

---

---

**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)  
**April 27, 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))
- 
- 

**Item 2.02. Results of Operations and Financial Condition**

On April 27, 2006, VIVUS, Inc. conducted a conference call during which members of its senior management team discussed financial results for the first quarter ended March 31, 2006 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 information in this Form 8-K and the exhibit attached hereto shall not be deemed "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. First Quarter 2006 Financial Results and Product Development Highlights on April 27, 2006, 4:30 p.m. ET.

## 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: **May 1, 2006**

3

---

## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
<b>99.1</b>	Transcript of VIVUS, Inc. First Quarter 2006 Financial Results and Product Development Highlights on April 27, 2006, 4:30 p.m. ET.

4

---

## VIVUS.COM

**Moderator: Leland Wilson****April 27, 2006****3:30 pm CT**

Operator: Welcome to the VIVUS, Incorporated First Quarter 2006 Financial Results conference call. Joining the call from VIVUS are Leland 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.

Following the speakers' prepared remarks, we will hold a question-and-answer session. To ask a question, please press star followed by 1 on your touchtone phone. If anyone has difficulty hearing the conference, please press star 0 for operator assistance.

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

Leland Wilson: Thank you for joining us today. During our year-end conference call in February, we laid out our strategy and goals for 2006. In the two months since then we've made solid progress on a number of fronts, and I believe we continue to be on track to achieve our goals for 2006.

One of the key achievements during the quarter was strengthening of our management team through the addition of Ted Broman, Senior Director, Chemistry, Manufacturing, Controls, and Dr. Barbara Troupin, Director of Clinical Development.

Ted comes to us from DURECT Corporation, where he was Senior Director of Project Management. Ted has extensive experience in pharmaceutical product development with companies such as Syntex, Cygnus and Matrix Pharmaceuticals.

Barbara joins us from a CRO in San Diego, where she provided clinical and operational leadership for this growing firm. She has seven years of director-level management and operations experience across all phases of clinical development.

Barbara received her M.D. degree from the University of Pennsylvania and an M.B.A. from the Wharton School of Business. In addition, she was a practicing physician in San Diego for several years.

Ted's initial priority will be the completion of the CMC section of the Evamist NDA; and Barbara will be instrumental in supporting the work of Dr. Wesley Day, Vice President of Clinical Development.

As I mentioned during the last call, an important element of our corporate strategy is obtaining patents on superior delivery systems. We believe that a long and blocking patent on a patient-preferred delivery system is necessary to prevent the quasi-generic competition seen in both the gels and patch sectors of the estrogen and testosterone markets.

To this end we are pleased to announce that a patent relating to the Metered Dose Transdermal Spray was recently granted by the U.S. Patent and Trademark Office. This patent, which expires in July of 2022 provides protection for the MDTs applicator used in our testosterone and Evamist products. VIVUS licensed the U.S. rights to these products from Acrux Limited in 2004.

Also in the first quarter of 2006 we continued to make excellent progress in clinical and regulatory for all of our products. In a moment I'll turn the call over to Peter Tam so that he can give you specifics on each of the programs.

As we projected during the year-end call, our cash burn in the first quarter was neutral. We strengthened our balance sheet through proceeds from the Crown Bank Note and the receipt of \$2 million milestone payment from MEDA.

We continue to be judicious with our funds while continue to build value in each of our programs. Later in the call, Tim will share specifics on the finances - financial results for the first quarter.

Now I will ask Peter to update you on the progress we've made with each of our products. Peter?

Peter Tam:

Thanks Lee. I will now briefly review each of the four clinical programs we have, the progress we've made in the first quarter of 2006, and some of the important milestones to look forward to this year.

For Evamist we have completed our phase III study and will be unblinding the study for data analysis over the next several days. Evamist is our novel, first-in-class estradiol spray being developed for the treatment of menopausal symptoms. With positive data, we expect to submit an NDA by the end of the summer. If approved, this will be the first novel spray of its kind introduced to the marketplace.

For ALISTA, our topical alprostadil product for the on-demand treatment of female sexual arousal disorder, the phase IIB study is ongoing. Enrollment was completed late last year. The study enrolled over 300 women who have undergone a hysterectomy and have been diagnosed with female sexual arousal disorder. The trial is approximately 75% completed, and we anticipate that we will complete all patient treatment late in the third quarter of 2006.

