

**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)

October 26, 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 October 26, 2006, VIVUS, Inc. conducted a conference call during which members of its senior management team discussed financial results for the third quarter ended September 30, 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. Third Quarter 2006 Financial Results Conference Call on October 26, 2006, 4:30 p.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: **October 30, 2006**

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EXHIBIT INDEX

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VIVUS, INC.

Moderator: Timothy Morris**October 26, 2006****4:30 pm ET**

Operator: Welcome to the VIVUS Incorporated Third Quarter 2006 Financial Results Conference Call. Joining the call from VIVUS are Leland Wilson, Chief Executive Officer; Dr. Wesley Day, Vice President, Clinical Development; and Timothy 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 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 those 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 touch-tone phone. If anyone has difficulty hearing the conference, please star zero for operator assistance.

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

Leland Wilson: Thank you. Good afternoon and thank you for joining us today. In today's call I will touch on some of the highlights since our last call; and then Dr. Wesley Day, our Vice President of Clinical Development, will give you an update on each of the clinical programs we have in development. Tim Morris, our CFO, will then review the Financial Results for the Quarter in the nine months ending September 30, 2006.

First, the highlights since our last conference call – As you know, in the third quarter we submitted a New Drug Application for EvaMist, our Metered Dose Transdermal Estradiol spray for the treatment of menopausal symptoms. This represents a significant milestone for VIVUS. I would like to thank all of our employees and consultants who participated in this submission.

I have been involved with a number of NDA submissions and I can tell you the time and effort that goes into an NDA filing is monumental. I would like to specifically mention the efforts of our clinical and manufacturing development groups for making this happen.

The EvaMist NDA submission is important to VIVUS for several reasons. First, it demonstrates our ability to take a product from in-licensing in 2004 through Phase 3 development to NDA submission in 2006. We will continue

to leverage this core competency as we move our other products to a Phase 3 development.

Second, EvaMist utilizes the MDTs delivery technology – the same delivery technology we employ with our transdermal testosterone product. Our experience with EvaMist will directly benefit the development of Testosterone MDTs.

And third, we believe the U.S. estrogen market has stabilized at \$1.1 billion, with Premarin dominating the market with sales greater than \$800 million. Market share for the transdermal portion of the market continues to grow, and prospects for future growth are excellent.

EvaMist, in our opinion, is not just another transdermal estrogen product. The patient preferred characteristics of the EvaMist spray delivery system, we believe, will for the first time enable a transdermal estrogen product to effectively compete with Premarin, the market leader.

Using EvaMist is as easy as taking a pill – no glass, no water, no swallowing – just a simple spray to the forearm. In addition, EvaMist dries in 60 seconds, it is invisible, it is non-irritating, it's not affected by washing, and will not transfer to clothing or other people.

Another potential benefit of EvaMist to over conjugated equine estrogens was discovered in focus-group discussions. When women were given the choice, they prefer to take Estradiol, the estrogen naturally found in their bodies, rather than a group of estrogens found only in pregnant mares' urine.

From a safety standpoint, transdermal estrogen eliminates the safety concerns related to first-pass metabolism associated with oral therapies. When a woman

takes Premarin, the liver reacts and mechanisms are set in action that work to rapidly eliminate the product from the body. High doses are therefore required to overwhelm the liver, allowing 10–20% of the administered product to enter systemic circulation while it can work to achieve its therapeutic benefits.

Exposing the liver to therapeutic doses of Premarin causes the liver to react and to alter its production of proteins and lipids. For example, Premarin is known to cause an increase in high-density lipid proteins, which are associated with a decrease in cardiovascular risk.

Premarin, however, also increases the levels of triglycerides, low-density lipid proteins, and C-Reactive protein – all markers associated with an increase in cardiovascular risk. In response to Premarin, the liver also increases production of factors that mediate coagulations, such as fibrinogen, Factor 7, antithrombin3, and TPA. Please remember it was Premarin that demonstrated an increase in thrombotic events, such as stroke and MI in the WHI Study.

Interestingly, Premarin also increases circulating levels of sex-hormone binding globulins, which in turn reduces circulating levels of free estrogen and free testosterone with possible impact on bone density, muscle mass, and even sexual desire. Given the potential convenience of the spray application and a favorable safety profile, we believe EvaMist can effectively compete against Premarin and can capture some portion of the oral market as well as a significant portion of the transdermal market.

