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 29, 2010

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 8.01. Other Events

On October 29, 2010, VIVUS, Inc., or the Company, conducted a conference call and webcast discussion of the Complete Response Letter from the U.S. Food and Drug Administration, or the FDA, regarding the Company's New Drug Application for the investigational new drug QNEXA® (phentermine/topiramate) Controlled-Release Capsules. A copy of the transcript of the conference call is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K and the exhibits 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.

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By filing this Current Report on Form 8-K and furnishing this information, the Company makes no admission as to the materiality of any information in this report. The information contained in this Current Report on Form 8-K is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission, or the SEC, and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

The Company cautions you that certain statements included in this report and the attached exhibit that are not a description of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of

forward-looking words such as “anticipate,” “believe,” “forecast,” “estimated” and “intend,” among others. These forward-looking statements are based on the Company’s 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 the Company’s response to the FDA’s Complete Response Letter; the FDA’s interpretation of the data the Company submits relating to teratogenicity and cardiovascular safety; the FDA’s interpretation of the data from the Company’s clinical studies, including the Company’s SEQUEL study (OB-305); that the Company may be required to conduct additional clinical trials; substantial competition; uncertainties of patent protection and litigation; reliance on sole source suppliers; limited sales and marketing efforts and dependence upon third parties; risks related to the development of innovative products; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that the Company’s response to the FDA’s Complete Response Letter will be sufficient to satisfy the FDA’s safety concerns, that the FDA will not require the Company to conduct additional clinical studies or that any product will receive regulatory approval for any indication or prove to be commercially successful. The Company does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Company’s Form 10-K for the year ended December 31, 2009 and periodic reports filed with the SEC.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Transcript of the Conference Call on October 29, 2010, 7:30 a.m. CT

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

Date: November 2, 2010

EXHIBIT INDEX

Exhibit No.	Description
99.1	Transcript of the Conference Call on October 29, 2010, 7:30 a.m. CT

VIVUS, Inc.

Moderator: Tim Morris
October 29, 2010
7:30 a.m. CT

Operator: Good day, ladies and gentlemen, and thank you for standing by, and welcome to the Qnexa update conference call. At this time, all participants are in a listen-only mode. Later we'll conduct a question and answer session and instructions will follow at that time. If you should require operator assistance during the program, you may press star then zero on your touchtone telephone for a live operator. As a reminder, this conference may be recorded.

And now I'd like to turn the program over to Tim Morris. Sir, please go ahead.

Tim Morris: Thank you, operator. Before we get started, I'd like to remind you that during this conference call VIVUS will make certain statements in this call that are considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "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 Vivus' written response to the FDA's CRL; the FDA's interpretation of the information VIVUS submits relating to the teratogenicity and cardiovascular safety; the FDA's interpretation of the data from our SEQUEL study, or OB-

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305; their request, if any, to conduct additional clinical trials; substantial competition; uncertainties of patent protection and litigation; reliance on sole source suppliers; limited sales and marketing resources and dependence upon third parties; risks related to the development of innovative products, and risks related to the failure to obtain FDA clearances or approvals and non-compliance with FDA regulations.

As with any pharmaceutical in development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that our response to the FDA's CRL will be sufficient to satisfy the FDA's safety concerns, and that the FDA will not require us to conduct any additional studies 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 forward-looking statements. Investors should read the risk factors set forth in the VIVUS Form 10-K for the year ending December 31, 2009, and periodic reports filed with the Securities and Exchange Commission.

With that we'll turn the call over to our president — our CEO, Leland Wilson.

Leland Wilson: Thank you, Tim. Good morning and thank you for joining us today. Joining me on the call, along with Tim, are VIVUS' vice president clinical development, Wes Day, and our president, Peter Tam.

We announced yesterday the receipt of a Complete Response Letter, or CRL, from the U.S. Food and Drug Administration regarding our New Drug Application for the investigational new drug, Qnexa. Overall, we are encouraged with the CRL for several reasons. First, the request for information by the FDA was clear and specific. Second, we have a plan to answer the FDA's questions and the timeline to submit the response is reasonably defined to approximately six weeks. And third, we believe sufficient data exists to address the questions, and that no additional studies are required.

The CRL included comments in the following areas — clinical, labeling, REMS, safety updates, and drug scheduling. In this call I will touch on the

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specific request for information for each area, and then share with you how we plan to respond.

In the clinical section of the CRL the FDA requested a comprehensive assessment of both topiramate's and Qnexa's teratogenic potential. Our written response will include a summary of the non-clinical and clinical data that currently exists on the teratogenic effects of topiramate. For Qnexa, we will summarize the non-clinical and clinical experience from our development program. Our response will also include a detailed REMS plan to evaluate and mitigate any potential teratogenic risk in women of childbearing potential taking the drug for the treatment of obesity.

Also in the clinical section the FDA asked us to provide evidence that the elevation and heart rate associated with Qnexa does not increase the risk for major cardiovascular events. To address this area we plan to provide analyses of data from the entire clinical program, including OB-305, SEQUEL, and OB-204 sleep apnea studies. Information on OB-305 and OB-204 was generated after the NDA was submitted in December of 2009, and was not a part of the original NDA.

