
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported)

February 23, 2006

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

000-23490
(Commission File Number)

94-3136179
(IRS Employer
Identification No.)

**1172 CASTRO STREET
MOUNTAIN VIEW, CA 94040**
(Address of principal executive offices, including zip code)

(650) 934-5200
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02. Results of Operations and Financial Condition

On February 23, 2006, VIVUS, Inc. conducted a conference call during which members of its senior management team discussed financial results for the fourth quarter and twelve month period ended December 31, 2005 and certain other information. They also reported on product development highlights and responded to questions. A copy of the transcript of the conference call is attached hereto as Exhibit 99.1. The transcript contains an inadvertent reference to VIVUS' Form 10-K for the fiscal year ended December 31, 2005 rather than the intended reference to VIVUS' Form 10-K for the fiscal year ended December 31, 2004.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. 2005 Financial Results and Product Development Conference Call on February 23, 2006, 4:30 p.m. EST.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VIVUS, INC.

By: /s/ Timothy E. Morris

Timothy E. Morris

Vice President and Chief Financial Officer

Date: **February 27, 2006**

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of VIVUS, Inc. 2005 Financial Results and Product Development Conference Call on February 23, 2006, 4:30 p.m. EST.

VIVUS, Inc.

Moderator: Timothy Morris**February 23, 2006****4:30 pm EST**

Operator: Welcome to the VIVUS, Inc. fourth quarter and full year financial results conference call. Joining the call from VIVUS are Lee Wilson, Chief Executive Officer, Peter Tam, Senior Vice President of Product and Corporate Development and Tim Morris, Chief Financial Officer.

At this time all participants are on a listen only mode. During the course of this conference call VIVUS may make projections or other forward-looking statements regarding future events or the future financial performance of the company.

We wish to caution you that such statements are just predictions and that actual events or results may differ materially. Investors should read the risk factors set forth in VIVUS Form 10-K for the year ended December 31, 2005 and periodic reports filed with the Securities and Exchange Commission. These documents contain and identify important factors that could cause the actual results to differ materially from these contained in our projections or forward-looking statements.

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Following the speakers' prepared remarks we will hold a question and answer session. To ask a question please press star followed by one on your touch-tone phone.

If anyone has difficulty hearing the conference please press star for operator assistance.

I will now turn the conference over to Mr. Leland Wilson, President and CEO. Please go ahead sir.

Leland Wilson: Thank you and thank you all for joining us today. In 2005 we continued to make excellent progress on the clinical and regulatory front for all of our products. Before I ask Peter to talk about specifics I'd first like to review our corporate strategy on how VIVUS is building a successful pharmaceutical company in today's environment.

We believe that limiting risk is central to this strategy. Non-approvable projects are extremely punitive, both in terms of time and dollars, and often put developing stage companies out of business. Most projects fail in development due to safety and efficacy concerns.

At VIVUS we bypass many of these safety and efficacy risks by choosing previously FDA approved chemical entities for which much is known about their safety and efficacy.

Our estrogen, testosterone and alprostadil products are examples of this strategy, all having been approved multiple times by the FDA. Previously approved chemical entities to be commercially successful must also serve billion dollar plus markets and they must have strong long-term patents.

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One of our strategies to obtain patents on previously approved compounds is to look for new patentable uses of these compounds. For example, alprostadil for female sexual arousal disorder is a good example.

We also look to develop new patentable superior delivery systems for these compounds. The key word here is superior. For example, the key to testosterone and Estradiol MDTs products is that they are not only superior delivery systems patentable but they also have superior delivery systems.

A long blocking patent life on a patient preferred delivery system will prevent the quasi generic competition by companies marketing both gels and patches. We make calculated exceptions to our core strategy from time to time and Avanafil is a good example of this.

Avanafil is a new chemical entity but it is from a well researched, safe and effective class of compounds from which there have been two recent FDA approvals. In addition, Avanafil meets the requirements of having a strong patent, serving large markets and it has a patient preferred characteristic.

Risk is also reduced at VIVUS by having a portfolio products and developments. Commercial success in any one of our development projects could provide excellent returns to our shareholders. We strongly believe however that all of our products will ultimately be FDA approved and commercially successful.

