FINAL TRANSCRIPT

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Event Transcript

VVUS - CCBN Virtual Healthcare Conference: Co-sponsored by Lippert/Heilshorn & Associates and RedChip Partners

Event Date/Time: Dec. 10. 2002 2:15PM ET

CORPORATE PARTICIPANTS

Leland Wilson
VIVUS - President and CEO

CONFERENCE CALL PARTICIPANTS

Peter Hall
CCBN - SVP

PRESENTATION

Peter Hall - *CCBN - SVP*

Welcome to the CCBN Virtual Healthcare Conference co-sponsored by RedChip Partners and Lippert/Heilshorn & Associates. My name is Peter Hall, and I'm a Senior Vice President here at CCBN and I'll be serving as your moderator for this portion of the Virtual Healthcare Conference.

A reminder to our live Webcast participants -- at any time, you may submit a question simply by typing your query into the question field on the lower left-hand side of the Webcast Player. I'll present these questions during the Q&A at the end of the company's prepared remarks. Should I have more question than time allows, please be assured that we will forward all of those questions on directly to company management for them to answer and respond to directly.

Our next presentation will be made by Leland Wilson, President and Chief Executive Officer of VIVUS. VIVUS, Ticker Symbol VVUS, is a pharmaceutical company engaged in the development of innovative therapies for the treatment of quality-of-life disorders in men and women with a focus on sexual dysfunction. Current development programs target female sexual dysfunction, erectile dysfunction, and premature ejaculation.

Please go ahead with your presentation, Mr. Wilson, and welcome.

Leland Wilson - *VIVUS - President and CEO*

Thank you, and thank you for the opportunity to present today. Yes, VIVUS is a specialty pharmaceutical company specializing in treatment of diseases which affect our quality of life.

And before I start, I'd like to remind everybody that I am probably going to make some forward-looking statements here, and please consult the 10-K and 10-Q, which may identify some of the risks and uncertainties that I may not be able to cover here today.

I think the first slide here to talk about why should you be interested in investing in VIVUS -- I think clearly the number one reason is we have a very strong pipeline of R&D products that are largely focused in the area of sexual function. We have broad intellectual property portfolio with 29 issued and 14 pending U.S. patents. We have approximately $29.9 million of (ph) unrestricted cash and equivalents at September 30, 2002. And we have a strong balance sheet with no debt.

Our focus in this company is to do work in sexual function, urological disorders. And today, we're going to talk about three areas -- male erectile dysfunction, female sexual dysfunction, and premature ejaculation.

First, a little overview of the male erectile dysfunction market -- I would like to remind people that VIVUS is a pioneer in this marketplace, that we launched our lead product, Muse, back in 1997 -- in January of 1997 to a rousing welcome, achieved sales of $130 million in the first year sales, et cetera. But this market has reached or is in the process of reaching at least partial part of the potential that we saw for this market back in the early 1990s. Today the market is about a billion-and-a-half dollars and still growing in the high teens on a yearly basis.

But it is not a satisfied market. And I'll give you a couple data points here to indicate that. First of all, current oral therapies are not appropriate for a significant segment of the market, and that is those patients which are taking nitrates. And there are about six million men in that area.

And the second point I'd like to make here is that there is a significant dropout rate to the oral therapies. A data point here is that (inaudible) information would indicate that one out of every four new-start patients returns for a refill during a 12-month period. Now, why is that? Well, I think there is a dissatisfaction both from a safety standpoint and from an efficacy standpoint. And this is -- still leaves a tremendous area for improvement in both of these regards for our research and development area. And we have projects which we think will answer both safety and efficacy questions in this marketplace.

First, a little bit on Muse -- Muse is a locally delivered -- that means that we place a small pellet in the urethra of a compound called alprostadil, which is a synthetic version of a naturally occurring prostaglandin which is present in semen. OK? This product was, as I said, first approved in 1996 and launched in January of '97. It has a wonderful safety profile. It is not

contraindicated with nitrate patients, and it has efficacy in many severe ED patients where oral therapies have failed.

