

THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

Provectus Pharmaceuticals, Inc. (PVCT.OB)



PETER R. CULPEPPER, CFO and COO of Provectus since February 2004, has spent 20 years in the financial field working for a wide range of companies and industries in the U.S. and abroad, especially high-growth startups. His experience with for-profit companies ranges from private startups to publicly traded, global conglomerates. He has also worked with large non-profits and a national CPA accounting firm. Mr. Culpepper led the national operating unit of a \$1 billion publicly traded telecommunications company, as well as numerous operating units in Eastern Europe for a global telecommunications company. He handled the capital reporting process for a \$5 billion global construction project and the formation of systems for a division that grew \$150 million in revenue in two years. Previous employers include Neptec, Inc., a privately held optical networking component manufacturer, Metromedia Companies and PageNet, the largest wireless messaging company in the world. Mr. Culpepper taught

undergraduate and graduate business courses for the University of Phoenix Online. He is also licensed as a Certified Public Accountant in Maryland and Tennessee. His professional affiliations include the American Institute of Certified Public Accountants, Financial Executives International and the Financial Executives Networking Group. Mr. Culpepper holds an MBA in finance from the University of Maryland, and he earned an AAS in accounting from the Northern Virginia Community College in Annandale, Va. Mr. Culpepper received a bachelor's degree in philosophy from the College of William and Mary.

SECTOR — PHARMACEUTICALS

TWST: Let's start with a brief history of Provectus and the concept behind your technological platform for drug development.

Mr. Culpepper: Provectus Pharmaceuticals is a development-stage company that has been in existence since April 2002. Since that time, we have been developing drugs for two main therapeutic areas, oncology and dermatology. Our lead oncology agent, PV-10, is being developed as a therapy for several different types of cancers, but we are farthest along in our therapy for metastatic melanoma. And then we have another compound, PH-10, which is being developed for serious skin diseases like psoriasis and atopic dermatitis, which is more commonly known as eczema.

TWST: Would you comment further on your clinical programs? Are you happy with the way things have been going up to this point?

Mr. Culpepper: Yes, our two therapeutic areas are each in categories that have multibillion-dollar revenue potential, so they are very large markets. We have completed enrollment in three Phase II studies, one for metastatic melanoma, and the others for atopic dermatitis and psoriasis. And we accomplished all of these milestones in the last five months. We have also treated all patients in the PV-10 trial for metastatic melanoma. The Phase I trials were to determine safety, while Phase II trials determine efficacy. So as soon as we assess the data for these three Phase IIs, we're in a position to enter into the final phase, Phase III, for each of these. So

we have advanced a long way. From a corporate standpoint, after the completion of Phase II trials is when big pharmaceutical companies generally like to do deals. And for a small company, that's very important. Provectus would consider partnering with a large entity to license our dermatology drug for eczema and psoriasis. The results of the Phase II data play an important part in the partnering process. We would also consider partnering for our oncology therapy. In terms of timing, our first partnership or licensing agreement would probably be for our dermatology therapy. So we're in a very good position, well advanced in the clinic, and we're very happy because the drug is working very nicely in cancer and dermatology. We can see it working already. The best point about Phase II for us is we've already seen and presented interim data for PV-10 for metastatic melanoma. We know it's safe, and we know it's working.

TWST: Is there a common science or technological platform that ties these two products together, the PH-10 and the PV-10?

Mr. Culpepper: There is. The active pharmaceutical ingredient, the API, is the same for both types of drug product candidates, and that is rose bengal. While it is the same API for both drugs, rose bengal is used in different formulations for the two drugs. For oncology we use a high concentration — 10% of the drug in a saline formulation. So the drug is a very dark red color. For dermatology it is a 10,000 times-less concentration — so 0.001% for dermatology — and is light pink in color. Rose bengal is a fascinating molecule. It is a light-sensitive molecule, that's why for dermatology, where you apply the drug on the surface,

