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Conference Call Transcript

AVAN - Q3 2007 AVANT Immunotherapeutics, Inc. Earnings Conference Call

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CORPORATE PARTICIPANTS

Una Ryan

AVANT Immunotherapeutics, Inc. - President, CEO

Chip Catlin

AVANT Immunotherapeutics, Inc. - CFO

CONFERENCE CALL PARTICIPANTS

Alan Carr

Needham & Co. - Analyst

Robert Ertsey

Unidentified - Analyst

Richard Auslander

Unidentified - Analyst

PRESENTATION

Operator

Good morning and welcome to the third quarter 2007 AVANT Immunotherapeutics Incorporated earnings conference call.

Before we begin our discussion, I would like to refer to Slide 1, and caution that today's speakers will be making forward-looking statements. These forward-looking statements are subject to risks and uncertainties that may cause actual future experience and results to differ materially from those discussed in the forward-looking statements. This communication may be deemed to be solicitation material and respective of the proposed merger of AVANT and Celldex. The Directors and Executive Officers of AVANT and Celldex may be deemed to be participants in the solicitation of proxies from the holders of AVANT common stock in represent of the proposed transaction.

In connection with the proposed merger, AVANT and Celldex intend to file relevant materials with the SEC, including AVANT's joint registration statement and proxy statement on Form S-4. Shareholders of AVANT are urged to read all relevant documents filed with the SEC, including AVANT's proxy statement,

because they will contain important information about the proposed transaction. Please be advised that the question and answer period will be held at the close of the call.

I would now like to turn the call over to Dr. Una Ryan, President and CEO of AVANT.

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

Good morning, ladies and gentlemen. I am Una Ryan, President and CEO of AVANT Immunotherapeutics Incorporated. With me on this call is Chip Catlin, AVANT's Chief Financial Officer. During the call Chip will review AVANT's third quarter and nine-month financial results, and then I will provide a summary of the proposed merger of AVANT and Celldex, and give you a brief update on our lead clinical programs. Following that we will open the call to questions.

Chip Catlin - AVANT Immunotherapeutics, Inc. - CFO

Good morning. We announced in our press release today financial results for AVANT's third quarter and first nine-month period of fiscal year 2007.

The press release is filed as an Exhibit to Form 8(K) with the SEC, and is available at AVANT's website on the Investor Information page. I will not review the financial results in detail on this call, as they are detailed in the press release. But for the three months ended September 30th,

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2007, we reported a net loss of \$5.3 million, or \$0.07 per share, compared with a net loss of \$5.5 million, or \$0.07 per share for the comparable three months of 2006.

For the nine months ended September 30, 2007, AVANT reported a net loss of \$16.4 million, or \$0.22 per share, compared to a net loss of \$14.2 million, or \$0.19 per share for the nine months ended September 30, 2006. The 2007 nine-month losses included one-time restructuring charges of approximately \$765,000. At September 30, 2007, our cash balances was \$20.3 million in cash.

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

Last week we issued a press release announcing the proposed merger between AVANT and Celldex, two companies with synergistic technology platforms and pipelines, to form what we believe will be a biopharmaceutical company well-positioned for growth and leadership. I would like again to provide a brief summary of the details of our proposed merger transaction, and why this combination is beneficial to both companies.

On Slide 2, I want to focus on the strategic fit of the two companies, importantly the senior management and Boards of Directors at both companies, think that the combination of AVANT and Celldex results in a fully integrated biopharmaceutical company. Together we will have a diversified product pipeline with a substantial number of vaccine and monoclonal antibody candidates, addressing high value indications in large and underserved markets, including oncology, infectious, and inflammatory diseases.

This combination creates substantial value, and mitigates our overall development risk with several therapeutic candidates expected to reach important clinical and regulatory milestones in the near term. Together AVANT and Celldex have complementary pipelines, including monoclonal antibodies and vaccines addressing a broad spectrum of indications in significant markets, strong technology platforms including Vector vaccine delivery, manufacturing and preservation technologies, and APC targeting technology.

Together these provide a strong engine to generate new clinical product candidates on an ongoing basis. Third-party funding and validation for our global health vaccine programs, abundant near-term development milestones to fuel interest in the combined company. Solid extended life Intellectual Property position, cGMP manufacturing capabilities to streamline existing infrastructure, and bring programs in-house, for greater quality control and cost savings. And an exceptional management team with a successful track record in all aspects of drug development, regulatory procedure, and commercialization.