Our biggest challenge at VIVUS in 2006 is simply to fund development while limiting dilution. To meet this challenge we must substantially increase shareholder value this year. To achieve this we must accomplish the following goals.

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We must remove the regulatory cloud over Testosterone MDTs by showing that there is an economically feasible way to demonstrate cardiovascular safety of testosterone in a Phase 3 trial.

We will do this by working with the FDA to finalize our strategy and we will demonstrate the viability of our strategy to our shareholders by obtaining a special protocol assessment from the FDA. We believe that achieving this goal will not only renew investor interest in female sexual desire disorder but it will also help the whole field of female sexual dysfunction to include Alista as well. Alista must also achieve successful results in its ongoing Phase 2B clinical trial.

For Avanafil we must complete a partnering deal before the start of Phase 3. Our loan from (Tanabe) will cover all required studies prior to the start of Phase 3 trials.

For Evamist we must get excellent safety and efficacy results from our Phase 3 clinical trial which is nearing end now. And we must submit a quality NDA sometime around the middle of this year. Achieving these goals we believe will substantially drive shareholder value.

Now I've asked Peter to talk a little bit about the specifics of what we've accomplished this year on each of the projects and where the projects stand. Peter.

Peter Tam:

Thanks Lee. I will now review each of the clinical programs we have, the progress we made in 2005 and some of the important milestones to look forward to in 2006.

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In 2005 we made significant progress in each of the four clinical programs at VIVUS.

For Alista, at least said the active ingredient in this product is alprostadil, which is a product that has a long history of safety and approved by the FDA for various indications. We are developing this product as an on demand treatment for female sexual arousal disorder. Alprostadil is a naturally occurring molecule found in human tissues as well as in semen. Even though this is a previously approved molecule we have new patents on the use of this compound for treating female sexual dysfunction.

Our patent position provides exclusivity for the topical application of this vasoactive agent for improving blood flow to enhance arousal in women with diminished sexual function. It is our view that the patents we have in this phase are blocking to those who are developing various classes of vasoactive agents for topical application for the treatment of female sexual dysfunction.

To date for Alista we have completed three Phase 2 studies which all demonstrated a positive effect with respect to increases in arousal, increases in satisfactory sexual events and/or increases in orgasm as compared to placebo.

For the last completed study we presented positive Phase 2 results for Alista at the annual meeting of the American Urological Association. This study was the first to evaluate the use of Alista in pre-menopausal women in the home setting. Results from this trial demonstrated that Alista resulted in significant increases in satisfactory sexual events.

Use of Alista also resulted in significant improvement in orgasm. And there were no serious adverse events reported in this study. In terms of the ongoing study – in the fourth quarter we completed enrollment in the current Phase 2B

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study of Alista. Over 300 women have now been enrolled into this study and these are women who have undergone a hysterectomy and have been diagnosed with female sexual arousal disorder. We expect to complete this trial by late 2006.

In the third quarter of last year, the FDA revised the guidance for approval of drugs for treating female sexual arousal disorder. For approval of Alista the FDA will require co-primary end points including both the number of satisfactory sexual events and improvement in the self-assessed level of sexual arousal.

We are collecting both end points in the current trial. If the current trial demonstrates efficacy for both of these end points, over placebo, we will be meeting with the FDA to discuss if this study could be considered a pivotal study for product registration.

The next two female health products are our testosterone spray and Evamist, our Estradiol spray for the treatment of menopausal symptoms. As Lee said both of these products have a superior delivery technology that is patent protected. These products utilize what we believe to be the next generation drug delivery technology which provides cosmetic elegance, convenience and reliable drug delivery.

Both of these metered dose spray products will be competing in billion dollar markets. For our testosterone spray, which is being developed for the treatment of hypoactive sexual desire disorder, or HSDD in women, we reported in the first quarter positive Phase 2 data. Results from the trial demonstrate that treatment with our testosterone spray in pre-menopausal women with HSDD significantly increased a number of satisfactory sexual events.

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As a result we held an end of Phase 2 meeting with FDA in the third quarter of last year. This was the second meeting we had with the FDA since the Intrinsa advisory panel meeting that took place in 2004. FDA provided guidance regarding the safety requirement that would be necessary to support regulatory approval for the use of testosterone in women.