directly on the psoriasis and eczema, you just need a small amount in the formulation because the light comes in and activates it, and then that kills the improper immune response for psoriasis and eczema. That's the problem — the plaque, the scruddy skin is not what it should be. And so our drug kills off the bad response and allows the body's skin to properly grow, and you have a nice replacement skin. So we modulate the immune system for the dermatology, and that's done by light. But inside the body, for solid tumors like melanoma as well as for a number of other tumors, including liver, for which we just began a Phase I study, and recurrent breast cancer, for which we have completed the Phase I study, you cannot get light to it. So we used a higher concentration, and the drug works in a way whereby it goes across only the diseased cells. And then it targets only the diseased cells, and it causes those diseased or cancerous cells to destroy themselves. So it helps by allowing the drug to go into the cancer cell, and the cancer cell kills itself as it should have in the first place because it's a bad cell. And then the immune system sees the destruction, comes in, cleans up the mess, and goes out and kills the metastasis, which is the proper response of the immune system. So in both cases, cancer and dermatology, our drug is helping the immune system to respond properly, and that's a great similarity between the two disease classes. And it's interesting because some popular psoriasis drugs now that are sold in the market suppress the immune system, and some have been reported to cause blood cancers. So people have always seen that there's a linkage between the immune system and cancer, and it's just ironic that the current drugs in the market for treating psoriasis are horribly tough on the immune system. And one of the warnings for taking those types of psoriasis drugs is actually a blood-related cancer.

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TWST: PH-10, your lead dermatology agent, is a topical treatment for plaque psoriasis. How does the FDA typically respond to topical treatments?

Mr. Culpepper: Well, that's good a question. The FDA has been very accommodative in the sense that in our studies, we are allowed to apply the drug on a daily basis for 28 days. So the FDA knows, based on our Phase I data, which was very good, that the compound itself is very safe, as there's a lot of good toxicity data. So the FDA allows the physicians to have their patients put it on once a day because it's safe and there is not a concern of the drug going below the skin. So it's very simple to use; it just needs to be applied. There's not an injection as is the case with a number of other psoriasis drugs. And so, therefore, it's straightforward and has more leeway from a clinical trial standpoint. If we did want to use it more than 28 days, which we might, the FDA would want us to do more extensive support data. We don't expect a problem from this, but we will go through additional data just to support that you can use it more than 28 days. But our study for eczema, and we've already talked about the data, shows that it works applying it once a day for 28 days. And we expect the same thing from this psoriasis study, for which we just announced the completion of enrollment.

TWST: Will these compounds ultimately replace a current treatment?

Mr. Culpepper: I would say the answer would be "no" because in oncology, for metastatic melanoma in particular, it's a true unmet medical need. There is no current standard of care for Stage III or Stage IV melanoma. Of course, for initial stage melanoma — Stage I and Stage II — surgery is the standard of care. For Stage III and Stage IV/recurrent, there is no standard of care. So there is room for new products to come in. You see there is nothing to displace because currently the therapies are very toxic chemotherapy agents, and they are not used very often because they're not really suitable. So if you look at the detail of the National Can-

cer Center Network to see what is recommended for physicians to use, there is a recommendation that they look to clinical trials just because there are no suitable alternatives for metastatic melanoma. And that's the case for a lot of recurrent cancers, of course. For psoriasis and eczema, which are very large markets, there are very high revenue-producing drugs to treat psoriasis and eczema. However, it's still judged to be a significant unmet need because the current drugs that are approved for psoriasis and eczema have the black box warnings and are not judged to be appropriate to use on an ongoing basis because they can cause problems. There is the potential risk of cancer and potential toxicity issues for the body. They can cause thinning of the skin, which is a whole host of challenges for ongoing treatment. So that's why the clinicians and our investors are excited about our drug because it's so safe.

TWST: Are there any companies working along the same lines as Provectus? If so, what are your advantages over them?

Mr. Culpepper: We are an unusual company in the sense that our molecule, rose bengal, is the basis for both the oncology and dermatology drug product candidates. The way that it works is a physical chemistry approach. Most other oncology/derm companies that we know of that are Phase I or Phase II trials use traditional biochemistry approaches — either biologics and agents that target particular pathways, particular receptors or enzymes, or the traditional genetic engineering approach to targeting. We are going completely opposite that approach, and thus we have a true, unique approach because we approach cancer and derm/skin issues from a physical chemistry. It's the way a molecule interacts on a physical chemistry basis rather than trying to pick a molecule or pick an agent that looks at a particular pathway or a biochemistry approach. So it's a fundamental

difference in how we approach it. And to our knowledge, none of our competitors are looking at a physical chemistry approach. Our approach is not in the mainstream. This is not the well-beaten path; we're taking a completely different approach, and that's unique about Provectus as far as we can determine. And part of the reason you could say that's unique in and of itself is that we have a molecule that's never been used before yet has existed for decades — that's rose bengal. It's been around as a diagnostic agent for decades. No one figured out how to use it as a therapeutic, or else it probably would have been tried a long time ago.

