UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported)

February 28, 2011

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 February 28, 2011, VIVUS, Inc. conducted a conference call during which members of its senior management team discussed financial results for the fourth quarter and year ended December 31, 2010 and certain other information. They also reported on product development and business 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. Fourth Quarter and Year End 2010 Earnings Results Conference Call on February 28, 2011, 1:30 p.m. PT.

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
Senior Vice President and Chief Financial Officer

Date: March 4, 2011

EXHIBIT INDEX

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. Fourth Quarter and Year End 2010 Earnings Results Conference Call on February 28, 2011, 1:30 p.m. PT.

VIVUS, Inc.

Moderator: Tim Morris
February 28, 2011
1:30 p.m. PT

Operator: Good day, ladies and gentlemen, and welcome to the VIVUS Fourth Quarter and Full Year 2010 Results Conference Call. At this time, all participants are in a listen-only mode. Later we will conduct a question and answer session and instructions will follow at that time. If anyone should require assistance while the conference is in progress, please press star and then zero on your touchtone telephone to reach an operator.

As a reminder, this conference is being recorded. I would now like to introduce your host for today, Mr. Tim Morris, Chief Financial Officer. Sir, please go ahead.

Tim Morris: Thank you, Karen. Before we get started, I would like to remind you that during this conference call VIVUS will make certain statements that are considered forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These states may be identified by the use of forward-looking words such as anticipant, believe, planned, estimated, and intend, among others. These forward-looking statements are based on VIVUS' current expectations and actual results could differ materially.

There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the timing and substance of our response to the FDA's request from the End-of-Review meeting; our response to the FDA's Complete Response Letter; the feasibility assessment of performing a retrospective observational study of fetal outcomes in infants

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born to mothers exposed to 100 milligrams of topiramate for migraine prophylaxis during pregnancy and the results from that study; the FDA's interpretation of and agreement with the information VIVUS submitted relating to teratogenicity and cardiovascular safety; the FDA's interpretation of the data from our SEQUEL study; the FDA's request, if any, to conduct additional prospective or retrospective observational studies or to provide further analysis of clinical trial data; substantial competition; the impact on future sales based on contraindications contained in the label and the extent of the Risk Evaluation and Mitigation Strategies program; uncertainties of litigation and intellectual property and patent protection; reliance on sole source suppliers; limited sales and marketing resources and dependence upon third parties; risk related to the development of innovative products; risk related to the failure to obtain FDA or a foreign authority clearances or approval and non-compliance with FDA or foreign regulations; and our dependence on the performance of our collaborative partners.

As with any pharmaceutical in development, there are significant risks in the development, the regulatory approval and commercialization of new products. There are no guarantees that our response to the FDA's CRL or their request stemming from the End-of-Review meeting will be sufficient to satisfy the FDA's safety concerns and that the FDA will not require us to conduct any additional clinical or retrospective observational studies prior to or post approval, or that any product will receive regulatory approval for any indication or prove to be commercially successful. VIVUS does not undertake an obligation to update or revise any foreign-looking statements. Investors should read the risk factors set forth in the VIVUS Form 10-K for the year ended December 31, 2010 and periodic reports filed with the Securities and Exchange Commissions.

I will now turn the call over to Mr. Leland Wilson, CEO of VIVUS.

Leland Wilson: Thank you, Tim. Good afternoon and thank you for joining us today. Joining me on the call, along with Tim, is VIVUS' President, Peter Tam.

The focus of today's call is to provide an update on the resubmission of the Qnexa NDA and the follow up from the meeting with the FDA on January 19th.

We'll also provide a brief update on the approval process for Qnexa in Europe and the filing of the avanafil NDA.

As you know, we received a Complete Response Letter for Qnexa on October 28th. Our response was prepared and submitted in December. We met with the FDA on January 19 to discuss our planned resubmission. We announced the results of that meeting in late January with what we believe was the only remaining request from the FDA.

Specifically, the FDA has requested that we assess the feasibility of performing a retrospective observational study utilizing existing electronic medical databases to review fetal outcomes including historical incidence of congenital malformations with an interest specifically on oral cleft and low birth weights in infants of women that have received 100 milligrams of topiramate for migraine during pregnancy.

I will now turn the call back over to Peter for more specific details on this issue.

