
**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) **November 18, 2009**

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-33389
(Commission File Number)

94-3136179
(IRS Employer
Identification No.)

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

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

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

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

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01. Other Events

On November 18, 2009, VIVUS, Inc. conducted a conference call and webcast discussion of avanafil Phase 3 results. 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. conference call on November 18, 2009, 7:30 a.m. CT.

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/ Lee B. Perry
Lee B. Perry
Vice President and Chief Accounting Officer

Date: November 24, 2009

EXHIBIT INDEX

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. conference call on November 18, 2009, 7:30 a.m. CT.

VIVUS, INC.

Moderator: Tim Morris
November 18, 2009
7:30 am CT

Operator: Good day and welcome to the VIVUS Incorporated Avanafil Phase 3 Results conference call. Today's call is being recorded.

On today's call from VIVUS we have Chief Executive Officer Mr. Leland Wilson; President, Mr. Peter Tam; Chief Financial Officer, Mr. Tim Morris; Vice President Clinical Development, Dr. Wesley Day; Senior Director Clinical Development, Dr. Charles Bowden, and Dr. LeRoy Jones, a urologist and ED specialist from San Antonio.

At this time, I would like to turn the conference over to Mr. Tim Morris. Please go ahead, sir.

Tim Morris: Thank you, Angel. Before we get started, I'd like to remind you that during the course of this conference call, VIVUS may make projections or other forward-looking statements regarding future events. We wish to caution you that such statements are just predictions and 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, 2008 and the periodic reports filed with the Securities and Exchange Commission. These documents contain and identify important factors that could cause actual results to differ materially from those contained in our projections or forward-looking statements.

1

I would also like to point out for those listening in on the webcast you may experience a slight delay in the transition from slide to slide. For your convenience, slide numbers will be given throughout the presentation. I would now like to turn the call over to Mr. Leland Wilson, Chief Executive Officer of VIVUS.

Leland Wilson: Thanks Tim. Today, we are pleased to announce the successful results of the first and largest of three pivotal trials of avanafil for the treatment of ED. Avanafil in this large well controlled study done under an SPA met all three primary end points at all three doses tested.

Results indicate that up to 77% of sexual attempts resulted in erections sufficient for intercourse and the maximum effect was achieved in 30 minutes or less. Importantly, peak efficacy was sustained for more than six hours. Based on adverse event reports, we believe that avanafil may prove to have the best safety and adverse event profile in class.

Slide 5 - Some have asked why develop another PDE5 inhibitor? Fortunately, the answer is relatively simple. The clinical and regulatory development path is straightforward with low clinical risk as compared to other NDAs. And more importantly, there is a substantial market opportunity for a new therapy with the characteristics of avanafil.

The PDE5 market is large and growing. Current sales exceed \$3.8 billion, both the number of prescriptions and the average price per tablet continue to grow, and gross margins are excellent. In addition, there is a high rate of patient switching, up to 40%, between products among current PDE5 users. This indicates that current users are looking for a better product. We believe what patients want is a product that is faster acting and has fewer side effects, and that is exactly what we see for Avanafil in the revised data.

2

Slide 6 - Avanafil is licensed from Mitsubishi Tanabe Pharma. From the beginning of the licensing process, we were impressed with the potential for avanafil to stand out from existing products on the basis of its high specificity for PDE5 and its rapid time to maximum plasma concentration. We believed early on that avanafil had the potential to be positioned as a true on-demand therapy for ED, the most highly valued characteristic in the ED market. Avanafil is protected by worldwide patents through 2020 and potentially beyond.

Slide 7 - Avanafil has time-to-maximum plasma concentration of about 35 minutes, compared to sildenafil and vardenafil with Tmax of about 60 minutes and tadalafil with a Tmax of about 120 minutes. The faster to Tmax, the faster the expected onset of action.

Slide 8 - This slide shows the relative specificity of avanafil, sildenafil, vardenafil and tadalafil for PDE5 and other important PDE enzymes. A high number means less activity against that type of phosphodiesterase. The closer to 1, the greater the effects.

Data for all eleven known PDE enzymes are available, but the ones shown are typically the ones related to off-target side effects. For example, sildenafil sometimes is associated with "Blue Vision," which is related to off-target effects of that drug on PDE6 found in the retina.