On the guidance provided by FDA we submitted a Phase 3 development program which is currently being reviewed by the FDA. We have another scheduled meeting at the end of this quarter to discuss our latest Phase 3 proposal and study design. If the FDA accepts our proposal we will then submit our Phase 3 protocol under Special Protocol Assessment.

Through this series of meetings and correspondence with FDA we believe we've made a great deal of progress with them, with respect to the efficacy of testosterone and the methods of analyzing long-term safety end points. We hope that this upcoming meeting will enable us to reach agreement on our Phase 3 program.

Our second proprietary spray is Evamist. This is the company's most advanced program nearing Phase 3 completion. Evamist is an Estradiol spray being developed for the treatment of vasomotor symptoms associated with menopause. We believe this is a superior product based on strong market research data which showed the high patient preference rate for this delivery system.

With regard to the development and progress, in the third quarter we completed enrollment in our pivotal Phase 3 clinical study for Evamist. Over 400 patients were enrolled at 43 centers throughout the United States. The study is nearing completion and we expect results from this trial in the second

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quarter of this year. On positive data we plan to submit an NDA by the summer of 2006. If approved this would be the first novel patented protected spray product introduced into this large market.

Despite the results from the Women's Health Initiative Study, or the WHI study, the current estrogen market is still a billion dollar market and the number of women entering their menopausal years is expected to increase about 50% over the next fifteen years. The recent published results from the nurse health study, an NIH funded study, involving 12,000 women show contrary to the WHI study, that there was a 30% reduction in the risk of heart disease in women who started hormone therapy early as compared to those who didn't use hormonal therapy at all.

I think we're beginning to understand better regarding the science of hormonal therapy and the importance of initiating hormone therapy early as a woman enters her menopausal years. The fact that estrogen remains to be the most effective treatment for this indication, as recognized by the FDA, and the growing market in this coming year will make this Evamist product a compelling product for our company. These are the three female products in our pipeline.

The next product update is our PDE5 inhibitor Avanafil being developed for the treatment of male erectile dysfunction. Avanafil — just a little background on it. PDE5 inhibitors have been demonstrated to be the mechanism of action for treating erectile dysfunction. The market for PDE5 inhibitors continues to grow at a steady rate at approximately \$3 billion. There is little brand loyalty so that new patients are willing to try novel compounds, novel entrants into the marketplace. For example, Cialis because of its ability to differentiate itself based on a different PK profile has taken a significant part of the market.

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There's also decreases in direct to consumer advertising. The barrier to entry into the market have now decreased dramatically.

According to our market research a significant number of patients are willing to try a drug with the characteristics of Avanafil. With regard to the development progress for Avanafil in 2005 we completed and announced a series of important studies.

In the second quarter we reported positive data from Avanafil twice daily dosing study. The study demonstrated no significant plasma accumulation of Avanafil after a twice a day treatment regime, which indicates that the drug was quickly removed from the blood stream. The important implication here is that you have a drug in Avanafil that offers a very unique dosing flexibility profile.

Studies have shown that the majority of men and women rarely have sex the night before and then the morning after so that the need for a long acting drug is a bit suspect. With Avanafil however, because of this unique PK profile the drug is there when you need it and gone when you don't. And for the rare instance that you wanted to engage in sex with your partner again within the same day, same morning, then again in the evening you can take Avanafil again within the same day. But when you don't desire to do that you wouldn't have to have the drug in your system over a protracted period.

We also announced positive Phase 2 at home data in 2005. In summary the 298 patient multi-center double-blind placebo controlled study was conducted without restrictions to food or alcohol consumption. And the subjects with erectile dysfunction were asked to attempt sexual intercourse 30 minutes, not one hour, after dosing. Unlike the other trials conducted for other PDE5 inhibitors.

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This is an important point because market research data demonstrates that the majority of subjects and their partners do not plan for sex. Most couples have sex rather spontaneously within thirty minutes of their decision to have sex. That's why we model the trial after this expected behavior. Results of our Phase 2B study show that 84% of Avanafil doses resulted in erections sufficient for vaginal penetration on the top dose tested. There were no treatment related serious adverse events in this study.

