
**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)

July 28, 2005

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)

(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 July 28, 2005, VIVUS, Inc. conducted a conference call during which members of its senior management team discussed financial results for the fiscal six months and quarter ended June 30, 2005 and the outlook for the remainder of fiscal 2005. 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 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

(c) Exhibits.

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. Financial Results and Product Development Conference Call on July 28, 2005, 11:00 a.m. EDT.

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: **August 2, 2005**

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of VIVUS, Inc. Financial Results and Product Development Conference Call on July 28, 2005, 11:00 a.m. EDT.

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Event ID: 1108517

Event Name: Q2 2005 Vivus Financial Results and Product Development Conference Call

Event Date: 2005-07-28T15:00:00 UTC

C: Leland Wilson; VIVUS, Inc.; CEO

C: Tim Morris; VIVUS, Inc.; CFO

C: Peter Tam; VIVUS, Inc.; SVP, Products and Corporate Development

P: Ian Sanderson; SG Cowen; Analyst

P: Brant Jaouen; RBC Capital Markets; Analyst

P: Michael Tong; Wachovia Securities; Analyst

P: Russell Gilbertson; Caris & Co.; Analyst

P: Ennis Yusovich; Griffin Opportunity Fund; Analyst

P: Marc Robins; Robins Group; Analyst

P: Operator;;

Operator: Welcome to the VIVUS Inc. second quarter financial results and product development highlights 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 in 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 10K for the year ended December 31st, 2004 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 those contained in our projections or forward-looking statements.

(OPERATOR INSTRUCTIONS)

I will now turn the conference call over to Leland Wilson, chief executive officer. Please go ahead, sir.

Leland Wilson: Thank you. Good morning, everybody. Pleased to be with you today.

Our agenda today is I will first review our clinical accomplishments and highlights for the second quarter, then Tim will discuss our financial results and Peter will follow that with a pipeline update and then we'll have a question and answer section.

I want to start out, as I said, by talking about our clinical accomplishments for this past quarter and I want to take a moment to pause and say that I've been obviously on this job now for almost 15 years I guess, something in that neighborhood, and the clinical

accomplishment of VIVUS this past quarter have to rank right up there with some of the best quarters that we've ever had. So I'm very pleased with the data that we have. And I'm going to take a few minutes to dwell on a couple of them, so bear with me.

The first one I think and most outstanding is that we had released the avanafil Phase 2 results. And I want to take just a few seconds to talk about that study. This study was a comparison multicenter, double-blind study, well randomized parallel-design and we're looking at it for a dose ranging study and the study size was very substantial, 284 patients here. Now, I want to just again say that few times in your life in doing clinical trials, which I've been doing for 30 years now, you get results that meet all your expectations for a clinical program.

Let's get down to goals that we had set for this clinical trial. The first thing we wanted to accomplish was to find what were the appropriate doses that we'll be able to take into Phase 3 testing. The second goal was to demonstrate comparable safety and efficacy to other PDE5 inhibitors that are on the market. The third one was to test the validity of instructing patients to attempt sexual intercourse 30 minutes after taking avanafil. I want everyone to remember that this is less than half the time recommended in the labeling for other PDE5 inhibitors. And the fourth goal was to test the concept of not limiting food and alcohol. I can say without hesitation that we met or exceeded every single goal in this clinical study, so my heartfelt congratulations to our clinical department for a job well done.

We found the maximum effective dose and for those of you who have studied the data carefully, it's clear that 200mg dose achieved the maximum response and that a 300mg dose would not be required. Now, this does not say that this is the dose that we are actually going into Phase 3 testing. Clearly, we'll work with the FDA and internal considerations here as long as with our partner, Tanabe, to determine the final dose. But it is nice to know that we did find the maximum dose in this trial.

We demonstrated also that we had at least comparable efficacy and safety and for those of you who have looked at our efficacy results, they're outstanding. So we can say that they're at least comparable on a safety benefit and on an efficacy analysis. And, in fact, there is hints in this study that we may have an opportunity to have superior efficacy specifically at the earlier time points, such as at 30 minutes.