When looking at the table overall, we think avanafil is the most specific for PDE5 with less interaction with other off-target enzymes.

Slide 9 - Currently available PDE5 inhibitors offer a range of times to onset and durations of effect. In a study by Giuliano, patients were asked to record when they had sex after taking one of three available PDE5 inhibitors. Predictably, nearly 80% of men had sex in the first two hours and less than 10% of men had sex at any time beyond six hours.

3

Slide 10 - This slide shows the market share of the three current US competitors over the past six years. In 2003, Viagra had the market to itself. In 2004, both Levitra and Cialis entered the market and were able to take away significant share from the market leader. Since that time Levitra's share has been relatively constant but Cialis' continues to grow market share, largely because it has been able to create a unique position around its 36-hour duration.

We believe avanafil's ideal position is full efficacy in 30 minutes or less with full effect lasting through six hours and excellent tolerance and safety.

Slide 11 - In summary, we believe there is an excellent opportunity for a new fast acting, low side effect PDE5 inhibitor. The market is large and growing, patients are looking for better therapies as indicated by the lots of patients switching. New entrants such as Cialis with a differentiated position are able to grow market share. We believe patients are looking for characteristics avanafil has been able to demonstrate in the revised study.

Here to talk about REVIVE is Dr. Chuck Bowden, Senior Director of Clinical Development at VIVUS and leader of the avanafil program.

Charles Bowden: Thank you, Lee and good morning. We're proud to share the results of the REVIVE TA-301 study with all of you this morning.

This study randomized 646 men with ED at 40 sites in the United States. After initial screenings, subjects enrolled in the study entered a four-week non-treatment run-in period. Those that reported at least four attempts at intercourse during that period with at least a 50% failure rate were randomized and assigned to one of the four treatment arms: placebo, 50, 100 or 200 milligrams of avanafil, followed by 12 weeks of active treatment. 550 subjects completed the study, a retention rate of 85%, and that rate was well balanced across all the treatment groups.

4

As part of the SPA agreement with the FDA, subjects were not restricted on food or alcohol consumption during the trial. We allowed subjects who were on stable doses of alpha blockers to participate and we did not exclude subjects on the basis of prior use of PDE5 inhibitors and, in fact, about 72% of subjects entering the study reported prior ED treatment.

As you will see in a moment, the results were outstanding with the majority of subjects having success in 30 minutes or less after dosing. Avanafil was well tolerated with a low frequency of adverse events typically associated with this class. At baseline, the average subject in this study was about 56 years old, but there was no upper limit on age and we included subjects in their 70s and 80s. The average subject had ED for more than six years and had moderate to severe erectile dysfunction at baseline based on a mean IIEF erectile function domain score of about 12, where a score of 10 or less is considered severe and 26 or greater is considered normal.

Although those are mean baseline scores, the study population included a wide range of ED severity. Also as agreed in the SPA, the study included three standard primary end points - change in responses to the sexual encounter profile or SEP questions 2 and 3, and the change in the International Index of Erectile Function, or IIEF, erectile function domain score.

As I'm about to show you, avanafil met all three end points at all three dose levels. So let's take a look at the data for these three primary end points. First we'll look at SEP 2. The SEP 2 question asked the subject whether he was able to achieve vaginal penetration during each attempt at intercourse.

The data is shown as the percentage of "yes" responses to the SEP 2 question comparing baseline to end of treatment for each treatment group. As you can see, all subjects at baseline began with a rate of about 45% to 48%. There was a dose-related increase in the rate of vaginal penetration with increasing doses of avanafil up to 77% at 200 milligrams. The p-values for all doses of active drug were less than 0.001.

5

Let's turn to SEP 3. The SEP 3 question asked the subject whether his erection lasted long enough for successful intercourse, and like SEP 2, the SEP 3 data are shown as the percentage of "yes" responses to this question, again comparing baseline to end of treatment for each treatment group.

All these subjects began with a low rate of success, about 12% to 14% at baseline. Once again, there was a dose-related increase in successful intercourse with increasing doses of avanafil. Success rate was 57% with the 100- and 200-milligram doses, or about a four- to five-fold improvement. All these differences were significant with a p-value less than 0.001.