TWST: Now that the trials have gone well, will partnerships be a part of your developmental plans?

Mr. Culpepper: Yes, definitely. As soon as we have the data on the psoriasis trial completion that we recently announced, for which we expect interim data in the not-too-distant future, we plan to retain a financial adviser, assuming that it's good data. We expect the psoriasis data to be good, just like we expected the atopic dermatitis data to be good, which we showed top-level at a conference just last month. So we expect the data to be good for both of our dermatology indications. On the basis of that Phase II data, we plan to enter into discussions for potentially licensing PH-10 to treat those two indications. Also we believe PH-10 could be applicable for a number of other dermatology issues, including wound care, MRSA and severe acne. So we would expect to enter into license discussions soon and are currently under NDA with a few derm players. So we are serious about licensing PH-10 on the basis of the Phase II data, and that's of course assuming the data is as good or directionally positive for the psoriasis results as we already see with the eczema results. So yes, the answer is "yes" for dermatology. And for oncology, we plan to develop the drug further ourselves. And what I mean by that is we're meeting with the FDA and talking to them about the regulatory pathway. We're seeking accelerated approval for melanoma because it's a deadly disease. Once you get melanoma, current

protocol is to cut it out first. Then when it keeps on coming back, it's judged to be recurrent and there are very high mortality rates. Your chance of living five years once you get recurrent melanoma is only 15%. So your odds of living a long time decrease dramatically once you get recurrent melanoma. Because of that, the FDA allows for accelerated approval, and we are seeking that. If we get that, then we don't need to do a Phase III and can immediately pursue a New Drug Application and commercialize it even as soon as the end of next year in the best case scenario. Worst case, which is still tremendously good, is that we'll have to do a Phase III. And at that point, we could even partner with a large company or take it ourselves to Phase III, since we have the capability to do that ourselves.

TWST: Because your solution uses rose bengal, which has already been approved for varied uses, does that give you a head start when filing for final FDA approval?

Mr. Culpepper: I would say its safety profile is a plus. There is a lot of safety data because of the prior use of rose bengal that helps out the case for using it tremendously, because the FDA knows that thousands of people over decades have used it without any issues at all. So it's very, very well-known, well understood. It's not a fancy biologic, meaning that it's not complicated. It's straightforward, it's stable, people are comfortable with it because it's not quirky, and it has decades of use. So that helps out the message from a safety standpoint. It doesn't help us so much on the efficacy standpoint because it's never been used as a therapeutic; it was only used as a diagnostic. Now a lot of it was put in the body. They actually directly injected it. In one diagnostic, they would directly inject it into your vein, so they'd put it intravenously. And then it's been used in the eye, which is interesting. People have used it for different applications, and it's been shown to be safe. So it helps us again

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on the safety. And physicians have all heard about it in the past and are comfortable with it. They've especially heard about how it's used in the eye, and they are comfortable with it themselves. So it kind of just opens doors so people would say, "Oh yeah, rose bengal, I used it in or heard that it was used in the eye," or "I heard it was used as a liver diagnostic for decades." Physicians, because it's such a widely used drug in the past, pick up on that, and they say, "Yeah, I can see how you increased the concentration. It makes sense you could use it in cancer. I wouldn't have thought of it myself, but now that you mentioned it and you could show me the data, that makes sense." And that's how we got the top melanoma physicians to be in our study — literally, top in the world here in the States and outside the U.S. — and the top dermatologists to be in the dermatological studies, because they were fascinated that here is a safe drug that is now being used therapeutically.

TWST: What do you expect to accomplish over the next few years?