And efficacy and safety in this trial was exceedingly good; no color vision changes and just a wonderful safety profile that we're able to demonstrate in this trial. So the goals were completely met for this study and we're very happy to say that we're now working to advance this clinical program with an end of Phase 2 meeting with the FDA as quickly as possible.

Next, the data that we announced during the quarter was the avanafil twice-daily dosing study. The goal of this study was to see if patients could take avanafil 12 hours after taking the first dose without risk of increasing their plasma concentrations. Now, you say why would we do something like this? I think it's clear that we want to establish a profile

because the market has been established out there right now largely because of the work with Cialis that you can have the weekend pill.

Now, what we wanted to establish here is to demonstrate that in that rare occasion when a patient wants to take the medication, say on Friday night, say at 7 o'clock, that he could have — begin sexual activity within 30 minutes and it would have a window of opportunity for sexual activity which would last at least three to four hours. So that would take him up to 11 o'clock at night. And then the next morning, if he wakes up and wants to have sexual activity again at 7 o'clock in the morning, he's certainly able to accomplish that with another window of three or four hours of activity. And then if he wanted to have sexual activity again on Saturday night and Sunday morning, et cetera, he would be able to do that with this medication.

It's a very simple concept that the marketplace is being defined to a great extent by this whole time of onset and length of duration of activity. We are at one end of the spectrum, that is fast onset and rapid disappearance from plasma and out, so fast in, fast out, there when you need it and gone when you don't need it, as in comparison to Cialis, which is relatively slow to get in and has — it stays around for quite some period of time.

So this study was looking at treating patients that wanted to have sexual activity more than once. This was an open label PK study comparing blood levels of avanafil in healthy volunteers taking a single dose of avanafil with blood levels taking — with those taking avanafil twice daily, every 12 hours, for seven days. And the results were that we saw no significant plasma accumulation of avanafil after taking it twice daily for seven days. So this gives us great comfort, then, that we can do this on at least an intermittent basis over the weekends, et cetera. And so this is very positive results and an important help to us to be able to position this product in the marketplace.

The third study was the nitrate interaction study and I will say that these studies are always very complicated. And we did learn a lot in this study, that in spite of some of the design issues that we can correct I think on future studies, we were able to meet the goals of the study with great ease here.

The study was conducted to evaluate effects on blood pressure and heart rate. And subjects pretreated with either placebo, avanafil or sildenafil citrate/Viagra and then they were challenged with nitroglycerine to test, as I said, the effects on heart rate and blood pressure. Overall, the results revealed that avanafil had less impact on blood pressure than Viagra and that is exactly what we hoped to demonstrate. And we think that we'll be able to refine this even more in future studies.

The next study was ALISTA data that we had in premenopausal women was presented by Ray Costabile at the annual meeting of the American Urological Association. And this was a double-blind placebo-controlled study, a crossover design and the purpose was to evaluate the response to ALISTA administered in 51 premenopausal women. The study showed that 64% of ALISTA doses resulted in satisfactory sexual events and the use of

ALISTA also resulted in significant improvement in orgasm, which we think is a very important endpoint in this area.

So when you look at this data, it is not all that different from what we see in the PDE5 kinds of studies, if you looked at it from a specific angle of number of satisfactory sexual events, et cetera. So the data seems not only comparable here, but comparable to Intrinsa data that was presented on testosterone, et cetera. So we think that this product is demonstrating the kind of efficacy that we need to have FDA approval and obviously we're working with the agency to define exactly what that is.

This is the first trial that we have conducted in premenopausal women and so we're very excited about this opportunity. Obviously it expands the market potential into a very large population which has sex more often and is more interested in sex, et cetera. And so this is a very important milestone for us to be able to demonstrate efficacy in these patients.

There were no serious adverse events in this study at all. And this is the first time that this data's actually been presented to the urology community. So we're very proud of that work and obviously it gives us great hope in going forward in the premenopausal population.