Peter Tam: Thank you, Lee. As Lee mentioned, we held a face-to-face meeting with the FDA on January 19, 2011 to discuss the items contained in the CRL and the information we planned to include in the resubmission of the NDA for Qnexa. As a recap, in December 2010, VIVUS provided a briefing document that included analyses integrating existing non-clinical and clinical data to provide a comprehensive assessment of the teratogenic potential of topiramate.

In addition, VIVUS provided new analyses to demonstrate that the heart rate elevations associated with Qnexa do not increase the risk for major cardiovascular events. These analyses examined heart rate and blood pressure in various patient populations as well as individual active and placebo patients who experienced serious cardiovascular events.

Our results demonstrated with statistical significance that blood pressure was consistently lowered across the various subgroups of patients and that heart rate in general tended to increase in patients with a low baseline heart rate and decrease in patients with a higher heart rate at baseline.

On the basis of these analyses, we believe there is no association between the small heart rate increase and major cardiovascular events. It is our view that this conclusion is further supported by the additional benefits of Qnexa treatment observed across the entire clinical development program, specifically improvements in blood pressure in particular in obese hypertensive patients, improvements in various glycemic markers in obese diabetic patients, and reductions in inflammatory markers such as c-reactive protein in the overall obese population.

The briefing document in response to the CRL also included cardiovascular data from our two-year extension study of Qnexa as a treatment for obesity, also known as SEQUEL, and the sleep apnea study in obese subjects.

VIVUS provided a synopsis of the final report for the SEQUEL study. In the CRL, no new clinical studies were requested; however, it also stated that in the event that any of the FDA concerns are not alleviated, additional clinical studies may be required.

At the January 19th meeting, the FDA focused the discussion on the teratogenic potential for topiramate, specifically the incidence of oral clefts observed in the epileptic drug pregnancy registries. The FDA cited four cases of oral clefts reported in the North American Antiepileptic Drug Registry and two cases reported in the U.K. Epileptic Registry. We believe that based on these six cases, the FDA is requesting that VIVUS assess the feasibility of performing a retrospective observational study utilizing existing electronic databases to review fetal outcomes, including historical incidence of congenital malformations with an interest in oral cleft and low birth weight in infants of women who have received prophylaxis treatment with 100 milligrams of topiramate for migraine during pregnancy. This assessment of feasibility is necessary before we can resubmit our NDA for Qnexa.

Subsequent to the January 19th meeting, the FDA confirmed in the meeting minutes the need to perform a feasibility assessment for the retrospective observational study. FDA recommended that analyzing data in women taking topiramate for migraine would provide a more precise assessment of risk than epileptic women in whom the dosages of topiramate are generally higher and the duration of exposure is longer.

As part of a feasibility assessment of infant outcomes, FDA requested that we examine infant birth weight given the fact that the Topamax package insert was recently modified to include language on low birth weight. Low birth weight is defined as less than 2.5 kilograms, or five-and-a-half pounds.

Again, because the data in the updated Topamax label was obtained in epileptic women and not women with migraines using Topamax at typically lower doses and shorter duration, we believe this is the reason the FDA has made such a request. Please keep in mind that in the Qnexa studies, which included 15 infants born to women exposed to Qnexa or topiramate, there were no reports of any fetal malformations or occurrences of low birth weight in our entire clinical program. In fact, the data from infants exposed to Qnexa show that no infants had a birth weight that was less than three kilograms, or 6.6 pounds, and that the probably of developing low birth weight based on our data has been shown to be less than three percent.

To date, as part of the feasibility assessment we have explored multiple North American and European registries and medical claims databases covering over 150 million lives and spanning many years. We have been working with several expert pharmaco-epidemiologists in assessing these claims databases in an effort to identify and estimate the number of mother-infant pairs that were exposed to topiramate for migraine prophylaxis during pregnancy.

We have shared these preliminary findings with the FDA. We expect to reach agreement with the FDA and if deemed feasible, initiate the retrospective observational study on fetal outcomes within the next two months. We will provide more details as soon as an agreement is reached.

At this time, although the details remain to be finalized, our goal is to resubmit the NDA for Qnexa before the end of the year.

Shifting gears, we want to provide you with an update on the submission of the MAA in Europe. We had previously been working with the authorities in the EU to ensure our submission would be adequate for approval. Prior to submission and upon completion of the pivotal phase three studies, we sought advice from the Scientific Advice Working Party, or SAWP, on the requirements for submission in Europe. The SAWP suggested that we provide two-year safety and efficacy data on Qnexa. We believe the SEQUEL study reported last September satisfied that requirement.

