategy unless you have a partner that wants to market and sell throughout the world."

CEOCFO: Pro-Pharmaceuticals has other proprietary carbohydrates; what else do you have going on?

Dr. Zucconi: "Yes absolutely! Oncology is our first target disease, DAVANANT® is our first product. However, carbohydrates are very poorly understood as far as their role as drugs. We have another proprietary carbohydrate we are testing in animal trials to treat fibrosis of the liver. We will also be testing it on kidney fibrosis. You may know that there are many people in the world with hepatitis-C; luckily the incidence in the U.S. is relatively low because we have excellent sanitary conditions. In other countries, China for example has well over a hundred million people with hepatitis-C. Hepatitis-C can be controlled, but not cured. Most of the people who get Hepatitis-C will wind up with fibrosis. Fibrosis is a scarring of the liver when it is damaged. When you insult the liver through alcohol, the main cause of fibrosis would be due to alcoholism. It also develops through obesity which also tends to over tax the liver. Although the liver can regenerate, when the insult is severe or over a prolonged period of time, and the condition becomes too advanced, the main treatment is a liver replacement, which is expensive and not widely available. We have seen through animal trials the ability to stop the progression of fibrosis and actually reverse the fibrosis itself through a treatment with our second carbohydrate drug. In this case, it is the drug. The drug goes to the liver, protects the liver, and allows it to heal itself. We are working with Dr. Scott Freidman of Mt. Sinai Hospital; who is helping us design the trials.

We are not in human patients yet, and we are not sure of the timeframe for completing the animal trials, or when we will be applying for an IND to treat human patients. However, the initial animal trials and safety trials were so significant that we are very excited about the potential to have a significant fibrosis drug down the road."

CEOCFO: What is the financial picture like for Pro-Pharmaceuticals today?

Dr. Zucconi: "The financial markets last year weren't very friendly to small cap companies. This was true especially for small biotech companies. We had a difficult time last year raising capital. However, one of our largest shareholders, who is also one of the co-founders of the company, earlier this year put together a fund that has given us an infusion of cash and has committed to a total of $6 million over this year. We are also looking at other ways to raise capital; through grants, partnerships and distribution agreements. Until you actually start selling a drug or form a partnership with a big company that gives you a significant up-front payment, you burn through cash with no income. We have also announced a rights offering, which is currently on hold. We are looking at multiple options to raising capital, even tough we are more fortunate than many small biotech's because of the commitment from the 10X Fund. We have the potential next year to start selling product."

CEOCFO: Why should potential investors be interested?

Dr. Zucconi: "We now have a clear path to FDA approval. We understand what we need to do and we have had multiple discussions with the FDA. We have enough data from our preclinical, Phase I and Phase II trials which show that we have a significant beneficial effect by adding DAVANAT® to chemotherapy in safety and efficacy. The trial will be relatively small and inexpensive. You might have seen Dendreon, what happened to them recently. We have a strategy similar to Dendreon, whereby they used longevity as their end point in the trial. That is the gold standard; you can treat or shrink tumors, but if the patient doesn't live longer, it doesn't mean much. When you go for longevity as Dendreon did and you show an increase in actual life extension of the patient, that is the gold standard. We have shown in our Phase II trials a significant extension of longevity of these end-stage patients. So now we understand we can reduce side-effects, and we can increase efficacy, so we have a clear path to approval with a relatively small trial for a PK blood test then completing a Phase III based on longevity with less than 300 patients. We are on the verge of going from a developing project, to a commercial company. The majority of the risk for what we have done over the past seven years is now behind us. We have a clear path, a clear understanding; we don't see any major roadblocks to getting approval. We never talk about a timeframe for approval because you are not sure, but we are not talking years, we are talking about a year or so. We think the risk is gone. It is a huge market. We are only starting out with colorectal cancer. Part of our strategy is to increase our oncology markets with other types of cancer and other chemotherapies, so we have a huge opportunity with colorectal cancer, then possibly breast cancer. It should be understood that we are not replacing chemotherapy, we are adding DAVANAT® to the chemotherapy people will be getting anyway."

CEOCFO: Final thoughts; what should people remember most about Pro-Pharmaceuticals?

Dr. Zucconi: "Pro-Pharmaceuticals is entering the next stage of a company; we are now focused on approval and commercialization, most of the development is over. It is a platform technology, and we are not talking about any one drug, we are talking about multiple drugs. In addition, the platform is extendable to multiple disease indications such as oncology and fibrosis and others we have on our drawing board, but right now we are focused on those two. We are very close to being a commercial company in one form or another either through partnerships, direct sales inside the U.S. and in other countries throughout the world."

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