And finally the IIEF erectile function domain scores, the third primary end point. Erectile function was significantly improved at all three doses of avanafil. The baseline scores in all treatment groups were 12.4 to 12.7, and this represented moderate to severe erectile dysfunction.

At end of treatment, there was a significant dose-related improvement in scores of active drug up to a mean score of 22.2, a near doubling of the score and a 10-point improvement on the 200 milligram dose. Although the mean end of treatment score was 22.2 in the mild range, many subjects reached a score that would put them in the normal range of 26 or greater. All treatment group differences were significant with p-values equal to or less than 0.001.

We also looked at the timing of each attempt at intercourse relative to dosing and an analysis of success rates by time after dosing. As you can see, more than a third of the attempts, 38%, were initiated in 30 minutes or less after dosing and more than 80% within the first hour.

So how successful were attempts at these different time intervals? Let's look first at the shortest interval, 30 minutes or less. Avanafil was effective during the first 30 minutes after dosing. In fact, 60% of attempts in this earliest time interval were successful as measured by SEP 3 in subjects taking 100- or 200-milligrams of avanafil.

6

So what about the other time intervals? On slide 21, you see the rates of successful intercourse for each of five pre-specified time intervals after dosing for placebo and each of the three doses of avanafil. You can see that the positive results of 30 minutes or less continue throughout this timeframe including the category of more than two hours after dosing.

In general, subjects taking avanafil were successful beginning with the earliest time interval, and that success is consistent across time for more than two hours. But what about that time greater than two hours? Let's look more closely at the duration of effect.

We looked at success rates greater than four hours and greater than six hours, again based on SEP 3. Here you see that the rate of success greater than four hours is in the 60-70% range for 100- and 200-milligrams, and even at six hours and beyond the rates are 77% and 83% for 100- and 200-milligrams, respectively.

So in this trial the effect of avanafil appears early, within 30 minutes, and persists for six hours or more. As you can imagine, we're very happy with the efficacy of avanafil in this study and we believe these data are comparable to the published data for the PDE5 inhibitors currently available. We're also very pleased with the rapid onset of effect and the durability of that effect.

Let's now turn to the safety and adverse event profile of avanafil in this study. There was a low rate of discontinuations for adverse events. There was also a low rate of serious adverse events, or SAEs, less than 2% in all treatment arms, and there were no SAEs related to study drug. There was one death in the study, a gunshot wound clearly not related to study drug.

Overall, we saw a low rate of adverse events of all types, and the types of events reported were consistent with the other drugs in this class.

7

This slide shows the adverse events occurring at a rate of 1% or greater in either the placebo or active arms of the study. As expected, the most common AEs in the active group included headache, flushing and nasal congestion. We were pleased to see that the rate of these events was as low as you see here. We had no episodes of "Blue Vision" or any changes in color vision.

How do these rates compare with the other PDE5 inhibitors? Here we show the rate of four common adverse events for avanafil and the three existing products. All these rates are placebo-adjusted and pooled across all active doses.

Let me qualify this comparison by saying that this is not from a head-to-head comparison in a single study. Even so, I think it demonstrates that the AE profile of avanafil compares very favorably with that of the three currently marketed drugs in this class.

We were optimistic about the eventual outcome of this study but even we were surprised when we saw the data. On the efficacy side we were impressed with the early onset of effect and the durability of that effect over time, and we were pleasantly surprised by the low rate of adverse events. Frankly, it's hard to imagine how the results could have been much better.

Any study of this kind depends on a lot of people to make it successful, so my thanks to everyone at VIVUS, our CRO partners, our investigators and the subjects who participated in this study for delivering such great results.

Now let me introduce Dr. Wesley Day, Vice President of Clinical Development.

8

Wesley Day: Slide 26 please. Thanks Chuck. These are great results for a PDE5 inhibitor and they well position the drug's product profile. They are also reassuring for expectations regarding the outcome of the remaining phase 3 studies.

Slide 27 - REVIVE was conducted under a Special Protocol Assessment and is the first and largest of four pivotal studies supporting the development plan for avanafil. The remaining phase 3 studies are now up and running, with expected completion rates ranging from mid-to fourth quarter 2010.

The REVIVE-Diabetes study is completely enrolled with over 375 diabetics with erectile dysfunction. Top line results for this study will be released in mid-2010.