In 2005 we also announced positive data from an Avanafil nitrate interaction study. The study was designed to evaluate the hemodynamic affects of nitrate in the presence of PDE5 inhibitors. The study was designed also as a comparator study to sildenafil, the active ingredient in Viagra. In this study subjects were pretreated with placebo, Avanafil and sildenafil prior to administration of nitrates. The study evaluated clinically significant hypotension which was defined as someone who experienced a greater than 30 mms of mercury decrease in their systolic blood pressure. The studies show that 11 patients out of 100 receiving placebo and nitrate had clinically significant hypotension.

In contrast 14 patients on Avanafil and nitrate developed clinically significant hypotension. Compare that to sildenafil. Twenty-eight patients developed clinically significant hypotension on sildenafil and nitrate. That's twice the number of patients developing clinically significant hypotension on sildenafil as compared to Avanafil.

We believe these are compelling data that differentiate Avanafil from the market leader. All of these studies were presented at two scientific meetings and were well received. We also had a very successful end of Phase 2 meeting with the FDA recently defining the Phase 3 program for Avanafil. We're

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working towards submitting our Phase 3 protocols to FDA under Special Protocol Assessment in the very near future.

I'm certainly proud of the progress we made in 2005 and look forward to further advancing our development program in 2006. With that I'll turn it over to Tim.

Timothy Morris:

Thank you Peter. The financial results for the fourth quarter of 2005 are as follows. Total revenues for the fourth quarter were \$9 million. This compared to the \$10.1 million we had recognized in the fourth quarter of 2004. Net loss for the quarter was \$1 million or 2 cents per share. The net loss was slightly higher when compared to the net loss last year of \$886 thousand or again 2 cents per share.

The decrease in the U.S. product revenues of \$2.3 million for the quarter was partially offset by an increase in international product revenues of \$1.2 million in the fourth quarter. The decrease in the U.S. product revenues in the fourth quarter of 2005 is due primarily to a smaller buy in that we had witnessed in the fourth quarter as compared to the buy in that we had saw in the fourth quarter of 2004. The slight decrease in the total net loss for the fourth quarter as compared to 2004 again is attributable to both the decline in product revenues offset by some increases in the R&D spending.

For the full year ended December 31, 2005 total revenues were \$14.7 million. Again this was down when compared to the total revenues of \$19.6 million for 2004. The net loss for 2005 was \$24.5 million or 57 cents per share as compared to the net loss of \$21.6 million or 57 cents per share for 2004.

The increase in the net loss for the full year is primarily due to lower product revenue. However the expenses are down when compared to the expenses

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from last year mainly due to the fact that we had over \$5 million in licensing fees included in R&D expenses in 2004.

At the end of the year cash, cash equivalent and available for sale securities was \$27 million. A net decrease of \$2.8 million from the year ending December 31, 2004 exclusive of the proceeds of the offerings we completed in Q1 2005 the change in cash was \$22.4 million. Again as in prior years Q1 2006 will be cash neutral. But as the cash used in 2006 is expected to be lower than in 2005 again mainly due to lower R&D expenses resulting from the completion of both the Evamist and the Alista study.

For Muse the worldwide product revenues were \$14.5 million in 2005. Revenues are down \$5 million from the total worldwide sales of Muse in 2004. Again the change in revenues in mainly due to the destocking of inventory at the wholesale level that occurred prior to the fourth quarter of 2005. The demand for Muse as measured by independent third party prescription data has begun to stabilize. But it is down from the demand of 2004.

Similar to prior year's wholesalers made purchases in the fourth quarter of 2005 that were greater than the current demand. Based on the fourth quarter demand for Muse we estimate purchases made by wholesalers in that fourth quarter of 2005 represent approximately four months of excess demand.

Given the stabilization of the demand and the strategic buying in the fourth quarter of 2005 we anticipate worldwide revenues of Muse in 2006 to be consistent with those seen in 2005.

With that we're going to open the call up to Q & A and back to Leland for a closing statement at the end of the questions and answer period.

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Operator:

At this time I would like to remind everyone in order to ask a question please press star, then the number one on your telephone keypad.

We'll pause for just a moment to compile the Q & A roster.

Your first question comes from Michael Tong of Wachovia.