Turning to Qnexa – in response to inquiries from investors, on August 16, we held a conference call with Drs. Gadde and Najarian to discuss the Phase 2 clinical trial results. The call was well attended, with over 150 participants, and lasted nearly two hours.

In addition, Dr. Gadde recently presented the Phase 2 results in a podium presentation at the Annual Scientific Meeting of the North American Association for the Study of Obesity. While the top line data had been previously released, this was the first time the medical community had the opportunity to examine the data in great detail.

The presentation was well attended and the data was well received. Data from other obesity compounds and development were presented as well. Although head-to-head trials have not been completed, the efficacy and safety profile Qnexa speaks for itself.

I will now turn the call over to Dr. Wesley Day, who will give an update on each of our clinical programs.

Wesley Day: Thanks, Lee. I will now briefly review each of VIVUS' four clinical programs – Qnexa, EvaMist, Testosterone, and avanafil — and some of the milestones we expect to accomplish by the next conference call.

Qnexa is our proprietary treatment for obesity. This program has made excellent progress over the last quarter. As we told you previously, we are required by the FDA to complete a standard battery of genotoxicity studies as well as some standard 3-month toxicology studies with Qnexa prior to initiation of Phase 3 in humans.

The genotox studies were completed this quarter, and I'm pleased to say that there were no adverse genotoxicity findings in any of the required studies. The 3-month toxicology studies in two species are underway and we expect the studies to be completed by year-end. We hope to give you an update on the non-clinical toxicology studies during the year-end conference call.

With respect to the formulation for Qnexa, plans are in place to begin the necessary human PK studies before the end of the year.

For EvaMist – as Lee mentioned earlier, we submitted the NDA on September 29 of this year. I would also like to thank the Clinical, Regulatory, and Pharm Science teams that worked so diligently to bring this program to fruition with the NDA submission. We look forward to continuing our work and partnership with the FDA during the NDA approval process. It is our goal to do everything in our power to enable approval of EvaMist as quickly as possible.

For Testosterone MDTs, our treatment for Hypoactive Desire Disorder in women, we submitted a Special Protocol Assessment, or SPA, for the Phase 3 safety and efficacy study in June. We received a response from the agency in the third quarter and we are preparing a response to the FDA. We will hopefully be in a position to provide you an update during the year-end conference call.

As you may know, on July 28, the EMEA – or the European Agency for the Evaluation of Medicinal Products – approved Intrinsa in Europe. Intrinsa is a transdermal testosterone patch under development by Procter & Gamble for the treatment of Hypoactive Sexual Desire Disorder. We believe the approval by the EMEA is an important milestone for us as it signals a positive international health authority review and acceptance for the safety and efficacy of testosterone in women with HSDD. While the EMEA has no regulatory authority in the United States, we are encouraged by this development and expect Intrinsa to be launched in Europe early next year.

For avanafil, our PDE 5 inhibitor being developed for the treatment of male erectile dysfunction, we have initiated the clinical and non-clinical

metabolism studies as reported previously. These studies are required by the FDA prior to the beginning of the start of the Phase 3 clinical trials.

These are the ongoing R&D activities at VIVUS, and I look forward to sharing more with you during the next conference call.

I will now turn the call over to Tim to discuss the Financial Results.

Timothy Morris:

Thanks, Wes. First, we're going to talk about the financial results for the quarter ended September 30, 2006.

Total revenue for the third quarter of 2006 was \$4 million. This compares to the \$3.3 million for the third quarter of 2005. The increase in revenue over the same quarter last year is primarily due to an increase in domestic shipments of MUSE. The increase in MUSE revenues is a result of fluctuation in inventory levels at the wholesalers and is not indicative of any trend. The increase in revenue from the third quarter last year was also impacted by changes in reserves against sales, which again do not indicate any particular trend.

Domestic demand for MUSE at the retail and government levels remained consistent with prior periods, averaging approximately 200,000 units per quarter. So in the third quarter of 2006, the VIVUS net loss is \$6.2 million, or \$0.13 per share, as compared to a net loss of \$6 million, or \$0.13 per share in the third quarter of 2005. The increase in net loss is primarily the result of increased operating expenses in the third quarter of 2006, compared to the same quarter last year partially offset by increased MUSE revenue.