The third study includes patients with erectile dysfunction that have had a radical prostatectomy, and is currently enrolling. Top line results from this study are expected late in 2010.

As part of the fulfillment of regulatory requirements for the safety assessment of avanafil, VIVUS has initiated a year-long open label safety study, TA-314, that will include over 600 patients followed for up to 12 months.

We have already met the 6-month completion milestone with more than 300 patients. We expect to complete TA-314 in the second half of 2010.

Slide 28 please - The avanafil development team will have a busy year ahead with a well orchestrated plan in place to complete phase 3 and the remaining clinical and non-clinical requirements necessary to support the planned NDA submission for avanafil.

9

All components of the development plan are on track, with the plan submission of the NDA by late next year or early 2011. We are excited about the prospect of being able to submit a second NDA for VIVUS so closely following the NDA submission for Qnexa as a treatment for obesity.

As part of the clinical pharmacology requirements for avanafil, VIVUS has successfully completed a thorough QT study to determine if avanafil adversely affects cardiac repolarization. The TQT study is an FDA requirement for all new chemical entities.

VIVUS has also completed a nitrate interaction study comparing avanafil and sildenafil to placebo for the occurrence of clinically significant hypotensive events. This study demonstrated important differences favoring avanafil as compared to sildenafil in the percent of subjects experiencing significant hypotensive events.

Finally, there are several clinical pharmacology studies that are planned or ongoing to support the agreed requirements for the NDA as discussed with the FDA. The complete plan for all non-clinical studies has been discussed and agreed with the FDA. The studies are on track and mostly complete, with results that we believe will support the planned NDA for avanafil.

In summary, all clinical and non-clinical milestones are on track and in line with our plan to submit the NDA.

Slide 29 please - I'll now introduce Dr. LeRoy Jones.

Dr. Jones is a practicing urologist who is an ED specialist in a large urology group in San Antonio. He has participated in over 90 clinical trials. He is an investigator in two of our avanafil phase 3 studies. We asked Dr. Jones to share with you some of his perspectives as a clinician who sees a large number of ED patients. Dr. Jones?

10

LeRoy Jones: Thank you, Dr. Day. As Dr. Day has mentioned, I'm a practicing urologist with a specific expertise in male sexual health. I see patients on a daily basis and they continue to ask about newer therapies available for erectile dysfunction. Many are looking for a faster acting agent. Thus far my clinical experience with avanafil has been very positive. Many patients like the rapid onset of action combined with a lower side effect profile. They also like the flexibility of being able to take the medicine with or without food or alcohol. Based on the results of this study, this drug appears to be highly effective and well tolerated.

The call will now be returned back to Lee.

Leland Wilson: Thank you, Dr. Jones. It has been a very busy year for VIVUS with successful results from two phase 3 programs, Qnexa and now avanafil. The avanafil data are outstanding. The study met its primary end points for all three doses tested. A highly statistical significant number of patients treated with avanafil were able to achieve erections sufficient for sexual intercourse when compared to placebo. Overall erectile function scores improved nearly two-fold from baseline for patients on avanafil.

Lastly, REVIVE data indicate that full efficacy was achieved in 30 minutes or less and full efficacy is maintained through six hours.

We'll now open the call for questions.

Operator: Thank you. The question and answer session will be conducted electronically. If you would like to ask a question, please do so by pressing the star key followed by the digit 1 on your touchtone telephone. If you are using a speakerphone, please make sure that your mute function is turned off to allow your signal to reach our equipment. We'll proceed in the order that you signal us and we'll take as many questions as time permits. Once again, please press star 1 on your touchtone telephone to ask a question.

11

We'll go first to Mike King of Merriman. And Mr. King, your line is live, sir.

Mike King: Sorry. I was muted. Can you hear me okay?

Operator: Yes. We can hear you just fine. Please go ahead.

Mike King: Okay. A couple of questions. First of all, can you discuss why you decided with an SPA? It seems like end points in these kinds of trials are fairly straightforward.

Leland Wilson: Dr. Day, would you answer that please?

Wesley Day: Hi Mike. Sure. The SPA has a couple functions. The first is as a small company we think that it gives us outward credibility for the fact that we have met and discussed the FDA — with the FDA such important and very expensive protocols.