Pending completion of the study, the data will be compiled and analyzed and the results announced before the end of the year. To date, the trial continues as planned. With positive results from this trial we will proceed with phase III development work and partnering activities in 2007.

---

For testosterone, as we discussed during the year-end conference call, we submitted a phase III development program which was reviewed by the FDA. As a result, we held another scheduled meeting with the FDA in March to discuss our latest phase III proposal and study design.

To date, we've held three meetings and multiple submissions to the FDA since the Intrinsa advisory meeting at the end of 2004.

Through this series of meetings and correspondence with FDA we believe we've made a great deal of progress with respect to agreement on the size of the study, the endpoints for the study, and the methods of analyzing long-term safety data.

Based on this last meeting, we will submit a revised proposal to FDA to obtain final agreement on the treatment duration of the study. We anticipate that we will be submitting our phase III safety and efficacy protocol under a Special Protocol Assessment in the second quarter of this year.

For avanafil, our PDE5 inhibitor being developed for the treatment of male erectile dysfunction, we continue to make preparations for the phase III clinical trials.

Based on our end-of-phase II meeting with FDA late last year, we will complete the usual preclinical and metabolism studies over the next 12 months.

The cost of these studies will be funded under our line of credit with Tanabe. Pending timely completion of these studies and entering into partnership, we should be in a position to start these phase III studies in the first half of 2007.

---

Our R&D and CMC groups have made significant progress in the past quarter, and I want to recognize them and thank them for a great job that they've done. We will continue to do so in 2006, in particular with the preparation and assembly of the NDA for Evamist.

We look forward to further advancing our development programs in 2006. With that I'll turn it over to Tim for a review of the quarter's financials. Tim?

Timothy Morris:

Thank you, Peter. The financial results for the first quarter of 2006 are as follows.

Total revenues for the first quarter were \$1.3 million. This compared to \$629,000 of revenues that we had recognized in the first quarter of 2005.

Net loss for the quarter was \$8.8 million, or \$0.20 per share. Net loss was essentially the same as the net loss in the first quarter of last year of \$8.8 million, or \$0.22 per share.

The change in total revenue for the first quarter of 2006 as compared to the total revenue in the first quarter of 2005 consisted of many components. Changes in specific reserves against sales occurred in both periods, however, the changes are not consistent and do not indicate any particular trend.

Other revenue increased due to the recognition of deferred revenue from the receipt of the milestone payment, which was received from MEDA in Q1 2006. The milestone payment will be recognized over the remaining life of the contract, currently expected to run into 2012.

---

Similar to prior years, wholesalers made purchases in the fourth quarter of 2005 that were greater than demand. However, the buy-in for 2005 was lower than the buy-in for 2004.

Based on the fourth quarter 2005 demand for MUSE, we estimate purchases made by wholesalers in the fourth quarter of 2005 represented approximately four months of excess demand.

As a result of the buy-in in the fourth quarter, we expect our sales in the first half of 2006 to be similar to those that we had seen in the first half of 2005. We estimate inventory at the wholesale level has decreased since the beginning of 2006.

Quarterly demand for MUSE as measured by independent third party prescription data and from other sources has been consistent over the last five quarters, approaching 200,000 units.

Effective January 1, 2006, VIVUS implemented FASB Statement 123R, share-based payment, which requires companies to expense the estimated fair value of employee stock options and other similar awards.

In the first quarter of 2006, the stock compensation expense under FAS 123R was \$490,000.

At March 31, 2006, VIVUS had cash, cash equivalents and available-for-sale securities of \$29 million. This compares to the \$27 million we had on hand at December 31, 2005.

The increase in cash, cash equivalents and available-for-sale securities of \$2 million is the net result of the \$5.4 million loan obtained from Crown Bank,

---

the collection of amounts owed at December 31, 2005 from customers as measured by a decrease of \$6.9 million in AR, offset by cash used in operations, investment and other financing activities of \$10.3 million for the quarter.

On the IR front, we have been very active this quarter with over 40 one-on-one meetings with analysts, portfolio managers and Wall Street professionals. We've made presentations at the BIO CEO meeting in New York and the Cowen Healthcare Conference in Boston.

IR roadshows were held in San Francisco, New York, Boston and the Midwest. Rodman & Renshaw sponsored roadshows in the New York and the Midwest, and Wachovia sponsored roadshows in New York and Boston.