EMA obesity development guidelines for efficacy state that demonstration of a significant degree of weight loss of at least 10 percent of baseline weight, which is also statistically greater than the associated — than that associated with placebos, is considered to be a valid primary efficacy criterion. We believe that Qnexa is the only orally administered weight loss drug in development that has met these criteria. We submitted the MAA in late December. We are glad to report that the MAA submission has been validated or accepted by the EMA and the review procedure commenced on January 19, 2011.

The EMA will seek assessment from the Rapporteur and Co-Rapporteur during this review period. We would expect to hear from the EMA with the day 120 list of questions in late May, early June. We would expect to address any questions or concerns and provide them with answers within 60 days from receipt of the questions.

The next step would be either the 180-day opinion from the CHMP, or a request for a hearing. The hearing would be scheduled within 60 days and the company would be asked to address any remaining questions. The CHMP would then issue their opinion on the MAA. Once approved we would then seek approval on pricing in the various EU member states. Assuming no delays in the process or requests for additional studies or analyses, we may have an opinion on the MAA by the end of this year.

Moving on to avanafil. For avanafil, we made significant progress towards the filing of an NDA in Q2 this year. We have completed the long-term safety study, TA-314. The results of this study were reported in December last year. TA-314 was an open label safety study of avanafil that evaluated the long-term safety and tolerability of avanafil. TA-314 was conducted over a one-year period in approximately 700 patients across 40 U.S. centers.

Patients completing either the 12-week REVIVE or REVIVE Diabetes studies were eligible to participate in TA-314. The study met all primary endpoints by demonstrating improvements from baseline in erectile function as measured by the Sexual Encounter Profile, SEP 2 and SEP3, and improvement in the International Index of Erectile Function, IIEF. TA-314 confirms the longer term safety and efficacy results observed from the previously reported placebo-controlled phase three studies of avanafil in patients with ED.

With that, I will turn the call over to Tim to discuss the financial results and provide guidance for 2011.

Tim Morris: Thank you, Peter. At the end of December, VIVUS had cash, cash equivalents and available for sale securities of approximately $139 million. This compares to the $207 million we had on the balance sheet at the end of 2009, for a net change of $68 million. As we stated on the last earnings call, we continue to conserve cash and have curtailed several planned expenditures.

For 2011, expenditures for clinical studies will be minimal. We will continue to support the activity necessary to refile the Qnexa NDA and to support the Qnexa MAA.

For avanafil, as Peter stated, we plan to file the NDA and will begin to prepare for a filing of avanafil in Europe as well.

Based on the current planned expenditures for the year, assuming no additional external studies or expenditures, we expect to end the year with approximately $100 million in cash.

As it relates to the rest of the financials, I refer you to the press release for more information on the year end and fourth quarter results.

On the investor relations front, we continue to participate in several investor conferences in March and April. Tomorrow I'll be in New York City and will present at the Citibank Healthcare Conference. We will also participant and present at the Cowen Healthcare Conference in Boston the week of March 7, the Roth Capital Growth Conference in Southern California the week of March 13, and the Needham Healthcare Conference in New York City on April 5 and 6.

We will also present more information from the SEQUEL study. On April 3 we will deliver an abstract at the American College of Cardiology in New Orleans. And on May 27th we will deliver another abstract on the SEQUEL study at the European Obesity Congress in Istanbul.

With that, operator, we'd like to open the call to questions and then we'll turn it back to Leland for some closing comments.

Operator: Thank you. Ladies and gentlemen, if you have questions at this time, please press star followed by the number one key on your touchtone telephone. If your question has been answered or if you decide to remove yourself from the queue, you may press the pound key. And our first question comes from the line of Christopher James from McNichol Lewis and Vlak.

Christopher James: Hi, good afternoon. Thanks for taking my questions. Can you guys hear me?

Peter Tam: Yes.

Christopher James: Just given — just a couple quick ones. You've covered a lot of ground. Just given that teratogenicity is not an issue with men, and I understand the commercial implications of my questions, but have you discussed the route to potential approval with Qnexa in just a male obese population?