- Michael Tong: Hi. Thanks for taking the question. Tim I'm wondering if you could just clarify a little bit more on your cash burn given where you are with your cash balance. Right now the way you look at it absent an Avanafil partner how long does the existing cash carry you in terms of operations?
- Tim Morris: Sure. That's a good question. We ended the year with \$27 million of cash like we said before. The first quarter should be essentially cash flow neutral so that you can probably estimate what the cash would be at the end of the first quarter. The cash used last year was actually lower than expected. I think we had told people we would use about \$25 million. We used about 22. We are not giving specific guidelines for 2006 except to say that we expect that the cash used in 2006 to be lower than that we used in 2005.
- Michael Tong: You know, I guess as a follow up to that, at what point do you anticipate your cash balance dropping to a level where you might want to refill your war chest, so to speak, so that you don't run in to a problem where you start a clinical trial and run low on cash?
- Tim Morris: Right. Well I guess a couple of things. We've always had enough discipline that we don't start clinical trials unless we have the resources to pay for them. So I think that's one thing.

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I think the second thing is that we do have, you know, a lot of activities ongoing right now. You know, we do expect to have some valuation drivers I think, coming up in the next couple of quarters that Leland had mentioned earlier. And so obviously, you know, we would look to take advantage of any increase in valuation, you know, when and if we see fit.

- Michael Tong: Great. Thank you.
- Operator: Your next question comes from Ken Trbovich of RBC Capital Markets.
- Ken Trbovich: Thanks for taking my question. Can you hear me?
- Male: Yeah. Sure can.
- Ken Trbovich: Sorry. Just wanted to make certain that I wasn't having problems with the headset. First question I guess on the development side. If you could help us out. I guess you've talked about sort of Avanafil – it sounds like there's going to be a lot of work going on behind the scenes in terms of drug interaction studies that we're not necessarily going to see data release on. Is that reasonable expense level that we should expect for you guys to incur this year with or without a partner? Or is that something that you also see as being somewhat dependant upon a partnership?
- Leland Wilson: Well I'll take that Ken. Peter you can chime in if you'd like to as well. Tanabe has agreed to basically allow us to fund all of the required studies that the FDA has put on us prior to the start of Phase 3. We can fund that out of the loan. So obviously you know that terms of that loan are very favorable to us. So that's a very nice deal. And, yeah, they are studies which require, you know, I'm going to put a ballpark estimate around \$4 million, \$3 million, \$4 million and Peter you can correct me on that, to complete. But having said

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that, they are time consuming and they must be done before Phase 3 starts. So that's where we are.

- Ken Trbovich: Okay. And then just with regard to the general direction on the R&D guidance comment. The fact that you've completed enrollment on Alista, does that mean that the bulk of the expenses are really essentially complete until we see the data analysis point once the trial is completed? Or are there recurring expenses between now and then that you expect to see on that trial as well?
- Leland Wilson: Yeah, not necessarily Ken. Obviously we'll complete the enrollment, or I'm sorry, the enrollment is completed. But we'll complete the trial in the third quarter. But I guess when you compare year to year, you know, we've obviously had the trial including the recruitment thereof ongoing in '05. And so just on a year to year basis we would expect the expenses for Alista to be lower in '06 versus '05.
- Ken Trbovich: Okay. And then the last question I'll get back in the Q. Just with regard to the testosterone situation. I know you mentioned — I guess Peter's indicated you've had two meetings since the initial Intrinsa panel. Could you just sort of characterize for us in a general sense whether or not you think that those meetings have been, you know, progressive in the sense of providing additional clarity or whether for example, this addition of a second endpoint that was brought up is sort of an example of how it's still a moving target and we need to maybe be careful that we don't get too excited about the timing on the program?
- Peter Tam: No Ken. I think the meetings that we've had with the FDA were extremely helpful. Should we call back in November of 2004 when the Intrinsa panel meeting took place? The FDA had a certain issue or at least Dr. Shames demonstrated that there were some questions about the efficacy. And it took

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us a little while to, you know, perhaps with some analysis of data show that it is an important and clinically meaningful change with respect to the efficacy provided by testosterone.

And I think the recent comments made by Dr. Shames at the ISSWSH meeting basically suggested that he has accepted the level of efficacy achieved by testosterone therapy. So there was certainly movement that we made and we believe we have certain influence over. As well as discussing with the agency regarding the safety endpoints. You know, how to analyze these endpoints and we've made some proposal to the FDA which they have accepted in terms of how to analyze these endpoints and how to basically gather these endpoints.