We will also be presenting at the Rodman & Renshaw Third Annual Global Healthcare Conference in Monaco on May 15 at 3:00 Central European Time. That presentation will be Webcast and available for review after the conference.

Also, on May 18 VIVUS will hold an analyst day in New York City at 12 o'clock local time. This day will consist of presentations on each of our development programs from a combination of principal and clinical investigators, as well as internal experts.

Buy and sell-side analysts, as well as portfolio managers are invited to attend. The presentations will be Webcast and archived on our website.

The goal of the event is to provide analysts with an in-depth overview of our programs, including a review of studies performed to date and the development pathway to approval.

---

They will also be able to speak with clinical experts in our field who have been involved in the trials for our products.

Specifically, Dr. James Buster, Professor of Obstetrics and Gynecology and Director of the Division of Reproductive Endocrinology at the Department of Obstetrics and Gynecology from Baylor College of Medicine in Houston, Texas will be on hand to discuss the phase III data from the Evamist trial.

More information on our analyst day will be available in the coming days on our website. We hope that you will be able to attend and look forward to seeing you all there.

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

Operator: At this time I would like to remind everyone in order to ask a question, please press star then the number 1 on your telephone keypad. We'll pause for just a moment to compile the Q&A roster. Please hold for your first question.

Your first question comes from Steve Sullivan of Horizon Financial Group.

Steve Sullivan: Yeah. Peter, can you repeat what you said about avanafil timeline, please?

Peter Tam: Yeah. Avanafil - right now we're completing the - some preclinical studies, as well as the metabolism studies so that we can go ahead and get phase III started. The timeline for starting phase III would be around middle or first half of next year, 2007.

---

Steve Sullivan: Now you're not going to start that until you have a partnership though, correct?

Peter Tam: That's correct.

Steve Sullivan: And in the meantime, the preliminary work is being funded by who again?

Peter Tam: By Tanabe, our partner.

Steve Sullivan: Okay, but you will not do a partnership before - you will not start this testing before a partnership is signed.

Peter Tam: The - for phase III you mean?

Steve Sullivan: Right.

Peter Tam: Yes. That's correct.

Steve Sullivan: Okay. Thank you.

Operator: Your next question comes from Victor Lau of Wachovia Securities.

Victor Lau: Great. Thanks for taking the question. Given the purchase of the manufacturing facility, is the current cost of goods - run rate good for future quarters? And two, can you provide us with the expected cash burn in '06? Thank you.

Timothy Morris: Yeah. Victor, the cost of goods sold will essentially be the same as last year. The purchase of the facility was really just a little bit more opportunistic than not. We had already expended some monies on that facility, obviously and

---

then we've got a mortgage note on it. So from a pure cash standpoint and a cost standpoint, it's not going to change the cost of goods very much. It really just allows us to control our destiny with MUSE a little bit more.

In terms of your question on cash burn, I think I'll reiterate what we had said at the year-end conference call is our expectation - our cash burn from 2005 was \$22 million. We expect our cash burn in 2006 to be lower than that.

Victor Lau: Great. Thanks.

Operator: Again I would like to remind everyone in order to ask a question, please press star then the number 1 on your telephone keypad. Your next question comes from Ilya Kravets of Rodman & Renshaw.

Ilya Kravets: Yes. Hello guys. Thanks for the call - for taking the question. Just two things. One, the analyst meeting in New York - can you just - (you didn't) tell me the date.

And second, on testosterone in the earlier remarks it was mentioned that you expect to file an SPA in the second quarter of '06 and - for the phase III. Can you just maybe tell us a bit about how you see this program, the size and the - maybe the approximate expense that you think will be involved? And any timeline for enrolling and completing both of the phases of the trial — the safety and efficacy?

Timothy Morris: Sure Ilya. On analyst day, we've set the date for May 18. It'll be at noon at the Four Seasons Hotel in New York. We've sent invitations out. That information will be on our website.

---

We'll be obviously sending out emails and follow-ups just to make sure that all the buy and sell-side analysts and portfolio managers can be there. So we can get you more information on that later, as well as some of the details.

On your second question, let me turn it back to Peter.

Peter Tam: Yeah. Ilya, the testosterone program - we are finalizing the efficacy - the phase III efficacy study, which we will be submitting under an SPA to FDA by the end of this quarter, the second quarter of '06.

And with respect to your question about size and scope of the study, we're not going to be able to disclose that at this point. So we're keeping that tight.