The second component is, you know, in this regulatory environment. I don't think anything is a given these days, and the SPA certainly adds some greater ability to discuss and agree with the FDA on the important end points and analysis that has to occur in the trial.

Mike King: And what about the safety database? Was that explicitly discussed, because in this environment it seems like FDA wants exceedingly high safety data on drugs for consumer markets.

Wesley Day: Yeah. The safety is always at the front of many discussions, and I think with respect to PDE5's the FDA has a pretty good or at least it's our opinion they have a pretty good comfort level with the class, and so there is a great deal of familiarity with what can be expected and the types of safety events that do occur with these treatments. So that part of the development program has probably been a bit more straightforward perhaps than other development programs.

Mike King: Okay. One or two more quick questions. You got the Deerfield facility in place. Lee or Tim, do you want to address what may be the strategy there about that facility?

Leland Wilson: Mike, it's Lee. Yes, I would say that our preference would be to obviously go through the risk reduction part of the NDA or the clinical trial work here and then pay off the balance of the Deerfield loan. Clearly, I think you know that Deerfield is sharing the risk of the clinical programs with us to some extent, and so we want to be able to take advantage of that as we finish up. Now, clearly, today's results really remove most of those risks, and so at some time we will pay off that loan.

Mike King: Okay. Great and then last question is can you remind me of the intellectual property on Viagra and the other PDE5 inhibitors in the class? Thanks.

Leland Wilson: I'll ask Peter to handle that.

Peter Tam: Yeah. The Viagra, the first PDE5 inhibitor on the market, has a patent that runs out late 2019. So certainly we don't expect any generic product to enter the marketplace. I think more importantly because as you have seen the data, the differentiating features that we have demonstrated for avanafil will keep the product in the marketplace for a long time to come. And plus the fact that we have worldwide patents approved in 23 countries available for avanafil composition as well as utility claims for the product.

Operator: And we'll go next to Michael Tong of Wells Fargo Securities.

Michael Tong: Hi. I was wondering if you have the data handy for the percent of patients that actually achieved IIEF score of 26 or better in each dose.

Leland Wilson: This is Lee. No, we don't. Sorry.

Michael Tong: I was just interested because you did mention that a substantial number of the patients hit that mark. Will you make that data available at some point?

Leland Wilson: Yes. Yes we will.

Michael Tong: And then secondly, I was wondering if you had actually looked at the rate of clearance of the avanafil molecule from the body given the consideration one of the earlier studies might have indicated a quick clearance, but that seems to run counter to the long duration of action.

Leland Wilson: I'll have Wes answer that as a pharmacologist. Thanks, Wes.

Wesley Day: Yeah, that's an interesting, important question. From a pharmacokinetics perspective, the half-life of the drug does not necessarily correlate directly with the duration of activity, and as you have mentioned we do see a pretty good duration of activity, which quite possibly exceeds the half-life. I think that's a function of the distribution of the drug. We do see a pretty rapid initial distribution of the drug throughout the body and a rapid Tmax, which we believe relates very well to the onset of action. But I think the effect occurs and it lasts a bit longer than actually the drug remains, and that's not an unusual effect for a drug like this.

Michael Tong: Okay. And then finally, for your NDA submission, are you expecting to have all four studies in the submission package?

Wesley Day: Yes. All of the studies that I have described today will be complete and a part of the NDA submission.

Michael Tong: Great. Thank you.

Operator: And we'll go next to Jason Butler of JMP Securities.

Jason Butler: Hi. Good morning guys and congratulations on the data. I had a question about the open-label extension study. Is there any requirement for a proportion of patients to come from both the 302 and 303 studies? Or can all of the patients with one year data come from the first trial?

Leland Wilson: I'll have Dr. Bowden answer that.

Charles Bowden: There is no specific requirement about the provenance of the patients rolling over from a parent study into the extension study. So far we're allowing — we allowed patients that successfully completed either this study, 301, and we are allowing studies that successfully complete 302, the diabetes study, to roll over into the long-term safety and tolerability study.

Jason Butler: Okay. Great. Thank you very much.

Operator: And once again, ladies and gentlemen, that is star 1 if you would like to signal for a question. We'll go next to Robin Davison of Edison Investment Research.