The next one is that we had done what I would call pioneering work and very significant work that we've been doing now in post-radical prostatectomy patients. So let me talk a little bit about the concept of this study. And patients that have radical prostatectomies, whether they be nerve-sparing or not, have a very low probability of being able to return to sexual function, either with erectogenic agents like a PDE5 inhibitor or MUSE or others or on their own. And so the goal here is to try to help patients recover their erectile function.

And alprostadil has been shown to have some very interesting characteristics in studies with spinal cord injury patients. It does two things. We think the mechanism of action here is to increase blood flow, which brings nourishment to the tissues. But it also has the potential of increasing neuro regeneration. And this is where most of the excitement comes around alprostadil as a neuro regenerative agent in both these patients, radical prostatectomy patients where they've had their nerves severed, and also in spinal cord injury patients. So this has great promise.

This study was done at the Cleveland Clinic by a physician named Rupesh Raina and the study focused on an individuals' ability to recover sexual function following radical prostatectomy. The study showed that 74% of patients who completed six months of MUSE treatment were able to resume sexual activity and 39% were able to achieve natural erections sufficient for intercourse without the use of erectogenic agents. So these numbers — although this was not a comparative study, we looked at other comparative trials that have been done in this area and these are superior results, in our opinion.

So very excited about this and obviously we're now expanding that into other clinical studies across not only the United States, but in Europe as well. So this is potentially a

very important therapeutic contribution to post-radical prostatectomy patients. Remember, this is the therapy now that is not given to produce erections for sexual intercourse. This is a therapy that is given on a repeated basis so that they can have the potential for having — specifically over a six to nine month period so that a patient can have the potential for having erections on his own or with an erectogenic agent.

Okay, and the final one we'll — I think that's it. Now I'm going to turn it over to Tim now and he's going to talk about a couple of other accomplishments other than the clinical area. So again, just everybody should feel real proud, as we do within the company, about these accomplishments. Thank you.

Tim Morris: Thank you, Lee. I'd like to talk briefly about the financial results for the second quarter and the first half of 2005.

For Q2 we reported a loss of \$8.6 million, or \$0.19 per share. That was higher than the same period last year where we had lost \$4.9 million, or \$0.13 per share, for the second quarter of 2004. The increase quarter to quarter was mainly due to higher R&D expenses, for the most part due to clinical trial costs for Evamist and ALISTA.

Total revenue for the second quarter was \$1.7 million. Again, this was slightly lower than the \$3.2 million we had recognized for the second quarter of 2004. Revenue from the domestic sales of MUSE was lower, mainly due to a couple of factors. First of all, we've seen that our wholesale order distributors continued to use the inventories of MUSE that they acquired late in 2004. We also have seen a fairly significant decrease in the inventory levels that were held by our wholesalers. In fact, the inventory levels are down by about 50% from what they were at the end of the year in 2004.

Also, we have seen a decrease in the retail demand for MUSE as compared to the same period last year. We've seen an overall decrease in demand of about 11% from the second quarter of 2004. Our average units from the sales of MUSE from a demand standpoint, this includes both U.S. retail and U.S. government, is slightly under 200,000 units per quarter. And lastly, we did have slightly lower revenues from the international shipments of MUSE as well.

For the first half of 2005, the net loss was \$17.5 million, or \$0.42 per share. Again which was slightly higher than the loss of \$15.8, or again \$0.42 per share, for the first half of last year. The increase in the net loss year over year again was mainly due to increased R&D expenses, in this case for ALISTA, Evamist and avanafil.

Revenue for the first half of 2005 was \$2.3 million. This was slightly lower as compared to the revenue in the first half of last year of \$5.1 million. Again, the decreased revenue here year over year was mainly due to the large volume that happened in Q4 last year and the decrease in the retail demand for MUSE.

As you guys have seen, the MUSE revenues, those tend to fluctuate the first couple of quarters, as anticipated, or slightly lower. However, our guidance for MUSE for the year

remains the same at about \$15 million. Again, that assumes we have a relatively large buy-in like we experienced in the fourth quarter of last year.

For cash, cash equivalents and available for-sale securities, which we refer to as cash, at the end of June we had approximately \$39.5 million. This was down from the \$50.4 million that we had at the end of March and also — but it was up from the \$29.8 million that we had at the end of the year. The decrease in cash for the quarter of about \$10.9 million was mainly due to cash used in operations again to cover clinical trial expenses.