Ilya Kravets: Okay. Then maybe will you be able to share that information once the SPA is accepted just so that we can try to project the expense for it and when the data might come out?

Peter Tam: Yeah. We'll look at it as to, you know, when we get the information from the FDA as to what we will disclose at that time.

Ilya Kravets: Okay. And just one last thing I guess on testosterone. The size of the trial that you are looking at, do you still think that it's feasible for a company the size of VIVUS and with the financial resources that VIVUS has to do it?

Peter Tam: Yeah. Yeah. I mean we're looking at some creative ways in terms of how we can conduct these trials, both the safety study that the FDA's asking for as well as the efficacy studies. And, you know, we're - we've been on - having ongoing discussions with the FDA. We think we can do these studies, and that's why we're having these dialogs with the FDA.

---

Ilya Kravets: Okay.

Leland Wilson: Ilya, I would say however, that we are going to need support in doing the phase III program for testosterone without question.

Ilya Kravets: Right. And then on avanafil, in the press release it mentions that you're looking to enter the partnership maybe this year. Is that - have you started to talk to some of the potential partners? Anything that's more or less further along? Or is it also dependant on completing some of those preclinical and metabolism studies that are ongoing?

Leland Wilson: No. This is Lee. I'll take that one. Yes, we're having good conversations with a couple of companies right now. We have been engaged in conversations. The issues have been around kind of the deal structure and the deal valuation, and I would say that as the market becomes clearer, that is the cost of entry into the market because the direct-to-consumer advertising is down - so it's more favorable to us. ICOS Lilly, as you may know, has announced very favorable results. And so the sun is starting to shine a little bit on this sector. But we're having really good conversations right now with a couple of companies, which I would like to have either one of them, but they need to be able to provide the kind of funding that we need here. So that's where we are.

Ilya Kravets: Okay. Great. And then just on - even just maybe some of the - a little bit on the strategy for launch and marketing since the phase III is basically done.

Leland Wilson: Yes. Our stated strategy all along is that we think we can take the easy or low-hanging fruit out of this marketplace fairly easily. This is a market that is fairly mature and what we're delivering is a preferred delivery system to patients. And so we think we can get the sales message done pretty easily. We think that VIVUS can handle that and we are going to be working to

---

develop our marketing plans once the NDA is in. And we'll also be hiring an experienced marketing executive to manage that program.

Ilya Kravets: Okay. Great. Thank you.

Operator: Your next question comes from Ken Trbovich of RBC Capital Markets.

Ken Trbovich: Morning. How are you?

Leland Wilson: Hey Ken.

Peter Tam: Hey Ken.

Ken Trbovich: Just wanted clarification, I guess, Tim, just with regard to the issue on the cost of goods sold side. You indicated that the purchase of the property isn't going to necessarily change the cost of goods sold going forward, but does that mean we should be expecting gross margins to sort of eventually even out to that 25% range that you hit last year, or where do you expect that you're going to be able to hit? Because it seems like the first quarter - I mean obviously the revenues are much lower than what they are in the fourth quarter, but the expenses here were much higher than they were even a year ago in terms of cost of goods sold.

Timothy Morris: Right. Obviously some of that's a function of volume and how much goes into inventory. The base expenses for the facility should be relatively consistent with next year. So I think as we get closer to a full year worth of cost of goods sold, you'll probably see that margin improve, very similar to the pattern we had last year.

---

Ken Trbovich: Okay. But then in total you think you'll hit that 20% or 25% kind of range for the year?

Timothy Morris: We haven't really given any guidance on that.

Ken Trbovich: I know. That's why we're...

Timothy Morris: But we have no reason to believe that it would be any different than last year.

Ken Trbovich: Okay. And then just with regard to the comments on Evamist and the analyst meeting, I just - I thought I heard you say, Tim, that you were going to have the data presented or someone there to discuss the data on the 18<sup>th</sup>? Does that mean that we should expect the first release prior to the 18<sup>th</sup>, or that that will be the announcement of the results on the 18<sup>th</sup>?

Timothy Morris: Well, what I can tell you is that we are going to have someone available on May 18. Dr. James Buster from Baylor will be

there to discuss the data.

Ken Trbovich:

Okay.

Leland Wilson:

And we're working on - and Ken, just for your information, we're working on a couple other physicians that would be able to answer questions on other products that we have as well. So we're working on putting together a - and Tim has done a lot of the work here - putting together a pretty nice analyst day for everybody.