Robin Davison: Hello. Good morning. I have got a couple of questions. First of all, did any of the earlier studies use doses higher than 200 milligrams? And is there any suggestion that you might get sort of better efficacy at a higher dose?

15

That was one question. The second one, an easy one, is the data that you presented based sort of ITT or is it the completer data?

And thirdly I just wondered, somewhere in the presentation you said that 11,600 attempts were recorded.

I wondered was that evenly balanced amongst the placebo and active groups. Were there outliers, certain patients who were very successful and had a lot more than the average of 21 attempts. Okay?

Leland Wilson: I'll have Dr. Day answer that question.

Wesley Day: Hi Robin. So I think your — the first question was regarding what doses we have tested. We did a pretty extensive dose response analysis in phase 2. In phase 1 we actually tested doses up to 800 and even 800 was a pretty tolerable dose. So from a safety perspective, we think we have got some pretty good doses. The 200 appears to be the peak dose. The FDA is pretty sensitive that you identify a dose where you get maximum effect with the best tolerability. So they want you to find the lowest dose where you can get that effect, and we think it's about 200.

The second question that you asked had to do with ITT analysis. Everything that we have presented was ITT-LOCF. And with respect to the balance between placebo and active, patient by patient there is a degree of variability, obviously as you would expect, but there was a good even balance between placebo and active treatment.

Robin Davison: Thank you very much.

Operator: And we'll go next to Len Yaffe of Stocdoc Partners.

16

Len Yaffe: Thank you. You touched briefly on what I think might be a very important differentiating feature and that's the nitrate issue. Do you think that there is any possibility for Avanafil to be able to distinguish itself in clinical practice in terms of being able to be used in patients with nitrate therapy? And if so, as a follow on for Dr. Jones, if he could discuss the percent of his patients who are on nitrate therapy who perhaps might then be a candidate for a PDE5 inhibitor and how he views that potential benefit if in fact it does exist?

Leland Wilson: Len, thanks for the question. It's Lee. Let me handle the nitrate question from a corporate perspective. I would say very clearly that we would want to have in our labeling the warning not to use our PDE5 with nitrates just as every other PDE5 has that warning in their label.

Now having said that, and that is obviously for prudence for protecting patients and obviously for corporate liability and all kinds of things. So that we very strongly believe and want that in our labeling. Now having said that, there are times when patients need nitrates, a critical medicine in certain situations. And it's important that if a patient is using a PDE5 inhibitor, and to my estimate almost all patients that require nitrates have erectile dysfunction, and Dr. Jones may want to speak to that, but so the question becomes one of if a patient is using a PDE5 inhibitor and they are likely to require nitrates, there potentially could be a choice in which PDE5 inhibitor to use.

Now I'm saying on a nitrate, on an emergency basis, not on an ongoing therapeutic basis, okay? So if they are likely to have an acute angina attack just based upon their cardiovascular profile, a physician may want to consider using a short-acting PDE5 inhibitor that is highly specific for PDE5, which as you saw in our table has much less activity against PDE1, which is associated with cardiovascular activity. And so there are reasons to believe that a drug such as avanafil would be a better choice. Now I walk that line very carefully here so that we all know that we are not recommending this use for patients that are taking nitrates, but in an emergency situation, there may be some benefit.

17

We believe that we'll be able to put the results of our nitrate interaction clinical trial into the clinical trial section of the NDA, but, of course, that will have to be negotiated with the FDA. And so maybe Dr. Jones can answer the second part of that question.

LeRoy Jones: Yeah. In general, I don't see a large percentage of patients that are currently using nitrates that also request PDE5 agents. I mean, in my practice it's probably less than 1% or 2%. I think most patients and most physicians are aware of the contraindications with the PDE5 agents and so I think we probably worry about it more than it actually exists. And again also to treat somebody with an acute heart attack, there are other options to treat them be it morphine, oxygen, and so you can look to other agents aside from nitrates. And so I think the nitrate issue, although we do need to understand it and be cognizant of it, we probably don't need to worry about it quite as much as we do.

Len Yaffe: Thank you very much.

Operator: And we'll go next to Boris Peaker of Rodman & Renshaw.

Boris Peaker: Yes. Hello. Can you hear me?