Peter Tam: Christopher, it's Peter. Yes, we have — we're keenly aware of this possible scenario and we have discussions internally about this, and I guess if and when this path is considered to be appropriate, we will certainly pursue it; but we are definitely aware of it and definitely the population would also not just include men, but women of non-childbearing potential as well.

Christopher James: Right. And then I believe the 20-week ultrasound can detect a cleft palate. Have you looked at any of that data and have you been able to find any pairs and —

Peter Tam: No, we haven't at this point. Right now we're going through the feasibility assessment and we've provided preliminary information to the FDA. The exercise primarily includes identifying these mother-infant pairs exposed to topiramate at the doses that the FDA has recommended. So that's really the basis of the exercise.

Christopher James: And then finally, if feasible, what do you think is the length of time of the feasibility study, the cost and who will actually conduct this study. And then what do you expect to find? I'm sorry, multiple questions in there.

Peter Tam: Let me answer the question — your last question, what we are expecting to find. We had previously conducted a meta-analysis, which show that there was no increase in risk for major congenital malformation. And, you know, the relative risk of that analysis is 1.03; so it was pretty clear. The upper bound of the 95 percent confidence limit was less than two.

You know, in terms of looking at this oral cleft certainly is — we expect a much lower number and we haven't at this point, you know, shared how many infant mother pairs there are, but we don't expect — I mean, given that what we know about the drug at the doses, we don't expect to see any increased risk given the information that we have.

And then I think your other question is who's going to be doing this study and how long. You know, at this point, I think until we have better clarity with the FDA, we're not going to speculate on that. But just to reiterate that our goal is to resubmit the NDA by the end of the year.

Christopher James: Great, thanks for taking my questions.

Peter Tam: You bet.

Operator: Thank you. And our next question comes from the line of Cory Kasimov of JP Morgan.

Cory Kasimov: Hey, good afternoon guys. Thanks for taking the questions and appreciate the degree of transparency on this call.

One thing I'm a little confused about — can you be a little bit more specific of what exactly "if deemed feasible" means? I mean who determines what's feasible and then if it's not feasible, what happens? .

Peter Tam: Yes, Cory, I think that's a great — that's a great question. It's really you know largely dependent on you know FDA's assessment in this regard. I mean, there are certainly statistical considerations and I guess, you know, from our perspective we can put in feasibility, we can fold in time and money as part of the feasibility assessment, but I'm not sure FDA is sympathetic to those two parameters. So I think it's more on the basis of does this analysis or study make statistical and scientific sense and that really will be the basis of their assessment.

So right now, that's why the FDA hasn't deemed that such a study is feasible or not feasible yet and we have done the first part of that and we will be providing the information with regard to the sample size, which they will be able to work off of to determine the feasibility. But again, it's a great question. I wish I had a better answer for you, Cory.

Cory Kasimov: OK fair enough. Do you have any feedback from the agency at this point, or are we going to have wait on any potential lines being drawn in the sand with respect to teratogenic event rates? Or is that something we have to wait on this subsequent —

Peter Tam: You're going to have to wait for that, Cory.

Cory Kasimov: Do you think you're going to be in a position to disclose that?

Peter Tam: Yes, we'll make that judgment once we've had a sense of — once we've had the discussion with the FDA.

Cory Kasimov: OK, and then something that may — sounds encouraging on the surface, may be or — maybe it is or maybe it isn't. When as they start to kind of separate out the migraine patients from the epileptics, you made comments in your prepared remarks about the different — obviously there's a different dosage, but also different duration of use. Do you know the average duration of use for migraine patients relative to epileptics on topiramate?

Peter Tam: Yes, we have some of the information. We're actually in the process of confirming those data. But yes, I think it makes intuitive sense to know that epileptic patients will continue to use their drug. I mean I think that's why the FDA has guided us to look at the migraine population. Our sense is that the migraine patients will tend to go off of therapy once they know they're pregnant. And we know that the doses are, you know, substantially different. You know, for example, the average dose for epilepsy is about close to 300 milligrams per day, whereas the average dose for migraine is a little bit less than 100 milligrams. So I think that's one of the reasons why — that's the major reason why the FDA has guided us to look specifically at the migraine population at the 100 milligram dose.

Cory Kasimov: OK, and then the last question I have, and again, I just want to be as clear as possible here. I mean you've disclosed a number of different times now that your October Complete Response Letter touched on five different issues that the agency brought up. Then, in your January meeting, I understand that the FDA focused on the teratogenicity issue, but were the other issues also covered there? Or is it teratogenicity and only teratogenicity that came up in January?