Now, if you'll remember, the first quarter we were essentially cash flow positive basically due to the \$9.2 million we had collected in accounts receivable in the first quarter. So we also did raise some money in the first quarter of this year, so if you exclude that, the net cash used for the first half of 2005, again was \$10 million.

One of the other accomplishments that we had for the second quarter was the fact that VIVUS was added to a new index, the Russell Microcap Index, which I think got final weighting on June 24th, 2005. Again, this is a new index from Russell which measures the performance of the microcap segment. It includes the smallest 1,000 securities in the Russell 2000 plus the next 1,000 securities based on descending market cap. The average market capitalization in this index was approximately \$217 million. And again, we think the inclusion in this index should increase exposure to VIVUS with certain portfolio managers and with certain investment professionals that do tend to buy and follow index funds.

For the second quarter we were very busy with our IR and PR activities. We had presentations from a PR standpoint at two important medical gatherings, as Lee mentioned. The first one was in early May at the 2005 annual clinical meeting for the American College of Obstetricians and Gynecologists, or ACOG. The second one was various presentations that were held at this year's AUA meeting in San Antonio where we had two podium presentations, one on ALISTA, one on MUSE obviously.

For the remainder of 2005 we're going to focus our PR efforts around a couple of events. First of all we'll have some media visits with health reporters and the like in September in New York City. And then lastly we're going to focus some PR efforts around various abstracts that have been submitted for the Sexual Medicine Society of North America Annual Meeting, again in November in New York City.

On the IR side we began a series of roadshows and one-on-one meetings, which targeted institutional and retail investors. During the quarter we had several meetings with professionals in New York, Minneapolis, San Diego, Los Angeles, San Francisco and in Paris. For the second quarter we had over 40 one-on-one meetings. We also had three presentations at top quality healthcare conferences and small-cap conferences, including the Rodman and Renshaw Conference, the UBS Global Pharmaceuticals Conference and the Wachovia Growth Conference in Nantucket.

Our planned activities to date in the third quarter is going to include broker luncheons in San Francisco, investor meetings in New York and in the southeast and various presentations to institutional sales force. For the remainder of 2005 we'll continue to be aggressive in scheduling face-to-face meetings here in the U.S. and in Europe and also look to seek out invitations to major healthcare conferences for the remainder of the year.

One other thing that we also had done in the second quarter is we changed our auditors. Effective June 28th the Audit Committee had terminated our relationship with KPMG. At the same time we hired a local firm, Odenberg, Ullakko, Muranishi, as the company's independent auditors. This change was made for economical and client service reasons. We expect at least a 30% savings on audit and related fees in 2005 as a result of this change and personally also expect better customer service coming out of OUM as well.

With that, I'm going to turn it over to Peter Tam, our senior vice president of products and corporate development.

Peter Tam: Thanks, Tim.

We continue to make good progress on the development of our four late-stage clinical candidates and I want to provide you with highlights for the progress we've made in the second quarter.

Evamist, our novel estradiol spray, is in Phase 3 development for the treatment of menopausal symptoms. Enrollment in this Phase 3 trial is progressing very well and right now we remain on target to complete enrollment by the end of 2005. The trial is being conducted under a previously granted Special Protocol Assessment from the FDA and ahead of the anticipated approval of Evamist, the company is beginning to create a marketing plan aimed at gathering valuable information from patients and doctors who treat women with menopausal symptoms. Additionally, we're also putting together all the preparatory work as necessary for an NDA filing anticipated next year.

For ALISTA. ALISTA is our proprietary topical on-demand treatment for female sexual arousal disorder. Enrollment in this current multicenter trial is going very well. To date we have enrolled more than half of our targeted patients in the trial and we will continue to enroll patients in the trial throughout the remainder of 2005.