Mr. Culpepper: The biggest thing would be to license PH-10 first so we get that first big pharmaceutical relationship. And we hope to complete that by about mid-2010. So we'll enter into those discussions this quarter. We've started the process, but we expect to enter into them more formally with a financial adviser towards the end of this quarter. And then we'll hopefully have consummated a license transaction by mid-2010. Then at the same time, we would have concluded detailed discussions with the FDA. We expect those discussions to be significantly advanced even this quarter, but we'll have clarity to be able to determine how to get our metastatic melanoma drug to market. We'll understand that throughout the beginning of 2010 and throughout 2010. Either the drug would be approved by the end of 2010 or certainly into Phase III by the end of 2010; either way it will be significantly advanced. And at the same time, because we would expect to have the cash and the relationship from a dermatology standpoint, we would be able to ad-

vance our liver study with PV-10. We've just started that, but we'll be able to advance the liver study and see if we want to use PV-10 for other cancers, because we believe it could be applicable for a number of cancers. We did a Phase I for breast cancer; we could probably do a Phase II for breast cancer if we wanted to, or we could do more proof-of-concept studies. For instance, PV-10 for prostate cancer. If it works on prostate cancer, then maybe for pancreatic cancer, maybe for non-small cell lung cancer. We have significant data that indicates our drug works against many cancer types, but it's just a question then of opening up a study in humans, and then we can show a big pharma it works in breast, it works in liver, it works in metastases of liver, and it works in these other indications. And of course, here is the pathway for melanoma to get to an approved drug. We certainly expect to partner up on oncology, just like the plan to partner up on dermatology — it would just take us a little bit longer on oncology. We'll try to push that as much as we can ourselves to maximize value for the shareholders.

TWST: How has the investment community responded? Do they understand the company? Are there any misperceptions?

Mr. Culpepper: I have to say it has been a story that's been unfolding for the last few years, and it's unfolded in the sense that, first, on the skepticism: How can you use this old-fashioned drug? Now the skepticism has been met with excitement: Yes, I see the data now shows that you can use it in humans and it works. So we've seen that metamorphosis from skepticism to excitement. It's a retail story though. So we've had plenty of funding ability; we've been able to raise the money we need from retail investors because it's a story that has played well. You have this unique drug that is actually saving lives now. We could say we've saved a number of lives — we have very high complete responses on the order of 30%, and we've treated over 100 people, so that's 30

people right there. And there is, apart from the complete response, a number of partial responses, which is plus, too, if those people live longer. Then we had another 30% of those. So that's over 60 people that have been significantly helped already just in melanoma. We have started a compassionate use study, so that has helped people. A compassionate use in Australia is in process, and we just started one in the U.S. And that's really good because the FDA sees that you can use this not just for liver cancer, not just for breast cancer, but you can use it for other cancers — head and neck cancers, and other cancers to the body. So that's the compassionate use program. So people are warming up to it. So now the institutional investors are starting to say, "How can I start to get involved? How can I buy the stock? You're thinly traded, how can I get a big position in the stock?" So we start to get more interest from large institutional investors, and we have two "buy" ratings from respected research analysts — these are independent analysts. We have a "market outperform" rating from Rodman & Renshaw, and we have a "buy" rating from Maxim Group. So two top Ph.D.'s are saying to Wall Street, "Provectus is a 'buy.'"

TWST: So when it comes down to your own drug development program, and partnerships and collaborations, what might be the biggest potential money-generating asset?

Mr. Culpepper: We would say it's probably 50-50 because the dermatology has a very, very large market potential for both psoriasis and eczema. Together, the dermatology has a multibillion-dollar potential market. And then with all the different oncology indications, in combination those are all multibillion-dollar markets. I think from a stock market or Wall Street standpoint, they view a breakthrough in melanoma as astronomically significant because nothing has worked in treating metastatic melanoma. So the driver of the value has been metastatic melanoma. And even though the revenue potential is significant on dermatology, there is no question about why we get a lot more attention because of metastatic melanoma.

So when a breakthrough in treating metastatic melanoma comes is probably when we start the Phase III, or get accelerated approval or do a deal. Then we would expect a significant multiple in the stock. Right now our “buy” ratings are at \$4 share, and we are trading at about \$1. So the “buy” ratings are based on doing a Phase III, and they’re significantly discounted. Once you get into Phase III or get accelerated approval, those “buy” ratings would likely go up significantly. So there is a lot of upside just a little further in the clinic.

TWST: Tell me about your management team.

