

Using A Different Approach Provectus Pharmaceuticals, Inc. Has Been Able To Develop Small Molecule Drugs For Cancer And Psoriasis That Will Target The Diseased Cells And Leave The Normal Cells Untouched

**Healthcare
Drug Manufacturers - Major
(PVCT-OTC: BB)**

Provectus Pharmaceuticals, Inc.

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**Dr. H. Craig Dees, Ph.D.
Chairman and CEO**

BIO:

Dr. Craig Dees, Chairman and Chief Executive Officer, Provectus Pharmaceuticals

Craig Dees, Ph.D., has spent more than 20 years in senior management positions at Photogen Technologies, Inc.; the Oak Ridge National Laboratory; LipoGen, Inc.; and TechAmerica, Inc. Dees was a founder, senior scientist and founding director of Photogen before Provectus was formed. His responsibilities have included product design and development in the fields of ethical vaccines, cosmetics, hu-

man diagnostics and over-the-counter pharmaceuticals. His development record includes the first live viral vaccine produced by recombinant DNA technologies and the first recombinant antigen human diagnostic assay. Dees has also successfully licensed a number of proprietary cosmetic products. In addition to design and development activities, Dees has been responsible for business and market applications, regulatory affairs, and commercialization of human and veterinary medical products. Awards include an R&D 100 for an industrial enzyme, an Inventor's Forum New Product Award for a skincare product, and a First Saber Award for outstanding research in virology. Dees holds a Ph.D. in molecular virology from University of Wisconsin, Madison. He earned his Master of Science degree in immunology from Auburn University, and his bachelor's degree in microbiology from Brigham Young University.

Company Profile:

Provectus Pharmaceuticals, Inc. (OTC: BB - PVCT) specializes in developing oncology and dermatology therapies. Its lead oncology agent, rose bengal based PV-10, is designed to selectively target and destroy cancer cells without harming surrounding healthy tissue, significantly reducing systemic side effects. Its oncology focus is on melanoma, breast cancer and metastatic liver cancer. The Company has received orphan drug designation from the FDA for its melanoma indication. Its lead dermatological drug, rose bengal based PH-10, also targets abnormal or diseased cells, with the current focus on psoriasis and atopic dermatitis. Provectus has recently completed enrollment in three of its Phase 2 trials -- PV-

10 as a therapy for metastatic melanoma, and PH-10 as a topical treatment for atopic dermatitis and psoriasis. It has also recently initiated a Phase 1 trial for PV-10 for liver cancer. Information about these and the Company's other clinical trials can be found at the NIH registry, www.clinicaltrials.gov.

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

CEOCFO: Dr. Dees, you are opening a new front on the war against cancer; will you give us a brief overview of what you do?

Dr. Dees: We specialize in developing targeted therapies for oncology and dermatology. Our oncology therapies are spectacularly different from what has been done in treating cancer in the past. Our lead therapy, PV-10, is designed to selectively target and destroy cancer cells, without affecting surrounding healthy cells. Similarly, some of flaws in the treatments for psoriasis and other chronic conditions are very much like those within cancer therapies. Our treatment for dermatological diseases, PH-10, also targets diseased or abnormal cells. We believe the very first step to fixing any of these flaws is to improve specificity of the treatment, and we believe we are accomplishing that. What we know how to do is make a small molecule drug virtually absolute only for diseased tissue which won't touch a normal cell right next to it. (So you have little or no side effects.) There are only minimal or trivial side effects and there is also a tremendous up-sweep in effectiveness of the drug because it targets only diseased cells. We know how to do this for small molecules. We

know how it works, and how to make new targeted drugs. We have a whole suite of these drugs that attack the root-cause problem for many diseases that are very difficult to treat.

CEO CFO: How does your platform work?

Dr. Dees: What our technology does is very different. It doesn't kill by poisoning, it doesn't go into the nucleus. There is what you might call a stomach inside the cell, called the lysosome, which contains hydrolytic enzymes. It degrades DNA, proteins, or fats and oils that are its foods. What our drug does is selectively go into diseased cells, where it localizes in the lysosomes, but it doesn't go into the nucleus so we don't have to worry about it being mutagenic or carcinogenic. You will see these lysosomes rupture and essentially you get the cancer cell to eat itself in a very precise way. So the drug triggers a very natural process to get rid of cancerous cells. It is not a poison or a carcinogen and only targets diseased cells.