And in discussions with them about the analysis and the various endpoints we went back with another proposal submitted and they are currently reviewing those data. I mean the proposal. So the bottom line is that we're seeing progress. The FDA has demonstrated the willingness to work with us and try to come to a common ground. And I think we're actually pretty close. I mean they have actually provided very clear guidance on the scope of the safety study that we would need in order to get the product approved.

Leland Wilson: Ken I would just add that it's very clear having probably met with them more on this subject than any other company, both in person, on the phone, etc; that they are interested in approving a product for this area. There is no doubt about that in my mind.

Ken Trbovich: Okay. Thank you.

Operator: Your next question comes from Ian Sanderson of Cowen and Company.

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Ian Sanderson: Good afternoon. Thanks for taking the question. A couple on Testosterone MDTs. So you mentioned you hope to meet with the FDA again by the end of this quarter. Has that been, a meeting, formally scheduled? And then following that meeting, assuming they accept your proposal, what would be the rough timing of an SPA submission? Again assuming they accept your proposal. And then under your proposal – not sure if you're willing to disclose any of this, but what would be the scope, the rough scope of a safety study and what would be the duration of that study?

Peter Tam: Yeah, Ian the meeting has been formally scheduled for approximately the end of this quarter. So that's been set.

Ian Sanderson: Okay.

Peter Tam: In terms of the SPA submission. That would be done the quarter following. So roughly around Q2 provided that we get agreement with the FDA on the overall Phase 3 program. And lastly, could you remind me again? What was your?

Ian Sanderson: Yeah, so just in very rough terms in your proposal what is the scope of the safety study proposal and what would be the duration of that?

Peter Tam: Yeah. We're going to keep that close to our vest. What I can say is that we believe, you know, we wouldn't propose anything that we can't do. And what we propose to the FDA is something that is reasonable and it satisfies, in our opinion, the requirement that they've set forth in their guidance to us based on our last meeting.

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Ian Sanderson: And do you know if at this point, I guess I should know, if the FDA has provided any sort of formal guidance to P & G on the Intrinsa development plan?

Peter Tam: No, I mean we don't know anything with regard to the Intrinsa application.

Ian Sanderson: Okay. And then lastly can you just characterize the stage of any sort of partnering discussions on Avanafil?

Leland Wilson: Yeah, I'll take a shot at that. Peter can chime in as well. We have a good ongoing discussion. It has not resulted at this point in a deal which, you know, shareholders would want us to sign. And so we're working towards that end.

I would remind people however that we are not delaying this project one bit. The Tanabe loan is funding all necessary development projects so it's not on the critical path at this time. It is on the critical path however for bringing in some additional funding so we can use it for other projects within the company. So we have given it a very high priority. We have very good interests. And we're having good discussions. And when we get a deal you'll be the first to know.

Ian Sanderson: And the Tanabe loan is strictly to fund Phase 2, ongoing Phase 2 studies? Are they not agreeing to fund Phase 3?

Leland Wilson: That discussion has not been had at this point.

Ian Sanderson: Okay. Thank you very much.

Leland Wilson: Uh-hum.

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Operator: Your next question comes from Ilya Kravets of Rodman and Renshaw.

Ilya Kravets: Hi guys. I have just a couple of quick questions. One of Avanafil the Pre-phase 3 trials, the ones that need to be done. What is your expectation on the timeline to have those completed?

And on the deal with Avanafil you said that there are interested parties but no interesting deals as of yet. What are the key problems that you see coming through? Whether they're uncomfortable with the data or the market dynamics or they're waiting for data? Things of that sort.

Peter Tam: Yeah Ilya hi. The Avanafil. There are certain studies like metabolism studies and some Tox studies that we would need to do. We expect to complete all those studies within this year under the Tanabe loan. So that's the — and then in terms of starting Phase 3. If we get the partner or the necessary funding to proceed to Phase 3 we certainly would be able to do that in the process of submitting protocols under SPA to FDA right now.

And in terms of a deal for Avanafil, you know, certainly there are market dynamics right now. I mentioned one of them during my update. And that is, you know, the cost of getting into the game, into commercializing this product was certainly extremely high because of a direct to consumer ad campaigns that these large pharmas have been able to place. But as you can see that really has dramatically decreased over the past six to nine months. And we expect the trend to continue.