Muse is an important part of our program here because it generates close to $20 million in revenue, and this revenue largely covers our operating costs for our company going forward. So, our business model is is that we have a revenue generator here in Muse and it is -- that is the reason why Muse is of importance to us that clearly as an investment decision it's the business model that allows us to cover the operating costs here. And we'll talk specifically about our projects and research.

Probably the most noteworthy or interesting at least (ph) at this point is our compound called Alista for treatment of female sexual dysfunction. I don't think there's much difficulty in people seeing the marketplace for this, unlike what we saw for Muse when we started our work in male erectile dysfunction in the early 1990s. It's recently been reported that there are about 40 percent of the women have some form of female sexual dysfunction and clearly this quote from "The Observer" magazine captures that there is a large potential market for this condition.

This is, again, a quality of life issue which is important to all of us, and there are no proved FDA-approved therapies in this area, and we believe that VIVUS is in the lead in bringing the first product to the marketplace for treatment of this disease.

This compound or product is called Alista, and the active ingredient in Alista is alprostadil. And alprostadil, as you remember from an earlier slide, is a -- the exact same ingredient which is in Muse and alprostadil is a synthetic form of a naturally occurring prostaglandin -- Prostaglandin E1, which is present in the semen. And this compound actually causes vasodilation, which leads to engorgement and the normal cascade of sexual events, but it also potentiates the sensitivity of afferent nerve sense -- afferent sensory nerves as well. So it has two mechanisms of actions that come into play here. And we filed our IND in September of 2000. We have 14 issued or pending patents in the area, as well.

Now, the big news that has occurred here is that we released the first data, which was an in-clinic trial on Alista, which showed positive results. And I'll spend a few moments talking about that trial. This was an in-clinic evaluation of the safety and efficacy of Alista for the treatment of female sexual arousal disorder. It was a double-blind placebo-controlled crossover design topically applied to the female genitalia. Seventy-nine post-menopausal women, age 40 to 70, with the primary diagnosis of female sexual arousal disease -- now, this is separated from female sexual desire disorder or orgasmic disorders, as well. But we think the arousal disorder is the predominant form of female sexual dysfunction out there.

The results indicate that compared to placebo, our 400 microgram dose of Alista resulted in significantly greater change from baseline than placebo for the end points of sexual arousal, satisfaction with that level of sexual arousal, and overall sexual satisfaction.

The response occurred importantly within five to 15 minutes after application, so the spontaneity of events here is idea. Alista was very well tolerated, both locally and systemically, and we have initiated a Phase II at-home study in the first quarter of 2002, and we expect top line results from that study toward the end of January -- next month.

And so this is a very important time for us. This is a very significant study. It's a setting where the drug will be used in a very similar fashion to what'll be used in the marketplace, and then our Phase III studies -- ongoing Phase III studies. So this is an important milestone for us, and I hope all of you are looking forward to that results nearly as much as I am.

Second compound I want to talk about is TA-1790. It is a PDE5 inhibitor, and this is a family of compounds for which Viagra is one, and it's a treatment for male erectile dysfunction among other indications that we'll talk about in a second here. But it has some important characteristics that I'd like everybody to know that potentially differentiate this from other PDE5 inhibitors that are either on the market or coming to the market.

Like the others, it is orally active, it is extremely potent, and is very selective for PDE5. In fact, we believe it is more selective than any other compound out there. So, selectivity here is important and may lead to fewer side effects and potentially even greater efficacy. We have strong patents from here (inaudible) Tanabe's patents that we licensed.

A little bit about the marketplace -- three other compounds that I'll talk about today. Sildenafil is Pfizer's compound you know as Viagra. Tildalafil (ph) is Icos (ph) Lilly's compound. It has FDA approvable letter, but additional studies have been required and they're expected launch later in 2003. They did receive an approval in the European Union (ph) just recently. Vardenophil is a compound from Bayer and Glaxo will be helping them market that compound and it's FDA approvable letter as well, and additional studies are also required to meet FDA's final requirements.