The FDA has recently communicated a change in their guidance to us for the development of drugs for treating female sexual arousal disorder. For the development of ALISTA, the FDA is currently requesting co-primary endpoints, which include both the number of Satisfactory Sexual Events and improvement in the level of sexual arousal using validated questionnaires. Due to this communication, we believe it is more appropriate at this time to categorize the current multicenter trial as a Phase 2B trial. This recategorization does not change our previously stated development plan for ALISTA, requiring additional confirmatory Phase 3 pivotal studies which we plan to commence following the completion of the current clinical trial.

For testosterone, our testosterone spray is being developed for the treatment of hypoactive sexual desire disorder in women. We previously submitted a written proposal for a Phase 3 program for testosterone-MDTS to the FDA for review and comment. The FDA has acknowledged receipt of our proposal and is currently reviewing the suggested protocol.

Our goal in 2005 is to establish with the FDA the size and scope of the Phase 3 protocol for testosterone-MDTS. And we'll update you once this has been accomplished.

For our product to treat male erectile dysfunction, avanafil is our PDE5 inhibitor being developed for the treatment of male erectile dysfunction. It is a highly selective orally administered PDE5 inhibitor. Previous studies with avanafil have demonstrated a rapid onset of action and the recent Phase 2 study confirms that avanafil is highly effective when taken within 30 minutes prior to sexual activity.

Based on these positive results, we will be requesting an end of Phase 2 meeting with the FDA to discuss the Phase 3 program before the end of the year. We are extremely pleased with this compound and how clean the Phase 2 study results were. We believe this is a differentiable product and look forward to sharing the full data with you in an upcoming scientific meeting.

I want to take a minute to thank our R&D group in that I'm very proud of the work that they've done, especially how they've been able to rally together to advance each one of these programs.

With that, I will turn it back to Lee for a wrap-up.

Leland Wilson: Again, as I said, from a clinical standpoint we've had an outstanding quarter and we obviously are — would like to have increased sales from MUSE going forward and we're optimistic that we'll be able to recover and still make our \$15 million sales forecast for the year. So we're on target from that and, as Peter said, we're on target for all the clinical development programs. And if we can continue to get the kind of results that we got this quarter, I think we're all going to be very happy.

So good quarter and with that, we'll open it up for questions.

Operator: (OPERATOR INSTRUCTIONS)

Your first question comes from Ian Sanderson with SG Cowen.

Ian Sanderson: It's Ian Sanderson from SG Cowen. And my first question is on the ALISTA change in endpoints, or the FDA adding a second primary endpoint. Will that change this current trial being recategorized as a Phase 2B, will that change the total number of trials you expect to do? In other words, do you — will this be followed by two Phase 3 trials most likely? And second — and therefore change the cost of development.

And second, in any of your earlier Phase 2 trials on ALISTA, have you done any patient questionnaire work that would lead you to believe that this is an achievable endpoint?

Second, on testosterone-MDTS, when might you expect the FDA to come around with some sort of pivotal trial guidance, either for you or for Intrinsa, the desire product?

Leland Wilson: The first one here on the change in endpoint, bottom line is it doesn't really change anything at VIVUS, both from the timeline and from an expense standpoint. We have always planned, as you know, to conduct additional studies. Most of the work done in sexual function has a fair number of significant size trials in that they all contribute towards the overall safety and efficacy data that's presented to the FDA. We will need to do two pivotal Phase 3 program which will — which we will accomplish after we complete this one. So it really doesn't change anything from that standpoint.

And yes, we have done a lot of workaround the arousal endpoint. We had considered that as a secondary endpoint. And, for example, on the premenopausal study which we just completed, we were able to show an increase in arousal in that study using validated questionnaires, et cetera. So we have done a lot of pioneering work in that area and so it doesn't really change anything and that will continue to go forward.

The current study just was not powered to handle that secondary endpoint of increased arousal. So that's the change, but it really doesn't change anything substantively in this development program at all. But we just wanted you to know that — where we were on this clinical program.

Now, on the testosterone, Peter, do you want to pick that one up?

Peter Tam: We're still waiting for the FDA on that one and we are in almost weekly communication with them to see where they are with their review process. We're still expecting to get a response back from the FDA to provide us clarity on the development program. So once we get that information, we'll certainly update you guys on that.