So what that means is that for pharmaceutical companies that are interested in playing this game they would be able to come in without a significant cost in terms of the barriers of entry into the marketplace. So we see that those

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market trends are coming in favor, you know, of getting Avanafil licensed in the near term.

Ilya Kravets: Right. So what's keeping the company, the interested companies from meeting you at the deal that you see? It's this new dynamic and the profile of Avanafil?

Leland Wilson: Yeah. I'll give you my direct forward answer to that is they will and it'll be under appropriate terms. And we will get this deal done. I'm very, very confident.

Ilya Kravets: Oh that's great. Good. Any timelines on that?

Leland Wilson: No we're not putting timelines on it. As you guys have been with me for a while know that it's very difficult to promise a timeline. Clearly we are not going to fund Phase 3 ourselves and so that – if we run into the timeline necessary to fund Phase 3 then we're certainly vulnerable to justified criticism.

Ilya Kravets: Right.

Leland Wilson: Having done a deal. So.

Ilya Kravets: And the Evamist plans for right after the filing for a sales force marketing and that sort of thing. Can you give us an update?

Leland Wilson: Yeah. It's been our strategy all along to market Evamist by ourselves. We think we can do this very effectively. Obviously we've demonstrated marketing success with products in the past. And we reap all the potential rewards for having done so. That said we've been contacted by at least two

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companies that are interested in having some kind of relationship with us regarding the launch of this product. In the United States and a couple companies elsewhere around the world but we do not have rights for the European market specifically.

Ilya Kravets: Right. And what is the level of interest that you've seen with Testosterone MDTs following Dr. Shames comments at ISSWSH? I know you're still waiting for clarity from the FDA regarding the FDA but with all the progress that's been had?

Leland Wilson: Yeah there's, you know, certainly if you all remember back before the Intrinsa advisory panel meeting stock prices were moving. Everybody was in a very happy place. We are nowhere near back to that happy place because of this cloud that's over us. We believe that the FDA will remove that cloud and renew interest.

And I would say for those of you that have looked closely at testosterone. There is no indication of any cardiovascular issue with testosterone. As a matter of fact if you look in the Intrinsa data the thing that you would observe is how extremely safe that product has been in all – in very substantial clinical trials. We've worked with testosterone in my previous life, and certainly Dr. Place in many regards considered the father of transdermal delivery testosterone. We know the safety profile of this drug very well and it is an extremely safe drug in our opinion.

Okay so the challenge then becomes one of demonstrating its safety. And so we will be able to do that. And once we have an SPA which clearly states how – that the cost of doing this is not prohibitive and that it is agreeable the Phase 3 programs are agreeable to the FDA that will take that cloud off it.

There is no question in anyone's mind, any researcher's mind about the value of testosterone for increasing female sexual desire in women who have female sexual desire disorder. It has been proven over and over again to be effective and I can tell you without reservation the demand for products in this area is amazing. It's been estimated at over 1 million women have taken off label testosterone for treating female sexual desire disorder.

And we've actually done some research in this area which would validate the tremendous off label use of testosterone. Compounding pharmacies will tell you that that it and menopause symptoms are their two major business of weight. So it is – there's a demand for it and it is good medicine. It does more than just increase female sexual desire. It has issues with maintaining body mass, muscle mass, feelings of goodwill or good mental strength, etc; that have all been shown positive in numerous studies.

And so it is in our opinion a very, very good product which will be demonstrated to the FDA's concern. Remember the reason they have these concerns is because they believe it will be very widely used. And so they're looking for that very, very small potential much like they looked at in the NIH study to show, which took thousands of patients and tens of years to demonstrate that there was an effect on cardiovascular issues.

So this is the market I think. Most people will agree that it's there. And it's a challenge now just getting to the regulatory process in a sensible way. We believe we'll be able to handle that pretty quickly.

Ilya Kravets: Right now I think that all of us have put in the time and analyzing the effort these days know the benefits and the clear efficacy. And even the safety I guess aspect of testosterone. There is a great need. My question was a little bit more towards a potential partner. Have there been new companies that have

approached you? Has there been initial conversation, interaction between yourself and some of the what I would guess would be the larger pharma companies?