Peter Tam: Well, we went there prepared to address all the issues relating to the CRL, and we provided a presentation on our position, our analyses and our summary findings for each one of those, but the FDA chose specifically to discuss this issue of teratogenicity, and that was all that was discussed between FDA and us after our presentation.

Cory Kasimov: OK, that's helpful. Thanks for taking the question.

Operator: Thank you. Our next question comes from the line of Alan Carr of Needham and Company.

Alan Carr: Hi, good afternoon. Thanks for taking my question. I just want to follow that one a little bit more. You did mention earlier on in your prepared comments that you felt fairly confident that this fetal outcomes study may be the only remaining item to be addressed by the FDA as compared to some of the other concerns in the Complete Response Letter. Is there any other information you can share with us that — you know, behind that comment, the reason behind that comment?

Peter Tam: Well, we have — Alan, it's Peter again. We have obviously been having conversations with the FDA and it's based on our ongoing communications with FDA. We believe fetal outcome is the remaining issue before we resubmit the NDA. So that's probably about the extent that I can share.

Alan Carr: OK and then — in any — you know, what sort of discussions have you had with European regulators on this? Have you had a recent discussion with them about you know how they feel about —the outcome study and that sort of thing?

Peter Tam: No we haven't, the process is we've outlined in the prepared remarks is that we've submitted the MAA. Right now we're in a quiet — they're in a quiet period and we have no idea in terms of what they are talking about. That's just part of the process. But we have shared pretty much all of our communications with the FDA regarding teratogenicity, our position with regard to teratogenicity, and all the correspondence with the FDA.

The MAA **[EMA]*** is privy to that information and we've shared those with them. We're just waiting for the 120-day list of questions from the MAA **[EMA]*** at this point.

Alan Carr: OK and then last one, I don't know if you didn't answer this question previously intentionally or unintentionally, but cost. Can you give us a sense of maybe the range of costs that might be associated with this fetal outcomes study?

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* Speaker erroneously referred to MAA when he should have stated EMA.

Tim Morris: Yes, Alan, this is Tim. We haven't given any guidance on the cost here but you know as a retrospective study it's clearly no where near what you would expect from a prospective study. The cash guidance I gave you includes any of our estimated costs. It's not — it's not trivial, but I would say that the costs are relatively minor as it relates to potentially running the study.

Alan Carr: But even at a larger scale it wouldn't be particularly expensive?

Tim Morris: No, it's not necessarily the size. I mean, this information all exists. To some extent it is all electronic, which it is, and so there's no need — it's not really comparable to a prospective study from a cost standpoint.

Alan Carr: Fair enough. Thanks very much.

Tim Morris: Sure.

Operator: Thank you. Our next question comes from the line of Andrew Vaino of Roth Capital Partners.

Andrew Vaino: Hey, thanks for — thanks for taking the question. Just quickly, are there any data that you're aware of, for example in animal models, to suggest what the degree of topiramate dose dependence used on teratogenicity?

Peter Tam: It's a good question. The animal studies, unfortunately, is fraught with issues. These are studies conducted by Ortho-McNeil or JNJ. The problem is is that these data or these studies were done or these events occurred in the presence of maternal toxicity. Typically, as you know, when you do teratogenicity studies you go — you dose up to the point of maternal toxicity and then you look at the doses below that to see the occurrence of any malformation. And unfortunately the studies that were run by Ortho-McNeil show that these events or these malformations that occurred in animals, they occurred in the presence of maternal toxicity. Now, we conducted our own teratogenicity studies in animals up to the point where they experienced maternal toxicity. And again, we shared the results and the results showed that there was absolutely no malformation associated with the dose.

Andrew Vaino: OK, thanks. And just to follow up on a previous question. I'm not sure — I'm not sure if I just missed the answer. What happens if this retrospective study is deemed not feasible?

Peter Tam: Well, if we agree with the FDA and the FDA agrees with us that it's not feasible, we'll submit the NDA right away, or you know as close to right away as possible.

Andrew Vaino: OK, but what if by not feasible it means that the FDA doesn't believe that an answer can be obtained.

Peter Tam: Right. That's — Did I answer your question?

Andrew Vaino: No, no. My question was what if the FDA determines that there's no feasible way to do this study.