Ian Sanderson: And do you have any hints on just how practical the FDA's guidance might be in terms of number of patients, duration of exposure, et cetera?

Peter Tam: Based on our meeting with them back in January, clearly they were — they were understanding of our needs and so forth and they realized that they also have to ensure safety. So they feel that certainly there's a common ground and that's really all that we can say at this point because that's all we know. But we do believe that the FDA is willing to work with us and I don't think they're going to be unreasonable with regard to doing trials for — to establish long-term safety.

Operator: Your next question comes from Brant Jaouen with RBC Capital Markets.

Brant Jaouen: Do you have any idea which of the questionnaires the FDA is going to be looking for?

Peter Tam: At this point the FDA has not specifically stated which questionnaire. All they've said was that they want to have two co-primary endpoints for arousal products. So they're looking for increases in SSE and some measure using validated instruments to determine increases in arousal.

Brant Jaouen: Which of the questionnaires have you guys used in the other Phase 2 studies?

Peter Tam: We've used the FSFI, the Female Sexual Function Index, which has various domains to assess arousal, orgasm, as well as desire.

Brant Jaouen: Okay. And that's the only one that you guys have used?

Peter Tam: Yes. Well, we also have other instruments. For example, we have certain questions and a diary pertaining to desire as well as arousal.

Brant Jaouen: Great. And did you guys — would you characterize those results as positive?

Peter Tam: Yes. As we said, those results are positive on both of those instruments based on a very small study that we completed in premenopausal population. So we're not concerned about this new requirement; it's just the fact it's been elevated to a primary endpoint. We just have to make sure that the studies going forward will be powered adequately to show differences in both the SSE, Satisfactory Sexual Event, as well as increases in arousal.

Brant Jaouen: Was FSFI the secondary endpoint that you had planned for the pivotal trial?

Leland Wilson: Yes, it is. But again, there's a lot of negotiation that goes on with the FDA right now. That question there has been validated — it has not been validated. We have not demonstrated the validity of that to the FDA at this point. We will and so it's part of the process moving forward.

Operator: Your next question comes from Michael Tong with Wachovia Securities.

Michael Tong: I just want to confirm what I just heard is that you expect to do two Phase 3 studies after completing the Phase 2B for ALISTA. Is that correct?

Leland Wilson: That's correct.

Michael Tong: And by not changing the timeline of development, so are you now thinking of doing the Phase 3 concurrently together?

Leland Wilson: Well, we're keeping our options open here. As you know, partnering discussions are something that's very important to us at this point and having a partner carry those Phase 3 trials. So there's a bit of consideration here for corporate partnering here and so we'll just have to see how that plays out.

Michael Tong: Okay, but in order not to change the timeline for the development, then the two Phase 3s pretty much have to be carried out together, right?

Leland Wilson: They will be.

Michael Tong: Okay.

Leland Wilson: Yes.

Michael Tong: Can you give us an idea of cash burn for the remainder of the year and also any update on partnership discussions on avanafil?

Tim Morris: Sure, Michael. I think we had previously stated our target for cash burn for 2005 was going to be approximately \$25 million for the first half. Obviously the net change in cash has been about \$10 million, so hopefully that gives you a little guidance.

Leland Wilson: Yes, and partnerships, I can say we're having very good discussions with a number of companies on ALISTA as well as avanafil. And so as soon as we know something, we'll let you know as well.

Operator: Your next question comes from Russell Gilbertson with Caris & Co.

Russell Gilbertson: First question just regarding PDE5 inhibitor in general. I'm sure you've read quite a bit about the effects, potential effects on site and on non- (inaudible) anterior eschemic optic neuropathy. How do you think that's going to affect the ED market?

Leland Wilson: Well, I'll make a couple of marketing comments and Peter can talk more scientifically perhaps. As you know, this market has flattened somewhat and so we're anxious to see if it gets second legs to it and see where it goes. Obviously it's a very big market, but I would like — I'd personally like to see further growth. And anytime you have negatives coming into the marketplace, it certainly doesn't help.