Peter Tam: Yeah, I mean Ilya. You know, prior to the Intrinsa advisory panel meeting we were having numerous discussions with the big pharma. And, you know, the interest is there. Right now everybody's on a holding pattern until they know, you know, what is needed on the regulatory front. And that's why it's very important, as Lee said, for us to get to the FDA and get an SPA prior to us doing that we're going to have to have them get agreement on the overall development program which hopefully we'll be able to clarify over the next quarter or so.

Ilya Kravets: Okay great. Thank you.

Operator: You have a follow up question from Michael Tong of Wachovia.

Michael Tong: Actually my follow up question has been answered. Thank you.

Operator: Your next question comes from Andy Kiernan of UBS.

Andy Kiernan: Yes. Hello. I've got two questions for you. The first one is on Alista. At one point you said you were going to shop the U.S. rights for that. Is that something that is continuing?

And then my second question is on Evamist. Since you chose to go it alone on Evamist is further shareholder dilution inevitable or are there other ways to pay for the roll out of that product?

Leland Wilson: All right well. I'm a shareholder too as you know Andy and a substantial one. And I fight dilution as much as everybody. We have that as a primary goal is to fund these things without dilution. And as you know there are creative ways to do this. Certainly corporate deals is one of them. But there are other non-diluted financing that we're looking at right now that may make some sense as well.

Andy Kiernan: Okay.

Leland Wilson: As far as U.S. rights to Alista. Yes we are interested in discussing rights. We have had in depth discussions prior to the Intrinsa advisory panel. That cloud that's hanging over testosterone is also hanging over the whole field of female sexual dysfunction. And our potential partners in this area want to know what the FDA thinks about female sexual dysfunction before they put hard cash on the line.

Andy Kiernan: Okay. Well I look forward to some shareholder value creation this year.

Leland Wilson: Thank you. I do too.

Operator: Your next question comes from Steve Sullivan of Horizon Financial Group.

Steve Sullivan: Yeah Lee. Alluding to the last question can you give us a little bit more details on your thoughts on non-dilutive, non-partnership funding?

Leland Wilson: Sure. There are Wall Street investment firms that will work with you. Not only Wall Street investment firms but even big CROs, etc; will work with you on non-dilutive financing to progress projects. And then with the payback at the end plus an internal rate of return for them. So we are looking at a number

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of those at the present time. So it's just one of the options but and they make sense to some degree. Say stay tuned and we'll let you know.

Steve Sullivan: Okay. Thank you.

Operator: Thank you. At this time there are no further questions. Mr. Morris are there any closing remarks?

Leland Wilson: Yeah I'd like to make a closing remark. First of all I would say we hired a new guy this year. Dr. Wesley Day. We're very proud of Wesley and the work that he brings to us and to run our clinical program. It's really been refreshing to see his level of expertise. And he came from the Pfizer organization where he had substantial responsibility.

But the interesting comments that Wesley makes to people that we talk to about, you know, what he found when he first came to VIVUS. And that is things that make me very happy. And I would like to share a couple of them with our shareholders.

The first one is, you know, they ask where are all the people that do this work? And how are you able to accomplish what you do for the kind of burn rate that you have? I would say I am most proud of #1 are the people here that work so hard for doing the work that we all, our owners and us specifically are working to. Most proud of them to be able to do that.

Second one is that I am very, very proud of this pipeline. I think this pipeline compares favorably to many large pharmaceutical companies. And Wesley has said that on numerous occasions. Four late stage development projects all for very large markets for which we have strong patent positions is a very strong place to be.

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All of us are disappointed that we have not achieved the shareholder value. Clearly I think removing the cloud from female sexual dysfunction will certainly help in that regard. Meeting our near term goals that I reviewed with you will also have a significant impact on that. And so I'm looking for 2006 here to be a year where we do increase shareholder value pretty dramatically.

And with that I'd like to thank all of you as investors. I beg your patience and I appreciate it very, very much. And you should feel comfortable that the people here are working very, very hard and capably on your behalf. So thank you again.

Operator: Thank you. This concludes today's VIVUS Incorporated fourth quarter and full year financial results conference call. You may now disconnect.

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