Peter Tam: Yes.

Andrew Vaino: You would then submit right away or —

Peter Tam: Yes, then there's really you know no path forward and you know FDA is going to have to make a judgment as to whether the REMS program that we've put forth is adequate to address their concern. And you know that's something that we can — you know obviously we are prepared to work very closely with the FDA to make sure that they're comfortable with the risk mitigation strategies that would limit the use or restrict the use of this drug in women of childbearing potential. So that's certainly a possibility.

Andrew Vaino: OK, thank you.

Operator: Thank you. And our next question comes from Brian Amin of WJB Capital.

Brian Amin: Yes, thanks for taking my questions. I know — you know there's been some speculation on the numbers needed to conduct a proper evaluation, you know to — for the teratogenicity risk. Can management maybe share with us thoughts on patient numbers required to complete a retrospective analysis?

Peter Tam: I think it'd probably be a little bit premature at this point. So we will however provide you with more guidance once we get a sense as to, you know, the details of the study.

Brian Amin: OK, and would it be fair to assume that you would need to rule out an odds ratio of three or greater to satisfy FDA regulatory concerns?

Peter Tam: Yes, that would be speculation at this point. It's all dependent on how many numbers and what FDA is most concerned about and so forth, so you're going to have to hang tight a little bit.

Brian Amin: OK, great. Thanks for the questions.

Operator: Thank you. And our next question comes from the line of Ian Sanderson of Cowen and Company.

Ian Sanderson: Good afternoon. Thanks for taking the question. There's — In your discussions with the FDA, have they ever given you a response to your proposal that you made last July to conduct a 10,000 patient post-marketing cardiovascular safety trial?

Peter Tam: Not specifically. I mean, we've had ongoing conversations with the FDA. They like the idea of doing a 10,000 patient type of a CV outcomes trial post-approval. You know, they didn't really comment — We talked a little bit about the endpoint, but that wasn't it. There was never ever any mention of a pre-approval cardiovascular study, not in any of the correspondence, not in any of the e-mails or any of the conversations, not at the End-of-Review meeting that we just had with the FDA.

Ian Sanderson: OK, and on the whole teratogenicity issue, is this just really a labeling issue or is this an approval issue in your mind? Because I remember you had proposed a pregnancy Category X or indicated that you would accept that and a pregnancy registry. Is this all to figure out whether that's required, or is this a yeh or ney on the approval?

Peter Tam: I think that really rests with the FDA. At this point, they're asking us to assess the risk and, you know, you can't. So it's a matter of looking at one, is there a risk? If there is a risk, how big is the risk? And, you know, how much additional risk mitigation you need to put around that risk if it exists. So I think that's really an FDA's decision and they really haven't provided real specific guidance in that regard. But keep in mind, you know this drug is being used out there. Topiramate is being used off label, on label, primarily by women of childbearing potential at doses that are substantially higher than what's in Qnexa, and so you have to keep that in mind. So I think FDA is aware of that and, you know, it's a discussion that we'll be able to have with FDA. And also just to keep in mind that it is Category C and as you said earlier, we are willing to accept a Category X just to be on the conservative side. So it's a judgment call on the FDA that they're going to have to make.

Ian Sanderson: OK, and then finally, do you a have any update on the commercialization plan for avanafil? Have you had any recent partnering negotiations there?

Tim Morris: Yes, Ian, this is Tim. I think what our plan is what we've said before is we do plan to file the NDA here in the second quarter. We believe once we've filed the NDA that those discussions will heat up from a business development standpoint. We've said —have stated before we do need a partner to commercialize, and our preference is to find a worldwide partner. We have rights to worldwide— except for the Far East. So that would be our plan there and I would expect once the NDA has been filed, we would expect those discussions to accelerate.

Ian Sanderson: Thank you very much.

Tim Morris: Sure.

Operator: Thank you. Our next question comes from the line of Thomas Wei of Jeffries and Company.

Thomas Wei: Thanks. Just wanted to clarify during the initial discussions that you had with the agency on January 19th, did they mention the statistical thresholds that they wanted you to achieve on these couple of metrics? The cleft palate and the low birth rate?

Peter Tam: No, no. They haven't, Thomas.

Thomas Wei: OK, and are you willing to share with us how many of these mothers and their children you have in your preliminary assessment of these databases?