Now Pfizer's been very clear and other companies as well to say that there is no correlation with this most recent eye condition. But FDA thought that it was prudent to put it in the labeling. So again, there's no — what Pfizer has said is that they can find no causal effect.

The thing that I think is important for us to understand is that avanafil has the potential for a superior safety profile here and all the studies that we've done so far, it gives us a very tempting hint that we do have a safer profile, for example, in the most recently

completed study. Now, this is a fairly large study, as you know, Russ, 284 patients. As a matter of fact, in the Cialis NDA I believe someone said that there was only one study done that was larger than that and it was only slightly larger. So this is a substantial study.

We saw no effects on the eye whatsoever. And that has characteristics of all of our studies. And so this safety benefit for avanafil may prove in the future to be even more important than what we're considering today.

Russell Gilbertson: Thanks. Now, with regard to ALISTA and the recategorization of your current clinical study to a 2B study, how do you think that's going to impact your ability to discuss partnering ALISTA?

Leland Wilson: No impact. All our discussions we're very clear that we're looking for someone to fund two Phase 3 programs and so that's — that has no impact on it whatsoever.

Russell Gilbertson: Well, maybe in terms of the financial support, but what about just having the unknown of the results of those questionnaires?

Leland Wilson: We're comfortable with our ability to validate those questionnaires to the agency. They have been validated by other companies. We're not privy to their data, but we know that they have been validated and — many times and so we're comfortable that we will be able to demonstrate the validity of those questionnaires as well.

Operator: Your next question comes from Eunice Levechevets with Griffin Opportunity Fund (ph).

Leland Wilson: Could I have a clarification on that one?

Ennis Yusovich: You know what? I'm not so sure I have one. It's Ennis Yusovich. More or less some of the questions have been answered, but really related towards ALISTA and the timeframe of it all, given when you would — all things going normal, when you would expect to be out and how other competitive factors come in, particularly recently this announcement on the NIH website of competing product that's out in the market know called Zestra (ph). It's a non-prescription. How does that work and where do you see yourself vis a vis others like Zestra, for example?

Leland Wilson: In the prescription world, ALISTA is way out front of everything else and we...

Ennis Yusovich: That we know.

Leland Wilson: ...and we believe it has the potential to be the first product approved for sure. Now, interesting work that is being looked at here with Zestra, and, as you know, that's an herbal supplement. And I'm not going to comment too much on that, but it'll be

interesting to see how that herbal supplement is able to demonstrate activity. As you know, there's been a number of products on the marketplace that have come and actually gone which have carried a tremendous amount of advertisement around them, sold a bunch of product and then disappeared. They have all proven to be non-effective.

And having worked in the area of sexual function I pride myself in being a pioneer in this area. It is dang hard to show clinical effectiveness and we understand the mechanism of action of increased arousal. I think it's well accepted now and this is work done by VIVUS' pioneering work that vasodilation and increased blood flow is the mechanism to treat arousal. And so it's hard for me to understand how this product not only is absorbed, because you need to have exquisite delivery technology in order to get the drug in, and then what is the active vasodilating agent.

So I would offer a fair amount of skepticism, having worked in this area quite hard. And as well as many major pharmaceutical companies have spent tons of money to try to develop a product. I think everybody's aligned now on vasodilation as the next...

Ennis Yusovich: How does that square — not to interrupt you there — with the recent study from Yale and Albert Einstein that really disregards vasodilation and increased blood flow as the active mechanism versus, let's say sensation? And I don't know, are you familiar with that study? I could get it over to you, but this came out about a month, month and a half ago.

Leland Wilson: I'm not. There's been a fair amount of work, though, done on sensation as a triggering agent for increased arousal. And without blood flow, it's our view that the reason women have arousal problems is due to very well known organic conditions and that is the same thing as in men with arousal conditions; decreased ability to have blood flow. And these things happen through surgeries such as hysterectomies, diet, atherosclerosis, certainly childbirth has dramatic effects here. And so what our goal and what we concentrate on is improving blood flow to those genitalia in those women that have decreased blood flow.

Operator: Your next question comes from Michael Tong with Wachovia Securities.