Total operating expenses of \$10.4 million in the third quarter were \$981,000 higher than the same quarter last year. Effective January 1, 2006, VIVUS implemented FASB Statement 123R, which requires companies to expense

the estimated fair value of employee stock options and similar awards. In the third quarter 2006, the stock compensation expense under FASB 123R is \$547,000. This amount has been allocated to cost of goods sold, R&D, and SG&A accordingly.

For the nine-month period ending September 30, 2006, total revenues were \$8.9 million, as compared to \$5.6 million for the same period in 2005. The increase in revenues is primarily due to increased domestic and international shipments of MUSE.

Net loss for the nine months ended September 30, 2006 was \$20.8 million, or \$0.45 per share, as compared to a net loss of \$23.4 million, or \$0.55 per share, for the same period in 2005. The decrease in net loss is primarily the result of increased MUSE revenues and decreased R&D spending as compared to the first nine months of 2005.

R&D spending in the nine months ended September 30, 2006 declined for VIVUS' four clinical development programs for sexual health, partially offset by an increase in spending related to our obesity product candidate, Qnexa.

For the nine months ended September 30, 2006, the total stock compensation expense under FASB 123R is \$1.6 million. Again, this is a non-cash charge. At the end of September, VIVUS had cash, cash equivalents, and available for sale securities of \$26.3 million. This compares to the \$27 million we had on the balance sheet at the end of 2005. The net decrease in cash, cash equivalents, and available for sale securities of \$677,000 is the net result of \$12 million in proceeds from our Registered Direct Offering, \$5.4 million in proceeds obtained in a loan from Crown Bank, and the collection of amount owed at the end of the year from customers as measured by a decrease of \$5.3 million in accounts receivable, offset by cash used in operations, investment,

and other financing activities of \$23.4 million for the first nine months of 2006. Excluding cash received from the sale of Common Stock and proceeds from the loan, the decrease in cash, cash equivalence, and available for sale securities in the first nine months was \$18.1 million.

On the IR front, the company will present at the upcoming Rodman & Renshaw Healthcare Conference on November 7, and the CIBC World Markets Annual Healthcare Conference on November 8. Both of these conferences will be held in New York City. We will also present at the RBC Healthcare Conference December 13 and 14 at New York City.

With that, we're going to open the call to questions and then back to Leland for a closing statement.

Operator:

At this time I would like to remind everyone if you would like to ask a question, please press star followed by one on your touch-tone phone.

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, good afternoon. Just one quick one for Tim. You still continue to see MUSE being flat to slightly down in '06 relative to '05; and then secondly, for Lee, when can we hear something about partnership and, you know, and what are some of the – you would say – hurdles or milestones that we should be looking forward to in order for you to get into any partnership?

Timothy Morris:

Thank you, Michael. On MUSE revenues, yes, we haven't changed our guidance for MUSE revenues even though there is some fluctuations quarter-to-quarter

and year-over-year quarter-to-quarter. We expect that the revenues for MUSE will be similar to what they were in 2005.

Leland Wilson: Yes, Michael – we can take them product-by-product. We have said that publicly a number of times that on Qnexa we need to take that product further into the development process before we think that we can realize its true value. And so we're setting out on a path to go ahead and do that so that – We're not attempting at this point to partner that product. It just has, in our opinion, too much potential that can be realized by waiting until we have further data in-house, such as Phase 3 data.

Now some of the other products –EvaMist, as we've said publicly, we are interested in taking this NDA all the way through approval; and then we'll reserve the right to look at potential partners at that time; or we may launch the product ourselves, whichever is more beneficial to us and our investors.

Avanafil, as you know, is a product that we have been trying to out-license. It has been a challenge. The primary challenges that we have seen in out-licensing avanafil have been what's considered to be a very significant barrier to entry into the marketplace because the high level of spending on direct-to-consumer advertising. Everyone agrees that the product has very significant benefits over existing products, and also that the NDA – our regulatory review process – is rather straightforward; but the challenge of the marketing expenses are one that is difficult to overcome.

We have just recently completed additional market research on how a product like avanafil could be launched into the marketplace without competing through direct-to-consumer advertising in a major way, but looking at switching existing patients onto the product. The results of that market

research were very promising. That now has been compiled and is part of our data package, which we are using in talking to potential partners.