Peter Tam: Thomas, not at this point.

Thomas Wei: OK, and then I wanted to clarify one other thing that you had mentioned. Are you specifically looking for women who were on 100 milligrams of topiramate for migraines and then discontinued the drug when they determined that they were pregnant?

Peter Tam: Based on FDA's guidance, we are specifically looking at women taking topiramate for migraine. As to how long the duration of exposure, we're keeping that open. That's one of the discussion points that we will have with the FDA.

Thomas Wei: I guess I'm still a little bit confused. So it could be that you're looking at women who continue to take it for migraines during their pregnancy, or the assumption would be that —

Peter Tam: Yes.

Thomas Wei: OK, so it would be open and a combination of those who …

Peter Tam: Right.

Thomas Wei: — who were taking it and those who discontinued?

Peter Tam: That's correct.

Thomas Wei: OK, and then just lastly, can you tell us who the Rapporteur and the Co-Rapporteur countries are for the MAA filing?

Peter Tam: Yes, so we have Sweden and France and those are the Rapporteurs that we have for the MAA.

Thomas Wei: OK, thank you very much.

Operator: Thank you. And our final question for today comes from the line of David Blaustein of Suttonbrook.

David Blaustein: Hi, thank you, Tim and everybody. Quick question on timing. Assuming best case scenario you do submit the application in the United States at the end of this year, how do you — how does the clock restart? Is it Complete Response Letter 1 and 2? Is it a new PDUFA? How do we think about, you know, potential approval timing from an FDA perspective?

Peter Tam: We believe that this will be a Class 2 resubmission and the clock would start right after resubmission and that it would run up to six months. So you can factor in six months for decision after the submission.

David Blaustein: So year-end submission and then a six-month decision?

Peter Tam: Around June timeframe.

David Blaustein: Around June?

Peter Tam: Yes.

David Blaustein: OK, good. Thanks very much.

Peter Tam: Yes, that assumes that it is a December submission for clarity.

David Blaustein: And you do not expect another panel or anything like that.

Peter Tam: No, we do not.

David Blaustein: OK. Thanks a lot.

Operator: Thank you, and we have no further questions at this time. I'd like to turn the conference back to Mr. Leland Wilson for any further remarks.

Leland Wilson: Well, thank you for your very thoughtful questions. It's been one of the most invigorating question-and-answer periods that I've heard and it was nice that Peter handled all the questions because this is his area.

I think there's a couple points that I want to make here. The first one is that I think you can tell by the call and others that we've had that we're going to be as open as absolutely possible with you about every step that we go along the way. We appreciate your continued support and we're going to give you that openness as best as we possibly can.

In the meantime, I think you would agree that we're making really substantial progress. I mean actually walking out of that meeting on January 19, we actually felt that we had clear direction about what we needed to do as far as this assessment of the feasibility study. We've gone to work very quickly. Peter and his group have performed remarkably on this and actually now have actually provided preliminary information to the FDA on the number of mother-infant pairs that we have in the database that we've scanned, which cover more than 150 million lives. So we've got a very powerful sampling here of the people in the United States that have been covered under this electronic databases that we're looking at.

OK, and then I think the other one is that we're going to resubmit by the end of the year and that's our belief. We believe it is feasible if we even — if it's determined by the FDA that the feasibility study should be done, we believe that we can provide that information back to the FDA in time to submit by the end of the year. We've been working with quite a large number of experts in this area in order to be able to do this and I can assure you this is not something that's being invented by us. This is something that is done every day, looking at these databases and there are real experts here that are advising us on how to go about doing those kinds of things.

So that part is going really well. Qnexa on the European front, you heard that they MAA submission was accepted and we're moving forward and waiting for the 120-day questions coming up.

And then lastly, avanafil NDA will be filed in the second quarter of this year. So we're making progress. We believe that we will — this year is going to hopefully finish out the effort that we need to put to get approval for — resubmit and get approval for Qnexa in the United States, and that's the one I think we're all looking forward to.

So with that, what I'd like to say thanks again for your continued support and we're going to have an update hopefully within two months after we meet with the FDA and understand their timeline, what they want us to do, et cetera. So we'll have some other kind of way of communicating back to you specifically what they're going to be telling us at that point. So again, thanks and appreciate your thoughtful questions today.

Operator: Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program and you may now disconnect. Everyone, have a great day.

END