Michael Tong: Just on the ALISTA Phase 3, does the inclusion of the questionnaire cause you to maybe perhaps have increased the patient population for the Phase 3 studies or do you think that's not going to be a cause for concern?

Leland Wilson: I don't think it is. The size of the Phase 3 studies are largely to demonstrate safety. Efficacy, as we have demonstrated now on three studies, can be demonstrated with relatively small numbers. And, too, the second endpoint, increased arousal, we certainly think that that's well within the capabilities of a relatively small study. So the bigger numbers and the et cetera are completely for demonstration of safety, in my opinion.

Operator: Your final question comes from Mark Robbins (ph) with the Robbins Group.

Mark Robbins: Sorry for some of the rudimentary questions, but help me out if you will, fellas. Just for curiosity, the buildup of the PDE5 inhibitors, is the number one concern as to why that is considered a bad thing, is that the eyesight problem or are there other organic things that could occur from the buildup of this drug?

Leland Wilson: I'm not quite certain what you mean by buildup here, Mark.

Marc Robins: Okay, I apologize if I didn't ask the question correctly. One of the aspects of your tests was the fact that the plasma metabolizes quickly in the body and, therefore, gets out of the system. And I was just wondering if a buildup over time is organically bad or is it bad because of certain known problems that occur?

Leland Wilson: I'll give you my opinion...

Marc Robins: That's cool.

Leland Wilson: ...as the CEO of VIVUS, but clearly we think the ideal product here is one that goes in quickly, has the ability to have sex quickly, and then gets out of the body. This is an on-demand therapy; it's not something we're trying to keep blood levels over a long period of time. And the reason I say that is that there have been a number — and a good example of why having the product around for a long time may not be a good idea is this muscle ache or back ache, et cetera. And Pfizer has seen that in studies, which they completed where they were actually giving once a day dosing, et cetera, or multiple doses, early studies that they did prior to their NDA. And also we see that with other products which have a long half-life. So it does have effects by having it around for quite some period of time.

But the bigger thing to us is that such effects as facial flushing, headache, those kinds of things, why have them around for a long period of time when you don't need to have them around? And, as I'm fond of saying, if you want to have sex twice a day, we have demonstrated with this study that you do not have plasma buildup so that you can take the next dose 12 hours later. And oh, by the way, we may think that — we might even be able to reduce that again even further. But you do not have plasma buildup so therefore, when you take your second dose, you're not actually getting more or higher blood levels than you would on a first dose.

Marc Robins: Got you.

Leland Wilson: That's the basis.

Marc Robins: Help me understand this, but it sounds to me like you've essentially — I mean haven't you done the majority of the safety work and we should go right on into the efficacy and therefore get this thing approved more rapidly? Am I missing something here or are we just trying to be very, very safe?

Leland Wilson: No, everything is in a classic phase of — classic NDA submission is or has been completed and to date, we have no indication that there are any adverse events which are of concern for the NDA at this point.

Now, I can say that we have two year ongoing — ongoing two year carcinogenicity studies and those are proceeding without a hitch at this point. We're going to have those completed next year. But all studies have been extremely clean for this product.

Marc Robins: All right, good. I'd like to move on to the pioneering work you've done with MUSE and post-prostatectomy surgeries. Are we at a point in the life of MUSE that this drug can now be used or now be accepted by the urologists as a therapeutic treatment? Are we at the tipping point in that lifeline?

Leland Wilson: Well, first thing I'll say is MUSE is not approved for this indication...

Marc Robins: Understood.

Leland Wilson: ...it is being studied for this indication and offers great promise. The difference between the two is that further studies will need to be done. We have those studies underway right now in at least half a dozen different sites in both U.S. and Europe. And when we get the results of those studies, we'll let you know. But I am extremely optimistic that MUSE has a second life as a therapeutic agent.

Okay. Thanks, everybody. Really appreciate it and if anybody else has any comments here, but I think we're just going to duck off on you. But again, thanks again for your support. Really appreciate it. I'll talk to you again soon.

Operator: Ladies and gentlemen, this concludes today's conference call. You may now disconnect.