And so that's pretty much where we stand on a partnering front. Testosterone, as we've said in the past as well, is not ready to partner until we have the regulatory path cleared from the FDA; and as Wes said, we're making great progress in that area. So as soon as we have it clarified as to exactly what the requirements are for the safety portion of the NDA, we believe we'll be able to get interested parties for that product.

Michael Tong: And Lee, if I can just quickly follow-up...

Leland Wilson: Sure.

Michael Tong: Testosterone – you've been in discussion with the FDA for a while with regard to the SPA. Now based on what you've seen, has the goalpost been moved, you know, as you go through the process? Or are we getting just more detailed, you know, back and forth between yourself and the agency?

Leland Wilson: Yes, I would say that we are – In our conversations with the agency, the goalposts have definitely not moved. We have been working together to arrive at a steady design, an endpoint, etc., that was both – that would meet the safety requirements of the FDA and was economic for VIVUS to conduct. And so those have not changed. Clearly, this is the first time to my knowledge a study has been done in the pharmaceutical industry or proposed in the pharmaceutical industry which looked at endpoints such as cardiovascular – incidents of cardiovascular adverse events as a major endpoint prior to the approval of an NDA.

Now what I mean by that is that you'd have to almost, in this kind of a study, demonstrate that your product does not cause an increase in these cardiovascular risk, as opposed to traditional studies where we have had to look at an adequate number of patients to see if there is any signal that there's any increase in any kind of risk involved here.

Now clearly, Procter & Gamble has done very large studies and there was no signal in any of the studies that they did towards increasing cardiovascular risk at any regard. This, as you may recall, came out of the timing of the results for the WHI Study, where it actually showed that when you combine progestins with estrogen, you increase the cardiovascular risk. So the premise was put forward then to show me that you're not increasing the cardiovascular risk when you combine testosterone with the existing hormones that are present in a woman or even in – with hormone therapy in a post-menopausal woman.

Excuse me. Also, this was under the cloud of the Vioxx issue, where there was a very, rather rare event here that was unable to be picked up in traditional clinical trials. So the FDA has moved towards – for this kind of a program towards a more restrictive and more definitive answer towards whether it increases cardiovascular events or not.

We are, in my opinion, about 90% there. All the major endpoints – structure, design, etc. – have been agreed to. What we are working with is getting approval on the details of the protocol, how the statistical analysis plan will be conducted, and how the administration of the study will take place. So we're comfortable with everything we have seen so far. There have been no changes from the agency during this period. I think everyone here that has worked with the agency understands that it is a laborious process of making changes and

establishing these kinds of first-of-class protocols because they have not been done before; and so it's a labor.

I can tell you that the FDA is absolutely interested in conducting this study and is working with us to get a trial design that is workable.

Michael Tong: Great; thank you.

Operator: Your next question comes from Adnan Butt with ThinkEquity Partners.

Adnan Butt: Thanks for taking the question. A couple of questions on Qnexa – Are you able to discuss at this stage what exactly you need to do before you can again begin discussing the SPA – the potential SPA with the FDA and/or if there is a Phase 3 trial design already in place?

Leland Wilson: I can take that and Wes can chime in as well.

Clearly, to get to an SPA you need to have your End-of-Phase 2 meeting, and at you're the End-of-Phase 2 meeting, we need to have some of these studies that Wes talked about earlier – the genotox study and toxicity studies – those completed and to go the End of Phase 2 Meeting.

At that meeting then, you can follow that with an SPA because after coming to that meeting will teach us exactly what the FDA believes the need for that trial design. Now the FDA has published guidance in this area, and we have had direct written correspondence with them, and minutes of meetings, etc. to outline the requirement of this study.

For our trial design, what's required now is 1500 patient years on therapy. That is 1500 patients on therapy for an average of one year. And as I said,

Adnan, in the past, there are additional studies that we would like to do that have implications as far as reimbursement, pharmacoeconomic studies; and also, we believed that Qnexa has the potential to have an impact on metabolic – or parameters for metabolic syndrome. And so we're going to be working closely with the agency to design and conduct studies in those areas. Does that help?

Adnan Butt: That's helpful. Do you have any plans to publish the Phase 2 data?

Leland Wilson: They're not in place right now, but that data will be published, yes.