I mentioned specificity of these compounds in this chart. Although a little bit complicated, you can spend some time with it later and call me if you have specific questions. But what it indicates here is a ratio or relative potency of these compounds toward inhibiting PDE5, which is the target enzyme, relative to other enzymes like PDE1, PDE6, PDE11.

Now, these are three important enzymes here that you do not want to inhibit. PDE1 is thought to affect blood pressure, PDE6 is know to affect vision, and we're not sure what PDE11 inhibits at this point, but research is ongoing in that area.

But it does indicate, for example, TA-1790 -- it takes more than 8,000 times as much compound to inhibit 50 percent of the activity of PDE1 as it does with PDE5. So you see here that TA-1790 is the most selective, and I'll point out a couple important areas here. Relative to sildenafil and PDE1, it is, you know, manyfold (ph) -- hundredfold more or less potent on PDE1 than is sildenafil, for example. And if you look at PDE11 and look at tildalafil (ph), or Icos (ph) Lilly's compound, it's indicated here that it is substantially more -- less potent against PDE11 than is tildalafil (ph). So that selectivity has to translate into a better profile (ph).

In the -- in the clinic, we have animal data to date that indicates that that's possibly true. The next slide would indicate here potentially less interaction with nitrates than is shown with sildenafil. This is an animal model in dog -- two groups -- one treated -- pretreated with sildenafil -- the second pretreated with TA-1790. And it indicates in the sildenafil group when they were given nitrates, they had about a 75 percent drop in blood pressure. And TA-1790 group had about a 25 percent drop in blood pressure. So, this is significant, and again, it's animal data indicating there is potential there for TA-1790.

We also have human data. A couple data points here from the human standpoint in our single-dose safety tolerance study which was conducted with 63 normal volunteers at doses up to 800 milligrams, which is many times what we think the therapeutic dose will be in the marketplace. We saw no clinically significant effects on blood pressure and no meaningful adverse affects at all in that study.

The pharmacokinetics of the drug would also lead us to believe that there may be an opportunity here for TA-1790 to offer patients better therapy. A couple of those points that I'll make here. First, the onset of action of TA-1790 seems to be significantly more rapid than it is with sildenafil, and we've seen this now both in a -- in a study that I'll talk about in a second, so we'll come back to that. But at 15 minutes, we see activity here versus 30 minutes in flaccid (ph) condition on sildenafil.

And the half-life, I think importantly here for TA-1790, is short. It's the shortest of all the compounds that are out there, and we would argue that the benefit of that is that the drug is in, it's available for a couple of hours which allows you to complete your sexual activity, and then it's out of your system so you don't carry it around for potential interactions with nitrates and other kinds of issues you have with carrying that drug on board for a longer period of time.

Our clinical program here -- we announced the results of a -- our TA-1790 study at a recent conference call here. And this was a multi-center in-clinic double-blind placebo-controlled evaluation of TA-1790 using a device called Regiscan (ph), which measures erectile capability. And the results of that study indicated that we had results at least comparable if not greater than (ph) those seen with Viagra. Peak penile response to TA-1790 importantly occurred at an earlier time point. In this case, at a 20 to 40-minute time -- period after administration as compared to a peak response with Viagra, which took 60 to 120 minutes after administration. And again here, TA -- what we think this is a very important component of TA-1790 that is as rapid absorption peak plasma levels and efficacy. And we're going do further studies that are going to clarify exactly how early the response of this drug can be, but we think it can be as early as 15 minutes, which is very, very rapid. T! A-1790 was well tolerated with no indication of hypertension or visual disturbances in this drug. So, continued a very powerful efficacy profile with a strong safety profile, as well.

The third area I want to talk about today is premature ejaculation. I think many people are again starting to see this group as -- group of patients as a large potential market, and in fact, in a recent article in the "New England Journal of Medicine," indicated that the incidence of premature ejaculation may exceed that for erectile dysfunction. We believe this market is equally as large if not larger than ED, as well. And there are no medically approved therapies available today. Few companies are working in this area, and VIVUS has been working in the area really for quite a few years. And we have seven issued or pending patents in the area and believe that we are the leader in the development of products in this area.