Leland Wilson: Yes.

Boris Peaker: I just have a quick follow-up question to what you mentioned. Specifically, could you remind us again when the patent expiries for the other compounds is? I thought you said 2019 for Viagra, and I'm just looking at the Pfizer report where it says 2012. So I'm a little confused.

18

Leland Wilson: Yes. I'll handle that, and maybe Peter can comment as well. If you look in the Orange Book, there is a patent for sildenafil, and it's a use patent, which expires in 2019. And it's our opinion that that patent is valid. As having been one of the participants in an original litigation that opened up the PDE5 marketplace to other companies, Pfizer was able to drop back from their original position that included all PDE5 inhibitors in their utility patent back to their position where they have just their product as the utility patent for this. We believe, and our counsel believes, that that patent is strong and it will be held valid in the United States. But I think it's important to understand that we stand strongly behind the characteristics of our drug, that is this rapid onset of action and sustained activity through six hours with an extremely beneficial side effect profile, and we believe strongly that we will be able to compete in the marketplace regardless of the patent situation of Viagra.

Boris Peaker: And what about the patent expiry for the other two drugs? Do you have the dates off the top of your head?

Leland Wilson: I don't have them off the top of my head, but they're out quite a distance yet.

Boris Peaker: Okay. Great. Thank you.

Operator: And we'll take a follow up question from Mike King of Merriman.

Mike King: Thanks for taking my follow-up questions. Can you talk about where or when, where and when you might present this data, or are you looking for publication, or exactly what the strategy is there?

Leland Wilson: I'll ask Dr. Bowden to take that question.

Charles Bowden: We obviously expect to present these data at a professional meeting and to publish these results in a major peer-reviewed publication. We haven't made a final decision about the venue for either the meeting or the publication yet.

19

Mike King: Can you just remind me, urology is usually in the spring, right?

Charles Bowden: Yes.

Mike King: Thank you.

Operator: And we'll take our next question from Steve Yoo of Leerink Swann.

Steve Yoo: Hi. Congratulations on good phase 3 results, and I've got a couple questions on the marketplace. Can you tell me if you can give me a feel for how many patients are on self-pay versus people who are reimbursed through their insurance for PDE5s?

Leland Wilson: I don't have the exact number, Steve, on top of my head but there is a substantial reimbursement for PDE5 inhibitors, and my recollection goes back to it has approached up to nearly three-quarters of prescriptions.

However, there is a high co-pay and in some plans it requires prior approval before the product is reimbursed. So reimbursement is available, tier 3 co-pay, and sometimes prior approval is required.

Steve Yoo: Okay. And you mentioned that there was plenty of switching in the market. Do you know what the primary reasons for patients switching from one drug to the other are?

Leland Wilson: Well, the work that we have done would indicate that patients are looking for a better product. And in our estimation that is it comes down to efficacy in use is the term that we use, and that is patients routinely take the medication and try to have sex before they have the full benefit

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of the drug onboard. And so we like to think that if you have the drug onboard faster, that you will have better efficacy in use, and that's the whole tenant of avanafil's profile.

Operator: And at this time, we have no further questions. I'll turn the conference back over to you, Mr. Wilson, for any closing comments or remarks.

Leland Wilson: Thank you, operator. This is another great day for VIVUS. It's rare for a CEO of any pharmaceutical company to be able to announce back-to-back phase 3 results for two potentially best in class drugs for two major markets.

In summary, avanafil was able to demonstrate full efficacy as measured by successful intercourse in 30 minutes or less. Full efficacy was maintained for all doses across multiple time points, from 30 minutes to beyond six hours. All FDA defined primary end points were met across all three doses of avanafil.

Avanafil was well tolerated as demonstrated by a high retention rate of 85%. There were no drug related serious adverse events in the study and Avanafil patients had low reports of common PDE5 subjects.

Before closing, I would be remiss not to recognize the outstanding work done by our clinical group including Peter Tam, Wesley Day and Dr. Chuck Bowden and many others in our department here at VIVUS. I also want to thank Dr. Jones for his clinical work on these trials and agreeing to speak with you today. Thank you. Appreciate your comments and questions. Talk to you again soon.

Operator: And that concludes today's conference. We thank you for your participation.

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