Now moving to Slide 3, I would like to outline the 2008 development pipeline. During early discussions between Celldex and AVANT, it became clear that our pipelines are an excellent strategic fit for each other. They combine complementary immunotherapy products and programs, targeted towards high value indications, including oncology, infectious, and inflammatory diseases. The depth of this pipeline consists of several late stage oncology and infectious disease treatment candidates with near-term catalysts. These are backed by earlier stage products advancing in tandem. We are very excited about the near-term development goals and initiatives.

In 2008 we will advance the development of a number of product candidates. In oncology, CDX-110, the lead candidate, is undergoing evaluation in brain cancer in a definitive Phase 2b/3 randomized study. CDX-110 has previously demonstrated a doubling in survival in newly diagnosed brain cancer patients, with tumors that contain a common mutation of the Epidermal Growth Factor Receptor, known as EGFR variant III.

CDX-1307 is the lead immunotherapy product based on the APC technology platform, targeting a tumor-associated molecule called the beta chain of human chorionic gonadotropin, or Beta HCG. CDX-1307 is currently in Phase 1 studies in multiple solid tumors, including to-date colorectal, pancreatic, bladder, breast, and ovarian cancer, and we anticipate data from CDX-1307 in these five indications in the second half of 2008.

The next oncology program is CDX-1401, targeting a proprietary tumor antigen. CDX-1401 will enter clinical development for multiple solid tumors next year.

Turning to our infection disease franchise, we have several single dose oral vaccine candidates in clinical development. These include CholeraGarde in Phase 2 for protection against cholera, and Ty800 in Phase 2 for protection against typhoid fever. We will also advance development of a combination travelers' vaccine against enteric disease called ETEC/Cholera, which is expected to enter a Phase 1 clinical study in early 2008.

Additionally in 2008, we anticipate the initiation of a Phase 1 trial for an infectious disease candidate, CDX-2401, as part of our Bill & Melinda Gates Foundation funded collaboration with Rockefeller University. CDX-2401 is an HIV prophylactic vaccine for the prevention of HIV infection, and it is based on our APC technology.

Lastly we believe there is substantial opportunities for our technologies in inflammatory disease. To this end, we will refocus our efforts on the anti-inflammatory agent TP10 for the treatment of wet and dry age-related macular degeneration, AMD, transplant or other inflammatory disease.

So on Slides 4 and 5, let's look at the transaction details. Now that we have reviewed the benefits of our proposed merger, I would like to take a few moments to discuss specific details of the transaction. The company will operate under the name AVANT Immunotherapeutics Incorporated, and is expected to trade on the NASDAQ capital markets with the symbol AVAN. We will have offices based in Massachusetts and New Jersey, and importantly, we will continue to operate AVANT's manufacturing facility in Fall River, Massachusetts. When combined these facilities provide a full suite of capabilities from discovery through production and commercialization.

The transaction is expected to close in the first quarter of 2008, following a vote by AVANT's shareholders. Following the completion of the transaction, Celldex shareholders will own 58%, and AVANT's shareholder will own 42% of the new company, on a fully diluted basis. We will also be instituting a reverse stock split, to ensure our compliance with NASDAQ's listing requirements, the exact size of which is still being evaluated. The reverse stock split will be subject to a vote of approval from AVANT's shareholders. We also intend to update our \$40 million shelf registration on file with the SEC following the close of the merger, and this will provide us with flexibility regarding our future financing needs.

On Slide 5, our management team and our Board will have representation from both companies. All of the management team members have substantial experience in discovering, developing, and commercializing biologic therapeutics. As you will see on Slide 6, in 2008 our pipeline is expected to generate a number of value creating milestones. Of course first and foremost we anticipate completing the merger in the first quarter of the year.

As you look to our development program, we will present important data on our three leading immunotherapy products. Phase 2 proof of concept data from Ty800 typhoid fever vaccine in the first half of 2008. Phase 2b randomized CDX-110 data in front line treatment of brain cancer in the second half of the year. And Phase 1 data on our lead APC targeting cancer program CDX-1307 in the second half. Throughout the year we also plan to initiate multiple Phase 1 studies in cancer and infection disease, along with announcing new studies generating from our human monoclonal antibodies program.

