CEO CFO

NORTHWEST BIOTHERAPEUTICS

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With A Platform Technology That Improves Survival Time, Lacks The Toxicity Of Current Chemotherapeutic Drugs And May Be Applicable To Any Cancer, Immunotherapy Company, Northwest Biotherapeutics, Inc. Is Well Positioned For A Breakthrough In This Exciting New Field

Healthcare
Biotechnology
(NWBO-OTCBB)

Northwest Biotherapeutics, Inc.

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Linda F. Powers J.D.
Chairperson and CEO

BIO:
Ms. Powers served as Chairman of NWBio for the last 4 years, before also becoming CEO in June, 2011. She brings more than 25 years' experience in corporate transactions and operations, including more than a decade specializing in building biotech companies through Toucan Capital. Ms. Powers is particularly well known for her experience in building biotech companies that are developing cell therapies, including both immune cell therapies (such as NWBio's DCVax®) and adult stem cell therapies. Such products -- consisting of living human cells -- require fundamentally different manufacturing, storage, distribution and handling than do pharmaceutical drugs ("pills in bottles"). Such living cell products also involve different clinical and regulatory requirements, and different business and cost/pricing models, than traditional drugs. The cell therapy companies which Ms. Powers has been involved in building over the last decade, both in the US and abroad (in Asia, Europe and Israel), are at the forefront of clinical trials and early commercialization. Ms. Powers has served for years on a number of related boards, including the M2Gen Board of the Moffitt Cancer Center, the Board of the Trudeau Institute (a world leader in immunology research) and others. As Chairman of NWBio, she has brought her lengthy experience to bear in helping to shape NWBio's overall strategy and programs. As CEO, she will now undertake operational responsibilities in addition to continuing her duties as Chairman.

Company Profile:
Northwest Biotherapeutics, Inc. is a biotechnology company focused on developing immunotherapy products to treat cancers more effectively than current treatments, without toxicities of the kind associated with chemotherapies, and on a cost-effective basis. The Company has a broad platform technology for dendritic cell-based vaccines. The Company's lead clinical trial, with a growing number of sites, is a 240-patient, Phase II trial in newly diagnosed Glioblastoma multiforme ("GBM"), the most aggressive and lethal form of brain cancer. The Company also previously received clearance from the FDA for a 612-patient Phase III trial in prostate cancer, and clearance from the FDA for Phase I trials in five other cancers. The Company has also conducted a Phase I/II trial with DCVax® for recurrent metastatic ovarian cancer.

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

CEOCFO: Ms. Powers, what attracted you to Northwest Biotherapeutics?
Ms. Powers: What attracted me to Northwest Biotherapeutics was that they have a platform technology that should be applicable to pretty much all cancers, and which is offering really a major improvement in survival times for patients, with no toxicity. The drugs that are out there today typically only add ten weeks of survival and they have a heck of a toxicity profile. Therefore, the combination of the effectiveness, the lack of toxicity, and the fact that it may be applicable to any cancer really was very exciting.

CEOCFO: Would you explain your technology?
Ms. Powers: Our technology restores the functioning of the patient's whole immune system, to attack the cancer in a natural way. What is happening in a patient who has cancer is that there is a selective blockage going on. The tumor is actually very clever. Tumors have ways of jamming the signaling that your immune system needs to use, just like an army on the battlefield radioing to each other. The tumor can also put out decoy signals, telling your immune system that everything is fine. Being a cancer patient is not like being an HIV patient, because with cancer you do not get sick with every opportunistic infection. It is

just the cancer that is not getting attacked. What Northwest's technology does is restore the signaling and give the key signals to the master immune cells that the tumor has been blocking. There are basically two signals, one is to shift out of surveillance mode into attack mode, and the secondly is to attack what? Northwest's technology gives the immune cells the biomarkers to tell it what to attack: the biomarkers on the cancer. Once the immune system gets the signals it needs, just like the army on the battlefield when it gets its battle plan, its marching orders, it then goes right to work in a natural way and kills the cancer cells.

CEOCFO: Has there been much research attempting to do what Northwest Biotherapeutics is doing?

Ms. Powers: There has been so much research. In fact, there has been more than one hundred years of research. The idea of immune therapies for cancer goes all the way back to the late 1800's, when a doctor named William Coley had some pretty striking success treating patients with certain kinds of immune therapy. However, things were not very well controlled in those days and even he was not sure what he did and had trouble replicating it. Ever since then, it has been a holy grail of the research community and the medical community to figure out enough understanding of the immune system to be able to mobilize it and harness it to attack cancer. After all these decades of research, we finally have gotten enough of an understanding to begin making it a reality. It is really exciting.

CEOCFO: What is the key to the Northwest technology?