Two compounds which we have in development -- one is VI-0134. And that proof-of-concept study was completed in '99 and it showed positive response that is was able to significantly delay the latency of ejaculation after vaginal penetration with an oral on-demand therapy. VI-0162 -- we

have a safety and efficacy trial underway for this indication, as well.

Now, we've asked -- many people have asked us, "What are these compounds and what is the mechanism of action?" But I would say that for competitive reasons, we're not discussing the mode of action of either of these compounds, and we ask for your understanding in that regard because this is now becoming a very competitive market and we've heard now within the last several months that two or three other large companies have entered the market and development of areas which I think VIVUS pioneered. And so we're going to keep that a little closer to our vest going forward.

The next product that I'd like to talk about is what we call the next generation of erectile dysfunction therapy. VIVUS owns the patent rights for the local delivery of phospodiesterase inhibitors to treat ED. So, for example, TA-1790, Pfizer's compound, Lilly's compound -- Icos (ph) Lilly's compound, and Bayer Glaxo compound -- we own the patent rights -- the use of this compounds (ph) for local delivery to treat erectile dysfunction. This is an important patent because we were able to show through research that we conducted at Tulane University that if you mix a PDE5 inhibitor with alprostadil, you get surprising response. And that is the potency is extremely good in causing vasodilation, and therefore, erectile -- treatment of erectile dysfunction. This data was presented at American Urological Association Meeting in April 2000 and two physicians in the group tried to -- decided on their -- quite on their own to look at patients that had failed both Muse and Viagra and! were really in mind to have implant therapies. And he looked at treatment of those patients with this combination therapy -- that is an oral Viagra followed by a (inaudible) Muse to see what the response rate. Well, the response was very powerful as you can see here. Twenty-six out of 26 failure patients achieved sexual intercourse on combination therapy. This study has been completed and duplicated many times now throughout the country with results which are similar in nature. So, it's a very potent mechanism of treating those patients which fail both Muse and Viagra.

Now this is important because as you recall I said in your earlier slide when we talked about the market a significant portion of patients are unable to be treated by current products in the marketplace, particularly those that have severe conditions such as diabetes or have had a prostatectomy, et cetera. So, we believe that that market is actually as big if not bigger than the current oral therapy market, which has now trended towards more of the younger patient population for a number of reasons which we can get into at a later date.

Our patent position at VIVUS is very strong and something we're very proud of. We have 29 U.S. patents issued primarily related to ED, female sexual dysfunction, and premature ejaculation, 14 U.S. patent applications are pending, three international patents awarded, 22 international patents pending.

Our manufacturing facility is paid for. It is in New Jersey -- in Lakewood, New Jersey. It is running at a very high certification for GMP (ph), and it's 90,000 square foot and doing everything you'd like to have a manufacturing plant do particularly these days with all the issues around GMP (ph). So, it's very -- a very nice plant and we invite anybody that'd like to come and look at that at any time to give us a call.

Our management group here has been with us for a substantial period of time and including during the transition with the Viagra launch on forward. We have extensive pharmaceutical experience and clearly we have the fiscal responsibility that has allowed us to survive in the post-Viagra era and to build a substantial pipeline of products and to have the opportunity that we're here presenting to you today.

So in summary, we have a growing pipeline of potential products which treat large, unsatisfied market. This group of compounds is led by Alista for female sexual dysfunction and obviously TA-1790 for oral treatment of male erectile dysfunction. We have an experienced management team -- strong balance sheet. We have a very strong intellectual property position in this area garnered largely because we were working in the area before everyone else was. And the areas of our primary interest, again, are FSD, ED, both oral and transurethral, and premature ejaculation.

And with that, I'll conclude my prepared remarks and open it for questions.

QUESTIONS AND ANSWERS

Peter Hall - *CCBN - SVP*

Thank you, Mr. Wilson.