Most of the agents that are currently available to treat cancer and chronic conditions are poisons and are some of the most horrific carcinogens too, such as in therapies 5-FU and Mitomycin C, that we use to treat cancer. Therefore, one of the possible long-term results is that even if these treatments put you in full remission, twenty years later you may get a treatment-induced tumor and succumb. The side effects are a product of how these poisons kill. In fact, what is used to kill cancer with most of the current treatments is very similar to what was used for things that couldn't be treated in the past, such as syphilis, or parasitic infections. A terrible poison would be used to see if we could kill the parasite a little bit faster than we could poison the patient to death. So typically, out of 100 patients, the results you would get is that you miraculously cured one, but you would poison nine or ten of them to death and you made the other ninety really sick because the differential just isn't there. Some of our radiation and chemical treatments are only 1.1 or 1.2 times more specific for cancer cells than normal cells. So you really hurt the patients and may get poor results.

CEO CFO: What are you working on right now with PV-10?

Dr. Dees: Our PV-10 drug has attributes similar to both antibiotics and vaccines. First of all it has shown activity in every tumor we have tried it on, in animal models, in animal patients and now in various human tumors. It has worked in melanomas and soon we are going to treat liver tumors. Most liver tumors seen in the US didn't originate in the liver but metastasized from other places like the colon or breast. Hopefully, we can demonstrate the same results in humans as those that we have seen in animals. PV-10 thus far looks very much like a broad spectrum antibiotic for treating cancer. Secondly, this treatment does something you haven't seen with other therapies. We have demonstrated remote tumors, deep visceral tumors and tumors in the lymph nodes clearing up in both animals and humans. So it induces a vaccine-like effect too. In other words, it appears from

We have solved the essential problem that other scientists and companies have not been able to solve; that is to make a cancer specific drug. We have found out how to make it simply, pragmatically and inexpensively; namely, to build it and make a very safe molecule.

- Dr. H. Craig Dees, Ph.D.

our data in animals that it is stimulating the host's defenses, which most other treatments don't. Most other cancer treatments wound or annihilate the natural defenses on the first shot. In contrast, treatment with PV-10 appears to stimulate natural defenses in a vaccine-like fashion and you can see remote tumors that weren't treated, regress. We have completed enrollment in our Phase 2 trial on melanoma. 80 patients are in our study, and the first 40 had a 60% objective response rate and a 75% rate of loco-regional control of treated lesions. A substantial number of patients exhibited evidence of a bystander effect, where it appears that PV-10 ablation induces the subject's immune system to fight untreated tumors elsewhere in the body. We are preparing to meet with the FDA to define the future direction that we are going to take with regulatory agencies.

CEO CFO: Do you have orphan drug designation now?

Dr. Dees: Yes, we do have orphan drug designation now, and it was one of the first things that we accomplished. We also have a compassionate use program in both Australia and the US. After the trials, when our investigators saw all of the results, they asked us to make the drug available for their patients, which we did through the compassionate use program. We have treated a substantial number of patients under this program. These patients either came from our Phase 2 trial or hadn't been treated before after we had completed our Phase 2 enrollment. We have treated more than 27 people under our compassionate use program. Again, world-class physicians, leaders in the field requested this, and we were able to make the drug available for their patients.

CEO CFO: Tell me more about the business strategy, what is happening in the next year or two years?

Dr. Dees: The business strategy from day one hasn't changed. What we do best is we are tremendous innovators. We are tremendous inventors. We think of novel ideas. We have projects that we haven't even worked on yet in our file cabinet of inventions because we are so focused on the current clinical trials. We are not marketers. We are scientists and we can hire marketing types. We can try to build distribution networks, but those networks already exist in the industry. Our strategy from day one has been to combine the two things: we do innovation, and then we either out license the drug or sell it through distribution agreements, or even sell out the company to one that has that marketing and distribution network in place. We are now up to the point where a number of our technologies are available for licensing. We are actively seeking a licensor or purchaser of our whole derma technology. So the strategy from day one is still continuing as we speak.

CEO CFO: Would you tell us more about the dermatology products?