In addition, we anticipate receiving a \$10 million milestone payment for Rotarix from our financial partner, Paul Royalty Fund. Rotarix in collaboration with GlaxoSmithKline has been approved in over 90 different countries worldwide, including the European Union. Rotarix is currently under review by the U.S. Food and Drug Administration, with a response expected in the second half of 2008.

Achieving these milestones will significantly enhance our Company's profile. Looking forward, the lead oncology program will be well into Phase 3. We will have proof of concept for the bacterial vaccine platform, which our market research indicates could have potential annual sales of over \$500 million. We will have made significant advances in our preclinical and early clinical pipeline.

Now on Slide 7. I would like to provide you with a brief update on the stages of advanced clinical programs. Our core business is the development of next-generation vaccines for a variety of needs, including travelers, global health, and food safety. Each of these vaccines is designed to provide rapid protection with a single oral dose. Moreover this technology offers the capability to create super vaccines, that combine protection against multiple diseases in a single product. These features should make AVANT's next-generation vaccines uniquely suited to address both large commercial markets and serious world health needs. This year we have made significant progress in the clinical development of our single dose oral typhoid fever vaccine, Ty800.

In May 2007, AVANT announced preliminary results from the NIAID sponsored double-blind placebo-controlled Phase 1/2 in patient dose escalation clinical trials of Ty800. The NIAID research has found a single dose oral vaccine to be well-tolerated in immunogenics, with over 90% of vaccinated subjects generating immune responses. In July AVANT initiated a company-sponsored double-blind placebo-controlled Phase 2 dose ranging trial in Ty800 in 180 subjects at five clinical sites across the United States. Enrollment was completed in late September, and results from this trial are expected in the first half of 2008.

CholeraGarde, our single dose oral vaccine against cholera is supported by the International Vaccine Institute, which plans to bring Phase 2 field studies with CholeraGarde in India and Bangladesh, beginning around year end 2007. The Bill & Melinda Gates Foundation has provided a \$21 million grant to the International Vaccine Institute in support of these studies, for which AVANT will manufacture the vaccine in our Fall River

facility. In early 2008 AVANT's expects an initiation of its ETEC/Cholera vaccine candidates in a Phase 1/2 trial. AVANT's long-term goal is to develop a combination vaccine containing CholeraGarde, Ty800, and S. paratyphi A, and ETEC, as a super enteric vaccine to address the travelers market.

This is the end of my introductory statement, and I welcome your questions.

QUESTION AND ANSWER

Operator

(OPERATOR INSTRUCTIONS) First question comes from the line of Alan Carr.

Alan Carr - Needham & Co. - Analyst

A couple questions on Rotarix and CholeraGarde. Can you review, I seem to recall that there was, that the GSK had submitted an NDA for one formulation of Rotarix, and that there was another NDA that was to follow later on. Is that correct?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

That was what they had led us to believe. They did submit a BLA in, I can't remember, I think it was June or May, and the PDUFA date would be April of '08.

It is important to us that the first thing they filed actual launch, because the launch is what triggers our \$10 million payment from Paul Royalty. If at some time in the future they decide to launch another product, that is also fine with us. So right at this point it is not important to us that a second one has been filed, and as far as I know they have not notified us of that.

Alan Carr - Needham & Co. - Analyst

The first one was that a powdered or?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

I think it's lyophilized and they intend to come out with a liquid form ultimately. But as I said in terms of AVANT's business it is the first to launch that matters.

Alan Carr - Needham & Co. - Analyst

Okay. I see. And any update on discussions with GSK on the royalty business and the patents there? Have there been any changes there?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

No, not really. I think that that has become almost moot. In discussions with GSK there certainly could be amounts that we might be able to agree on.

But anything that we would settle with GSK would at this point have to go to Paul Royalty Fund. So it is not really in AVANT's interest to spend a lot on legal fees if we are not going to see any of the benefit. In discussions with Paul Royalty, they have certainly been friendly to us, but they have securitized their business with bondholders, and they are not willing to go to their bondholders on this.