We'll now move to the Q&A session of the presentation, and I'll remind our audience again that to submit a question, simply move to the query question field, submit your query at the left-hand side of the Webcast Player.

The first question we have actually asks about competition and says that they notice that a lot of your competition has partnered

with some major pharmaceutical companies. Does VIVUS have any plans to do so with any of its products? And particularly, this questioner asks about Alista.

Leland Wilson - *VIVUS - President and CEO*

Yes, we do. Alista plays an important role in a couple of ways. I mean clearly let me just say a couple words about who do we think the physicians are that are going to be prescribing Alista. We think it's largely going to be the general practitioner that treats females, and that is the OB-GYN across the country. And so, clearly, you need a substantial sales organization in order to be able to reach this.

But in light of the Viagra launch as well, there's going to be a substantial direct-to-the-consumer ad campaign that's going to be needed to generate the kind of awareness, et cetera to bring patients into the marketplace here. So, we are looking for a partner and we are looking for that for financial reasons, as well. That is a key part of our structure going forward to raise the money necessary to fund other things in our development program.

So, yes, Alista is the first up on the marketplace for licensing opportunity. I can say that we have very strong interest from most major pharmaceutical companies for Alista, and largely waiting for the at-home data, which we think will be available towards the end of January that I mentioned earlier. So, we're hopeful that we'll be able to conclude a deal sometime during 2003. That is, I think, a very substantial financial opportunity for VIVUS.

Peter Hall - *CCBN - SVP*

Next question, Mr. Wilson, asks you to comment regarding the 14 pending patents that you have. Do you have any guideline on when -- on the approval process and how you measure that and expectations ...

Leland Wilson - *VIVUS - President and CEO*

Sure, they ...

Peter Hall - *CCBN - SVP*

... along those lines?

Leland Wilson - *VIVUS - President and CEO*

Yes, patents are -- as I said earlier, are very important to us and they allow us to spend the kind of money that we need to develop products that would give us a -- some exclusivity in the marketplace. So, really, without a patent, you're not in a very strong position in this area. In all of our development programs, we first must have strong patent positions before we will go forward with spending the money.

These four -- all the 14 patents that are pending are spread out over time and largely are related to the areas of sexual function. So, I can't give you off the top of my head any specific -- more specifics with that. They are approved much like the FDA when all the review of (inaudible) et cetera have been completed and the Patent Office is able to conduct and finish their review and get it out to us.

But, no, we've been very successful in achieving patents in this area, and so we believe that most if not all of those will be issued.

Peter Hall - *CCBN - SVP*

Next question asks, again, of you a little further elaboration on the market size for the various markets that you're entering.

Leland Wilson - *VIVUS - President and CEO*

Sure. The oral ...

Peter Hall - *CCBN - SVP*

Could you -- could you comment a little bit more on that?

Leland Wilson - *VIVUS - President and CEO*

Yes, you bet.

Peter Hall - *CCBN - SVP*

... earlier in the presentation.

Leland Wilson - *VIVUS - President and CEO*

You bet. The oral male erectile dysfunction market is about a billion-and-a-half today. That's 98 percent Viagra, and it's growing. About 18 percent is I think the last figure that I saw in the United States. So, it's substantial and growing.

Interesting to note that the average age of a patient receiving a new prescription for Viagra has declined, so it's going more towards the younger population which has good, intact nerves where potentially a PD5 inhibitor may work better.

So, but it has left a vacuum, I think, at the top end of this market where Muse was originally launched for the treatment of significant organically caused erectile dysfunction, such as radical prostatectomies, et cetera. I believe that that failure market (inaudible) oral therapy market is bigger than the oral therapy market is today. And a couple data points here -- there are many times more patients that have tried Viagra and are not -- have not returned to the market for other prescriptions for it than are taking Viagra. So there's some data that that marketplace is really substantial, as well. So there's two markets there.