Ken Trbovich:

Okay. But the data won't be any later than the 18th then is what it sounds like...

Leland Wilson:

No. We will have the data out before the 18th ...

---

Ken Trbovich:

Okay. And then just...

Leland Wilson:

...if everything goes on schedule. Now we haven't done a lot of this stuff yet so there's, you know, a lot of work that needs to be done between now and then so.

Ken Trbovich:

Well it sounds like long nights and weekends, but just to be clear then, the goal on the NDA is this summer?

Leland Wilson:

Yes.

Ken Trbovich:

Okay. All righty, I appreciate it. Thank you.

Leland Wilson:

Okay. Thanks.

Operator:

Your next question comes from Marc Robins of The Robins Group.

Marc Robins:

Afternoon, gentlemen.

Leland Wilson:

Hey Marc.

Marc Robins:

Just a - you know, just a roundup on all the other questions. Anything going on in the MUSE arena and radical prostatectomies?

Leland Wilson:

Well, it continues to be a very interesting field. The physicians that are doing work with MUSE for a therapeutic, actually, effort for post-radical prostatectomy patients are getting more and more excited about it all the time, and - but as you know, that is an off-label indication and we are conducting

---

studies in the area. And then when we get these studies done, we expect to proceed forward with a potential label indication for that product.

Marc Robins:

And then I've been doing a little more work in the area of TURPs and the new technology that is displacing that arena. And is there an opportunity for MUSE to be used in that as well, or less so, or not at all?

Leland Wilson:

Yes. Less so, Marc. The issue here is that during a radical prostatectomy, even nerve-sparing radical prostatectomy, there's significant damage done to both the vascular system and the nerves. And what we found with MUSE is by having increased blood flow — that is on a three or four times a week basis where we have increased blood flow — that we maintain tissue health in these patients that are unable to have nocturnal erections, for example. And also there's some good data that's been done now showing that prostaglandin E1 or alprostadil, the active ingredient in MUSE, has some capability of neuroregeneration. So it has kind of a double approach to this area, and the preliminary studies, as you probably have seen - independent studies done out of The Cleveland Clinic, which has now been published, have given MUSE - it's been the best data so far of any of the products that have been tested in this - for this indication. So we're quite excited about it and - but it's early, and there's ongoing clinical trials right now.

Marc Robins:

Thanks so much and I look forward to the 18th.

Leland Wilson:

Thank you.

Operator:

At this time, sir, there are no further questions. Gentlemen, do you have any closing remarks?

---

Leland Wilson:

Yes. It's Lee. You know, since February, which seems like just the other day when you do these analyst calls, we went over kind of our goals for the years. And I think the first one that I want to reiterate to people is that we expect to drive shareholder demand this year. That is a primary goal for us, and I think we have the ammunition to make that happen.

Some of that ammunition is that we're clearly working to announce the Evamist data, and assuming that we get positive data out of those trials, we're going to complete an NDA and submit that this summer.



We're also working on the ALISTA program to complete our phase IIb study. Many of you remember that this was going to be a phase III trial until the endpoints were changed by the regulatory authorities kind of midstream on that trial. But this is an important trial to us. It's powered to be a phase III trial and it'll give you and everyone else a very solid look at the potential efficacy of this product.

And the - and we're also finalizing the safety and efficacy studies for phase III for our testosterone program. The news that Peter broke to you today is that we are going to submit the Special Protocol Assessment in the second quarter.

We have made extensive progress and I say the royal "We" as the CEO. I sit here and Peter and his group have done all the work on this, but they've made great progress with the FDA in this regard. So we're honing in something here that makes sense for us to go ahead and do.

And we're also initiating the remaining preclinical and metabolism studies for avanafil that the FDA wanted us to do before we started our phase III programs. So remember going back, you know, we were hopeful to go into phase III before we had these studies done, but the FDA has made it necessary

---

for us to complete these studies. They're short-term studies. They're very straightforward. They're not in any way long-term clinical trials or anything else like that. So they can be done fairly quickly, and we'll share those results when those are available as well.

But all in all we're - we have a very busy schedule this year, and we look forward to increasing your value as well as all of the shareholders here within the company.

So thank you. I appreciate your participation, and I look forward to seeing a lot of you on the 18th in New York.

Operator:

Thank you. This concludes today's VIVUS First Quarter 2006 Financial Results conference call. You may now disconnect.

END

---