Dr. Dees: Some of the problems of hard-to-treat derm diseases like psoriasis are quite similar to cancer. If you look at psoriasis, the current standard is systemic therapies with broad immune-

suppressants, and if you watch the TV ads you will see the disclaimers, such as you might get TB, or lymphoma. One of the fundamental problems with these psoriasis treatments is the systemic route of delivery, and the second problem is that the therapies are not specific, again identical to the case with cancer, so the fix is exactly the same. For dermatitis, we changed the route as we did cancer, put it on topically and you have a drug that is absolutely specific for the disease that is not going to produce broad-scale immunosuppression. It is not even taken up systemically; but if it did it would be excreted intact in about fifteen minutes through the liver. So you fix the same problems, you get a topical therapy where you don't have the side-effects and you are not going to be sitting around waiting to see if lymphoma is going to develop. So with the chronic dermatitis diseases the essential problems are the same and the essential fix is the same, and again it is a very specifically targeted drug.

CEOCFO: Drugs without side effects, it almost doesn't seem possible!

Dr. Dees: PV-10 has very minimal side effects and is very well tolerated. It is something that we have been looking for in the medical and scientific community for years. Some of the ways that have been tried is to use very specific monoclonal big protein targeting agents and complicated encapsulation vehicles. However, these are technically complicated and I would call them awkward and expensive. We have learned how to do this on a very small molecule, 1000 molecular weight, so it just goes very specifically to the diseased cells. Once you solve that problem, the other problems essentially vanish or become minimal. In addition, we can make these new compounds at will. We can do this at will because we know how it works; namely, exactly why it goes to these diseased cells. I think back to the 1990's, when there was a scientist who got a human lipoprotein, a huge molecular weight structure. He made it very toxic by peroxidizing it. He was able to treat combi-

nations of cancer cells and normal cells in a Petri dish (tissue culture). He showed back then that that very toxic moiety would kill only the cancer cells, and wouldn't touch the normal fibroblast next to it; and he showed exactly where it went. Ours works just like that, it goes to the lysosomes; it is working by the same mechanism. However, that is not a product; you can't put human lipoproteins in a bottle and sell it. What is different about what we have is we know how to make a small molecule do the exact thing that he saw way back when, and that is a product that you can protect, ship, tag and label. In addition, you can make it inexpensively and it has low regulatory barriers. It is a big leap, but again there is precedence in the scientific literature, just not a practical solution of how to do it, but a very similar demonstration to ours, which is practical.

CEOCFO: What is the financial picture for Provectus Pharmaceuticals?

Dr. Dees: The financial picture is good. We have \$4 million in cash and no debt, as of the end of September 2009. With only \$300,000 more needed for the completion of our current clinical trials, we are in good financial shape. Our burn rate is minimal, approximately \$233,000 per month.

CEOCFO: You said the medical community is paying attention, is the investment community paying attention as well?

Dr. Dees: Yes they are. Two major independent analysts who are very knowledgeable of the industry cover us. We also have had numerous investors interested in funding the company, and who have participated in funding. In addition, we also have approximately 20 million warrants that are close to being converted.

CEOCFO: Why should investors be interested in Provectus?

Dr. Dees: We believe we have solved the essential problem that other scientists and companies have not been able to solve; that is to make a cancer specific drug. We

have found out how to make it simply, pragmatically and inexpensively. Many other have tried and failed, but we have succeeded, and that is what makes us different. From what I see currently in our melanoma trials, we are confident and encouraged by the data and believe we can make a difference. What you look for in a new drug is the ratio of benefits versus side effects, and our drug's side effects are near zero, and the results speak for themselves. I believe if investors look at our Phase I and II results, Provectus is quite compelling as an investment. We are financially sound and are entering discussions with the FDA. Not only has interim data published for the first 40 patients demonstrated a strong objective response rate, but also we are pleased that the compassionate use protocol also is doing extremely well. This is a very exciting time for Provectus and our investors.

CEOCFO: In closing, how do you contain your frustration when you have an effective treatment and you cannot get it to people as quickly as you would like?

Dr. Dees: That is a very good question! I have taken calls over the last two days from maybe six melanoma patients and three high-tech scientist friends of melanoma patients, asking about this drug. In fact, I had two or three patients that said, "I researched everything, I have stage-IV melanoma and I have come to the conclusion that this is the thing for me to do personally." Initially that would have been terribly frustrating, so based on our trial results, we saw that there were low side-effects, everything appeared to be low risk so we responded to the physicians' and the patients' requests to make this drug available on a compassionate use basis. So that has lessened our frustrations as inventors, but this is a commercial enterprise and we have a fiduciary responsibility to our shareholders as well as ethical ones to the doctors and patients, as well as to the FDA. So we weigh and balance all our responsibilities continuously.



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