Female sexual dysfunction market -- you know, it's indicated that at least 40 percent of the women complain at some point of female sexual dysfunction, and the key time point here for that to occur is around menopause. Number of things occurring at that area -- time in their life, and clearly the hormonal changes, et cetera; some of those actually cause a decrease in blood flow to the area such as loss of estrogen to the area. And there's other things that cause female sexual arousal disorder just like in men, and they include smoking and high-fat diets and all those things.

But importantly, about one-third of the women in the United States undergo a hysterectomy at some time. We do not yet have a nerve-sparing hysterectomy -- people are working on it -- like we do with the nerve-sparing radical prostatectomy in men. So there's a lot of issues -- childbirth, et cetera that cause this number to be substantial.

And I think, you know, the social pressures today on being able to enjoy sexual activity throughout our lives is increasing, and the awareness of people that this is an OK thing to do and has increased dramatically over the last 10 years. So, this market, I believe, is as -- at least as big as the male side if not larger.

And then the final one is premature ejaculation. And, again, I cited some data here to indicate that it is as large if not larger than the male erectile dysfunction market, as well. (inaudible) the incidence -- we were on to this market very early on because when we did some of our early market research back in the early 1990s when we talked to urologists about the visits that they had for patients with sexual dysfunction, the visits for premature ejaculation outnumbered those for erectile dysfunction substantially. And so we've been working in this market for a long time and we believe it is substantial, as well.

Peter Hall - *CCBN - SVP*

I think we have time for one more question, and let me make it a three-part question because there are some questions here.

Can you comment on the current cash position of the company and perhaps to whatever extent you can the financial outlook for 2003? That's sort of part A (ph).

And part B (ph), we have a question from the Internet that asks you to comment a little bit on the stock's performance in 2002. Given all the positive developments there, if you could comment on how the ...

Leland Wilson - *VIVUS - President and CEO*

Yes.

Peter Hall - *CCBN - SVP*

... stock has performed in your eyes.

Leland Wilson - *VIVUS - President and CEO*

Sure. Our cash position is 29.9 million as of September. No debt. Very clean balance sheet going, et cetera.

Our financial outlook for 2003 -- well, we think there's a couple of opportunities here. One -- clearly we're going to have at-home data for Alista, and we think that spells an opportunity here to license the product and to gain milestone payments, et cetera in that -- in that area.

But, you know, I'm not eliminating the possibility that we will go out for another round of financing. It's dependent -- largely dependent upon the financial markets and how open the window is, and clearly it's been closed for a long time and it doesn't show any signs at this point to open.

The good thing is that we have Muse on the market and we're able to fund a significant portion of our work going forward out of Muse revenues, et cetera. So, we can -- we can pick it and make it work to our -- to our conditions and the conditions in the marketplace, and we're not a slave to those conditions in the marketplace to a great degree.

Our stock performance during the year -- I mean clearly we went up to 10 very early in the year on positive data. We have

had, in my opinion, a very successful year in our development programs. All of our products have continued to develop with good news on very significant areas. Clearly the Alista data was very powerful. Even though it was an in-clinic study, it was powerful. That data was released was the first time to my knowledge where a well-controlled study indicated that we could change the female sexual arousal disorder condition.

The news on TA-1790 was equally as strong, showing that we had strong efficacy, very early onset of action again with this in-clinic study, and a strong safety profile going forward.

And so we've -- in light of the number of patents that we've had, in light of the number of clinical achievements that we've achieved, I'd have to say that our stock performance has not kept up. And so we're looking for a catch up, if you will, at some point. And I think, you know, that we all understand the capital markets over this past year have been tough. The markets in general have been tough, so we're looking for some relief in this area. And hopefully we have some pent-up demand by our holders and potential holders out there in the marketplace that we -- that are waiting to see the Alista data, and if that's positive, I think we're going to be in pretty good shape.

Peter Hall - *CCBN - SVP*

Well, that's great. We're out of time, and I want to thank you for your presentation today, Mr. Wilson. We enjoyed it.

And again I want to thank our Webcast listeners and remind those listeners that to listen to the next Webcast, please close your Media Player and return to either www.ccbn.com or www.redchip.com or www.lhai.com and click on the agenda page.

Thank you.