Mr. Culpepper: The management team is also unique, like everything else about the company. It was founded in 2002 by the scientists who invented how to use rose bengal. They are ex-Oak Ridge National Lab scientists, all with different disciplines. This might be the reason why we’re different from other companies, as you don’t have a bunch of Ph.D./M.D.-types who are thinking just one way; they just have the same perspective. These three guys all have completely different backgrounds. One is a chemical engineer, one is a physical chemist and one is a molecular biologist, and they all have Ph.D.’s. So they think about how to attack problems completely differently, and they were thinking about how to solve a practical problem. They are the ones who came together, figured out how to use rose bengal differently than everybody else. And again, there are decades of use of this compound, and there are

a financial adviser, are going to license PH-10 for treating the dermatology issues. So one of those two pivotal events would probably be the most significant ones that would drive significant changes for the company. We would have to determine how to deal with an ongoing relationship with a big pharma entity because that’s much more involved for a regular interface. So we would have to have a beefed-up team, which we could facilitate through outsourced consultant relationships but would have to have a team that would have an ongoing collaboration or a co-development-type relationship with the big pharma teams to facilitate an ongoing license relationship.

TWST: What is your summary message? What are the highlights and strengths that distinguish Provectus as an investment today?

Mr. Culpepper: Provectus is developing oncology and dermatology therapies that are destroying cancer and handling dermatology issues that have never been done before in a safe manner. So the way that Provectus is treating cancer and dermatology diseases is radically different because of the safety profile. And because it’s so radical and because it’s so effective at destroying, it is setting the stage for a tremendous adoption. We are on the cusp of a tremendous ground swell of recognition for Provectus. So an investment now in Provectus might result in a very nice return simply because we’re so far in the clinic, and we’re so close to the realistic po-

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hundreds of scientific papers on it — literally hundreds — which could be accessed by going to pubmed.gov, then typing in “rose bengal” and going to the National Library of Science database of publications, where there are hundreds of publications. So there has been a lot of work done to try to figure out rose bengal, but it took our three founders to figure that out. They put the patents together and assigned the patents to Provectus. So the management team are the people who came up with the idea. I personally am just lucky to have found them because I was looking for a company that was doing something different in cancer. My oldest child is a brain cancer survivor. We were in the New York area being treated by literally the top people in the world, and that’s when I realized that traditional chemotherapy approaches are extremely challenging and extremely toxic to the body. Further, they are very, very ineffective because the combination is very toxic and very harmful to the normal tissue, and they are not very specific to disease tissue. So I realized from working with top institutions of the Northeast that the problem with cancer is there is a lot more of a groupthink mentality than I had realized. So when I learned that these guys were doing something completely different and not part of the groupthink — and obviously not in the hotbed of scientific exploration here in East Tennessee, not in New York or Philadelphia, or any of the other top biotech places like Boston or San Diego — I was interested in them. So they’re thinking about this completely differently and come from a different perspective. Once I heard about it I wanted to join up, and fortunately they hired me.

TWST: What do you see as a potential wild card that would force your organization to make or address any changes?

Mr. Culpepper: Getting accelerated approval or getting the nod from FDA that we are on the right path for accelerated approval, or that we meet what they suggest is appropriate for accelerated approval, or if they’re giving us the leeway to continue to move in that path — that would be significant enough because then we wouldn’t have to do Phase III work and then have to think about commercializing the drug. This would immediately mean setting up a relationship with a large pharmaceutical company, which would be some sort of sales and marketing distribution agreement. So that would be a very near-term significant event. Then almost as significant would be announcing that we, with the help of

tential for Big Pharma relationships. And getting to the three to five years or just a longer time frame, this is the kind of drug that once it starts off being used for one indication, say, metastatic melanoma for cancer, and psoriasis and eczema for dermatology, we believe drug companies are going to want to use it every which way they can possibly think of. It might have potential for other indications, such as pancreatic cancer and breast cancer, prostate cancer, lung cancer, liver cancer, gall bladder cancer, kidney cancer, all these different solid tumor types. This drug can effectively kill the cancer. And you don’t have the safety issues that other drugs for metastatic melanoma have. And they’re all unmet needs. These are all blockbuster potentials with one compound. On the dermatology side, there are a number of different applications, and that’s what’s really radical. But the other really neat aspect about this is not only is it safe and kills the cancer, but it also helps the immune system get trained. So in both cases, once you take care of the problem, the immune system is on high alert and can go out and kill the cancers that metastasized. That is, the same type of cancer. So you treat the melanoma, kill the melanoma and the other metastases of melanoma; the immune system is properly trained. So it’s like an in vivo vaccination. That is a really nice aftereffect; so you get that sort of special ongoing protection because of this drug. So it’s got the one-two-three punch. A one punch is nice, but we have the one-two-three. And that’s what’s going to bode very well for investors long term.

TWST: Thank you. (KL)

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