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So I think that, you know, it was an annoyance but I don't think it's a huge economic loss to AVANT, and it is always a question of weighing legal fees against benefit. I think as we have said before, when they do launch in the U.S. and we do see how the sales ramp up, at that time we can calculate how much difference it would make to the timing of the royalties that would come above the cap. No, I think when we have that information, we can really come down to what is its best move for us. Right now I think just waiting is the best and most prudent position for AVANT.

Alan Carr - Needham & Co. - Analyst

Okay. And regarding CholeraGarde and the trials in Bangladesh and India, do you have any more information on the timeline for those or-?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

Yes, the Gates Foundation has become a little more bureaucratic in recent years, and so they go through a number of different Steering Committees and Advisory Committees, but it is all progressing well. They are going to progress with our material that we have already made. We will have to release it and send it to them, and I believe in the second half of the year they will start their studies.

Chip Catlin - AVANT Immunotherapeutics, Inc. - CFO

They will start actually around the end of the year, first half '08.

Alan Carr - Needham & Co. - Analyst

How long do you think those trials will take, do you have a sense of that?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

I think there are many trials here, Alan. There are several Phase 2s. We have to look at young people and at babies.

We have got to look at people with HIV infections, and we have to look at the use of the vaccine given concomitantly with the Measles vaccine. I think to have them all finished will take a while, but I think that we will see results from some of those components as they get finished over the year.

Alan Carr - Needham & Co. - Analyst

Thanks very much.

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

You are very welcome.

Operator

Your next question comes from the line of [Robert Ertsey], please proceed.

Robert Ertsey - Unidentified - Analyst

Good morning. I have a question on Ty800. You will get trial results probably in the middle of '08 on the Phase 2, are you considering licensing that vaccine as a standalone global vaccine, in addition to your own program of developing the combination super vaccine?

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Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

Yes, it is a good question, Robert, because we would have a different answer for different components of our super vaccine. But, yes, I do believe there is a market for Ty800 as a standalone. And so it will in fact be advanced both ways. If you will remember for CholeraGarde we will only be advancing that in the developing world, provided we get third party help to do it, which we are getting.

But it will move forward in the U.S. for travelers as the ETEC/Cholera combination, and that will start trials in early '08.

Robert Ertsey - Unidentified - Analyst

A question on CholeraGarde, some Asian countries, like India and China and Vietnam, there is a developing biotech industry. Are you looking at partnering with any companies over there for the production and distribution of CholeraGarde in Asia?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

I think it is a very sensible solution. There are announcements coming out this morning about companies doing that. We do plan to have discussions because I think that will be very useful for our developing world markets, and it will suit the goals of the Gates Foundation and the IVI.

However, we have to be very careful that if an overseas manufacturer is our commercial manufacturer, that they are or that they become FDA compliant, so that in a way that the vaccine could be offered for sale in the U.S. So with those provisos the answer is yes, that is a good route for us to look at.

Robert Ertsey - Unidentified - Analyst

And one final question on TP10. You mentioned on the last conference call that the scientists at Celldex had some ideas about improving TP10. Did that refer to improving the molecule itself, in terms of half life or pharmacokinetics, or does it refer to manufacturing at a lower cost?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

It refers to manufacturing. The people at Celldex are very familiar with making proteins and biologics, and coming from the Mederex background. It does not refer to the pharmacokinetics, which I will not say are perfect, but are in fact almost ideal.

TP10 as you know is heavily glycosylated, and it's terminal half life is 70 to 90 hours. So it has always been absolutely magnificent in terms of PK. So I am not saying it couldn't be improved, but we are not putting any effort into that. It simply is in to lowering cost of goods.

Robert Ertsey - Unidentified - Analyst

Thank you very much.

Operator

Next question, [Richard Auslander], please proceed.

Richard Auslander - Unidentified - Analyst

Good morning, Una and Chip. You indicated that you are proceeding with the complement block for macular degeneration, I believe that is a complement-mediated disease. Is that going to be your primary usage of the complement blocker?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

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We haven't closed the merger yet, Richard, so we aren't, we would love to be, but we aren't operating as a single company. Obviously the clinicians and scientists and our advisors on both sides are still reviewing which indications, which programs will be prioritized. I would say it is one of the ones we are very interested in. It is one that potential partners are very interested in, but it is one in which we have less clinical data or dosing data than we have for the systemic indications.