Ms. Powers: The key to the Northwest technology was figuring out number one, which type of immune cell is the master immune cell. In other words, who the General of the Army is, because if you are going to give the key signals, the marching orders, you have to give them to the right party who can implement them. Therefore, one key thing was figuring out that the dendritic cells are the master cells of the immune system. The immune system has so many players. It is like a huge diverse army with all different kinds of foot soldiers, tanks, artillery, airplanes and everything else that you are familiar with. You have T cells that you hear about with HIV, and B cells that make antibodies, and natural killer cells and others. There is a bewildering number and diversity of players, so the one key thing that we figured out is the master cell that needs to receive the signals.

The other key thing that we figured out was what we already went over: namely, what is the problem in the cancer patient? We know that the patient's immune system is functioning -- it is still there-- because the patient does not have the flu every week. So what is the problem? A lot of other companies and other products were designed to take the same approach as the vaccines that kids get, such as preventive vaccines for infectious disease. What those vaccines do is they try to make the signal louder; they try to amplify the signal. As we already discussed, Northwest's view of the problem that needs to be addressed is that it is a blockage in the communication flow of the signals. It is like the radios went out on the battlefield or the phone was unplugged from the wall. It does not matter if you shout or whisper: if the radio is out, shouting or amplifying the signal is not going to do anything. So the other companies that took the approach of amplifying the signal, their trials all failed, and they did not achieve clinical results. In contrast, our approach where we are restoring the flow of signals that I described is like turning the radio back on, or plugging the phone back into the wall, so that now the message is getting through. It is a message that the tumor was blocking, which is what the immune system needs in order to do its job. This approach seems to be working well.

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CEOCFO: Where are you in the process?

Ms. Powers: We are pretty late-stage in the process. It takes an exceptionally long amount of time and an exceptionally large amount of money to develop a new medical product. It takes more than a decade of time and usually hundreds of millions of dollars. We are more than a decade into this. We spent more than a decade in clinical trials and we are now in what we hope will be the last clinical trial for the lead product that we have, which is an immune therapy for brain cancer. So, we are now on the home stretch. We are down to the last eighteen to twenty-four months after more than a decade of work up till now.

CEOCFO: Why did Northwest Biotherapeutics select brain cancer as its first target?

Ms. Powers: Because brain cancer is a much bigger problem and unmet medical need than people realize. Brain cancer comes in two forms. First is primary brain cancer where it starts in the brain. That is where it first appears. The other type is metastatic, meaning the cancer started somewhere else first (breast, colon, lung, and so on) and it spread through the patient's body. When that happens, eventually it ends up spreading to the patient's brain and that is actually what kills the patient. Both types of brain cancer are a very severe unmet medical need. In the case of primary brain cancer, when the cancer first shows up in the brain, there is a particularly aggressive form of this that goes under the initials GBM, which stands for Glioblastoma multiforme. This is one of the most lethal cancers there is, as it kills people in fourteen months. It is on a par with pancreatic cancer: the worst of the worst. By

demonstrating the strength and effectiveness of Northwest's immune therapy in such a bad cancer that moves so fast in patients, we can start with a major impact in the marketplace. Also, in business terms, the regulatory pathway is streamlined for products that are for particularly bad diseases like that.

CEOCFO: What is the competitive landscape?

Ms. Powers: Certainly, there are other companies and academic groups working on immune therapies similar to this. There is never a total absence of competition: there is no competition you are probably working on something that may have a questionable market. In terms of the other competition, the most important point is that, out of all the clinical data that has been reported publicly, the technology of Northwest has produced the longest survival extensions in the patients by quite a margin. There are competitors taking approaches where the immune therapy is similar. For example, there is another company developing an immune therapy for brain cancer where it is partially personalized: where the immune cells are personalized, but the biomarkers of the cancer are off the shelf (synthetic). Northwest's product is fully personalized. In our case, the biomarkers are from that patient's own tumor, so they are definitely a fit. Again, we have longer survival in our patients than the product that is only partially personalized. There are also companies developing immune therapies that are not using the immune cells themselves, but are using just some of the signals, the biochemical compounds that are signals themselves. Those have not tended to work very well. They have not had very much extension of survival. But who knows, with some further tweaking, maybe a later generation of that that type of product might be improved. There are also companies developing similar immune therapies for other cancers. There is one developing for ovarian, and there is one developing for kidney cancer. It is early days right now. However, the thing that we think is the most important is what the data shows and what the actual clinical results are. So far at least, the longest extension of patient survival with no toxicity, among all the publicly reported data, has been Northwest.

CEOCFO: Why was this the time for you to take over as CEO of Northwest Biotherapeutics?