Adnan Butt: And finally – when do you hear – expect to hear from back from the FDA on the EvaMist filing?

Leland Wilson: Yes, the first thing you'll hear back from them is at the end of 60 days they'll have a comment whether they accept the NDA or not or whether there's some issue around the FDA; and so that would be the first comment. You typically do not hear back from them for several months after that, and then typically the response that you get are around the CMC – or Clinical Manufacturing Control side – such as, you know, the manufacturing processes, etc. So you start working on that.

Typically, you do not hear about the safety and efficacy side of the NDA review process until you get fairly close to the nine-ten month period; and we're currently projecting that approval could occur about 12 months from submission.

Adnan Butt: But you will let us know when the NDA has been accepted.

Leland Wilson: Yes, we will.

Adnan Butt: Okay, I'll get back in queue. Thanks.

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

Ilya Kravets: Hi, guys. Just a couple of quick questions on some of the products – the PK study that you mentioned, can you just elaborate on that, the timeline for actually having data from that and does that mean that you already fixed your once a day dose; and then on EvaMist, maybe just a little bit more flavor in terms of preparations for launch if you're deciding to take it yourself and, you know, with 12 month in front of you, I guess that some kind of a launch plan would have to start taking shape fairly soon.

Leland Wilson: Okay now first on the Qnexa, on the PK timeline – we have a number of formulations which have been developed by two different drug development – they’re formulation development companies that we are going to put into a PK trial. That trial is scheduled to begin in November and that’s a single-dose PK study. And what we’re looking at here is to determine the blood levels that we’re able to achieve with those formulations and pick the one which we think is best for the product and best duplicates what we were able to achieve in the Phase 2 study at Duke University. So that’ll be about it.

Now, will there be additional tweaking that may be required as we look at those different prototype formulations? Yes, there may well be, and then so you would go back and adjust them, and whether or not another PK study would be required, we don’t know at this point. But right now we’re hopeful that we’ll hit it head on, and right on target, and we can make the appropriate adjustments and move forward.

Formulation development is not trivial, and as I talked earlier, we have a fair number of things to do from a regulatory standpoint before we can start a Phase 3. So we’re working diligently on both fronts to move them both forward as fast we can.

And EvaMist launch plans – yes, classically when you submit the NDA, you shift your workload over to the launch activity; and so there’s a number of things going on in that area: market research that needs to be done, we’re commissioning that work, and to see how we best can position EvaMist into this marketplace. There is a number of things that need to be done with pharmacy benefit managers, and we are working on that as I speak. So there’s a lot of activity that’s been kicked off as far as the launch plans are concerned; and we’re working to meet the – our goals being ready to launch that product 12 months from now or soon thereafter the approval.

Adnan Butt: And finally, just to follow up on Qnexa. Can you give us a timeline for your expected filing over the IND for Phase 3?

Leland Wilson: Yes; not the IND, but the one we expect to begin Phase 3. Yes, we’re going to begin Phase 3 definitely next year and I don’t know whether, Tim, whether we’ve nailed that down to the exact month that we’re going to do it; but we’re looking somewhere towards the mid-year and so that’s about as close as I can come right. And clearly, you guys understand that we have to work with the agency to get everything done in that regard and, so a great deal. The vagary here is exactly when that’s going to occur is how to fast we can get the turnaround on this product.

Adnan Butt: And the plan right now is to ask for an SPA for the Phase 3, is that right?

Leland Wilson: Yes, it is.

Adnan Butt: Okay, thank you.

Operator: At this time there are no further questions, sir. Are there any closing remarks?

Leland Wilson: Okay, well, I want to thank everybody. I mean, clearly the stock price has been a roller coaster over the last little bit here. I would like to say that there have been no developments at VIVUS that would cause that to occur – that is, there are no changes in the profile of any of the products that we have. It is completely external to our company.

The results of the data that were presented back at the Obesity Study were exceptional in every regard. There was additional data presented there, all very positive; and I think the response there to the product was extremely well received as well. So we’re very confident in the Qnexa product and its development timelines, and our ability to execute on that as well as the other products in our development pipeline.

So with that, I’ll sign off and I thank you for your support, and we’re working diligently on your behalf. Thank you.

Operator: Thank you. This concludes today’s VIVUS Incorporated Third Quarter 2006 Financial Results Conference Call. You may now disconnect.

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