So we will have to see what is the best mix of progressing with this on our own in the company, and what is best to do with partners. But from the market size point of view it is very favorable, because in AMD, whereas the VEGF inhibitors are very good for wet AMD, we believe that a complement inhibitor should be able to address dry AMD as well, which is vastly underserved at the moment, and a very large market, increasingly as the population ages.

Richard Auslander - Unidentified - Analyst

I would agree it is major markets for both dry and wet. You have had very successful second phase clinical trials with men in CABG. Do you plan to look at continuing these trials, perhaps in a Phase 3?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

That has been a more difficult decision. We always felt that since males represented three-fourths of the potential cardiac surgery market that it was reasonable. We have found of course all of our partnering was put on hold while we were through the process of our merger, but we found just in discussions that the interest really lay in AMD transplant, and perhaps in the chronic inflammatory diseases.

So I think we would not progress with that on our own. We have always said that should a partner be interested, we would do it with them, but in fact the interest, because I think of some of the pressures on cardiac surgery, pricing, the interest really in the indications that I have listed here, AMD, transplant, and perhaps chronic glomerular nephritis, or something like that.

Richard Auslander - Unidentified - Analyst

You also are considering I assume Crohn's and lupus in the inflammatory?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

We are considering them, yes. In fact, one of both blessings and curses of a complement inhibitor is that complement underlies so many diseases. It is a question of one where you have the best data from animal studies, and where the trials are most doable.

So at the moment we are not ruling out anything. The combined company will have a lot of strategic discussions on the programs. Both what we will do in-house, and what we will do with partners, so we are not eliminating anything. I am just giving I was sense of where the greatest interest seems to be at the moment.

Richard Auslander - Unidentified - Analyst

Sounds very sensible. One last question if I may, as you are coming back towards the complement direction, do you expect to begin anything on your CETi vaccine?

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

That one is, as you know, was sort of put on hold when torcetrapib had its problems for Pfizer. Now that we are seeing quite encouraging results coming back from Merck, we are looking again at the possibility of finding a strategic partner for that one, because I think everybody is more encouraged by these data. I think the chance that we will do it in-house is low. We have got so much on our plate.

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That one is a very interesting market, is a very long, difficult and expensive later stage development, better conducted by a company that is already in that area with the sales force in that area. So we certainly resurrect partnering discussions, but I think it is unlikely to be an in-house product for us at the moment.

Richard Auslander - Unidentified - Analyst

Very good. Thank you very much.

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

You are welcome.

Operator

Ladies and gentlemen, that concludes our Q&A session. I would like to turn the call back over to management for closing remarks.

Una Ryan - AVANT Immunotherapeutics, Inc. - President, CEO

Thank you all for participating on today's call. If you have additional questions, please feel free to call Chip or me directly.

I would remind you again that this press release and conference call contain forward-looking statements, which are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed in any such forward-looking statements.

And we look forward to updating you on our programs and proposed merger next quarter. Good bye.

Operator

Thank you for your participation in today's conference. This concludes the presentation. You may now disconnect. Good day.

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This communication may be deemed to be solicitation material in respect of the proposed merger of AVANT and Celldex. In connection with the proposed merger, AVANT and Celldex intend to file relevant materials with the SEC, including AVANT's Proxy Statement/Registration Statement on Form S-4. **SHAREHOLDERS OF AVANT ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH THE SEC, INCLUDING AVANT'S PROXY STATEMENT/REGISTRATION STATEMENT ON FORM S-4, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION.** Investors and security holders will be able to obtain the documents free of charge at the SEC's web site, <http://www.sec.gov>, and AVANT shareholders will receive information at an appropriate time on how to obtain transaction-related documents for free from AVANT. Such documents are not currently available.

The directors and executive officers of AVANT and Celldex may be deemed to be participants in the solicitation of proxies from the holders of AVANT common stock in respect of the proposed transaction. Information about the directors and executive officers of AVANT is set forth in the proxy statement for AVANT's most recent 10-K, which was filed with the SEC on March 16, 2007. Investors may obtain additional information regarding the interest of AVANT and its directors and executive officers, and Celldex and its directors and executive officers in the proposed transaction by reading the proxy statement regarding the acquisition when it becomes available.