Ms. Powers: We are entering the home stretch now. These next twenty-four months are going to be the real inflection for this company. In the prior years, I would say the scientific component of the company's operations was maybe a bigger portion of the focus. Now, it is absolutely execution, execution, execution. It is the operational aspect of completing the clinical trial, which is a huge managerial task with a lot of moving parts. The science is already established at this point. So, the gentleman who was serving as the CEO for the four years prior to my stepping in, in June, was the original scientific founder of the company. We reached the natural transition point that every company that continues onwards reaches, where the nature of the operations shifts from being more scientific to being more operational, logistics, management, and business strategy. There are also a lot of issues in regard to the market strategy, the pricing strategy, the reimbursement strategy and the manufacturing. Those are the dominant issues now, for the next twenty- four months, as we go through our inflection, and that fits my background from the business world.

CEOCFO: That is a transition that a lot of companies do not make when they should!

Ms. Powers: It is always a big transition to go through. Happily, in our case, the scientific founder himself was an enthusiastic supporter of the transition. So, that was great.

CEOCFO: What is the financial picture like today for Northwest Biotherapeutics?

Ms. Powers: The financial picture is stronger than it has been at any time in the last five to six years, which is quite exciting for us. Early in the summer we closed two significant financings -- significant in the scheme of things for the company. Those two together totaled about $7.5 million, and we also entered into an agreement for a financing facility for up to $25 million on top of that $7.5 million. That facility is essentially equivalent to a shelf registration. With those financing mechanisms as well as some ongoing interest from investors who already have positions in the company, we feel like we are really strongly positioned financially for this home stretch push. I have to say that, like all small biotech companies, for Northwest the Great Recession was really tough, and the company made it through that very, very tough period on a shoestring, while a lot of small biotech companies did not make it through. We are quite excited to have come out the other side and now to have these major financings in place. So, things are looking bright.

CEOCFO: What is in the pipeline for Northwest?

Ms. Powers: The pipeline is amazing, especially for a small biotech company like this. The most important piece of information about the pipeline is that Northwest Biotherapeutics has two programs that are at late-stage clinical trials. It is virtually unheard of with a small biotech company to have two programs reaching the late stage simultaneously. Even Dendreon, the flagship company in this space, only had one late-stage program. In Northwest's case, the second late-stage program is for prostate cancer, and we have a large 600 patient Phase III clinical trial previously cleared by the FDA. Phase III is the last phase of trials. That is exciting. So, brain cancer and prostate cancer are Northwest's two late-stage programs. In addition, we have completed a Phase I/II trial in ovarian cancer and we have FDA approval to proceed with Phase I trials in five other cancers. So, it is quite an extensive pipeline.

CEOCFO: How do you as CEO deal with the frustration knowing you have something that could do so much good and yet the process is so long and drawn out?

Ms. Powers: Some days it is so heartbreaking, because patients are so much in need of better treatments than what they have available today. These immune therapies are treat-

ments that will give them longer extension of survival, and normal quality of life, so they are not spending that whole extension of survival throwing up all day, as the immune therapies are non-toxic treatments. It is very difficult to be a patient and to wait while new therapies go through a process taking more than a decade. I would like to see these proceed twice as fast, and finish in half that time. We do have to remember, though, that this is pioneering an entirely new category or type of treatment of cancer. This is similar to where antibody drugs were twenty years ago. The drugs that we are familiar with today, such as Herceptin, Avastin and Erbitux -- those drugs consist of antibodies and that was a whole new category of drug twenty years ago. Where we are today is the dawn of a whole new category of these active immune therapies, and I think the timelines will get faster as you get into the second, third, and fourth product. Therefore, we kind of say to ourselves that pioneering takes extra effort. It takes extra time to pioneer, and we are paving the way for faster timelines to come after this hopefully.

CEOCFO: There are many companies in your sector, why should potential investors pay attention to Northwest Biotherapeutics?

Ms. Powers: Biotech investments are high-risk/high-return investments. However, Northwest Biotherapeutics has survived, produced strong results and gotten to such a late stage in the process, where we have greatly reduced the risk: “de-risking” as the investor community likes to call it. In addition to the de-risking, investors can still have the upside as the market cap of Northwest is still very low. There are not very many industries where you can get the kind of returns that you can get in the biotech industry. The worrisome thing for an investor is when the company is at an earlier stage and has not been so de-risked yet. Northwest has now reached the stage where it has consistent, strikingly positive results across multiple different cancers, and across many years, with a decade worth of clinical trials. Yet, as just mentioned, Northwest’s market cap has not yet gone through its inflection, so the whole upside is still there. That is the kind of combination of circumstances that is well worth looking at for an investor.

CEOCFO: Final thoughts, what should people remember most about Northwest Biotherapeutics?

Ms. Powers: I would just refer your readers as a comparison to look at the inflection, the value run-up that Dendreon went through when it reached the end of its late-stage clinical trial and had a successful outcome of that trial. They went from a market cap of $300 million to a market cap of $5 billion and that is an amazing upside potential. In the clinical trials Northwest has conducted so far, the length of survival extension that Northwest has produced in prostate cancer patients is considerably longer than even the survival extension that Dendreon produced, so stay tuned!

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