As part of the clinical section the FDA requested that we formally submit the final study report from the SEQUEL study. SEQUEL was a 52-week extension study for a subset of 672 patients who completed the previously reported 56-week CONQUER study. Top

line results from the two-year SEQUEL study were announced by VIVUS on September 21, 2010, and a final study report is being prepared for submission to the FDA. There were no other requests or issues raised in the clinical section.

For labeling, the FDA reserved the right to comment further once our response has been received.

We have previously submitted a REMS plan with the original NDA filing. The REMS program was updated in August, following the Advisory Committee meeting. In the CRL the FDA requested that a discussion of an already-submitted REMS plan continue after the written response to the CRL has been accepted.

For safety, as is common, the agency requested a safety update of any new adverse events. The only study that had not been previously included in the last safety update was the SEQUEL study; no other Qnexa studies were undertaken since the last safety update.

And finally, on scheduling, as expected the FDA stated that if approved, Qnexa would be a Schedule IV drug, due to the phentermine component.

Importantly, the efficacy of Qnexa exceeded the FDA guidelines for approval, with greater than 10 percent weight loss and improvements in all cardiovascular and metabolic endpoints. The CRL did not include any questions regarding Qnexa's efficacy.

Regarding our response to the CRL, we believe we can address all of the FDA's questions with the information that currently exists. As we said in the press release, we're preparing our response, which we expect to file in approximately six weeks. In accordance with the PFUDA guidelines, the FDA should respond to our resubmission within two weeks of receipt. If the resubmission is accepted for review, the FDA will classify the submission as either a class one or class two submission. A class one submission typically has a two-month review cycle; class two submissions have a six-month review cycle. The clock starts on the day of the resubmission.

We will soon report our Q3 results, but I can tell you today that our cash position at the end of September 2010 was in excess of $155 million. We believe these cash reserves are sufficient to see us through the approval of Qnexa.

We remain confident in the efficacy and safety of profile of Qnexa that was demonstrated in our extensive clinical development program, and look forward to working with the FDA towards the approval of Qnexa.

With that I'll open it up to questions.

Operator: Thank you, sir. Ladies and gentlemen, if you would like to ask a question at this time please press star then one on your touchtone telephone. If your

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question has been answered or you wish to remove yourself from the queue, you may press the pound key. Again, to ask a question please press star, then one on your touchtone telephone.

Our first question in our queue is Adam Cutler with Canaccord. Please go ahead.

Adam Cutler: Hi, thanks a lot for taking the question. Wondering if you can just give us a little bit more color on how you plan to address the cardiovascular and teratogenicity questions, given that while you have the SEQUEL data, which is new since the NDA and the Advisory Committee meeting, presumably there was already a fair amount of analysis done on those two issues as part of your original NDA.

Leland Wilson: OK, let's try to get Peter or Wes involved here. Which one of you want to take that one?

Wesley Day: Hi, this is Wes. And as you know, we did present a comprehensive summary of the teratogenic risk both within Qnexa, as well as the meta analysis on pregnancy registries for topiramate as part of the Adcom. But in addition there's been extensive analysis that has gone on subsequent to the Adcom that was specifically driven by issues raised within the Adcom.

So we've performed a number of issues, and the questions that are raised by the FDA as part as this CRL will essentially be a consolidation of learnings and analysis and data sets that we've assembled both in preparation as well as subsequent to the Adcom meeting.

We've also engaged an extensive number of outside experts, teratologists, on the non-clinical side as well as the clinical side. We've got various cardiologists involved in the review and assessment and development of additional data sets. And these extensive analyses will be consolidated into large documents that put all of these learnings together and best enables the FDA to have a very broad, extensive assessment of these two issues across not only our clinical program but all available literature.

Leland Wilson: OK, I would just add a couple of things, maybe a little broader perspective here. I think the first thing that I would observe is that topiramate, as you know, Adam, has been on the market now for more than 15 years; has been one of the top-selling drugs, has been prescribed and used at much higher doses, at least four times what we are applying for approval for. And the registry for teratogenicity has yet to be able to define whether or not topiramate at these high doses has a signal or not.

I mean, that's encouraging, at the very least, because this has been going on a long time, with lots of patients, et cetera. And so we have not been able to get a definitive opinion at this point. Our opinion, you know, is topiramate is not a teratogen, and we are pulling together the data that we believe will show that as Wes has described.

OK, Peter, any comment on that one?

Peter Tam: No, I think you guys have covered it.

Adam Cutler: OK, so sorry, can I just ask a little bit of follow-up on the cardiovascular part? I think I have a good understanding now on the teratogenicity part. But on the cardiovascular part, I mean the good news is that the FDA did not ask for any additional studies. It seems that obviously the most thorough way to evaluate risk of major adverse cardiac events is a cardiovascular outcome study, so it's good that they're not asking you do to that now and it's something that if you need to do it you could do it post-marketing. But how do you — how will you address that issue of the potential risk for MACE from your current data set, given presumably what's a small number of events?

Leland Wilson: OK, well first thing I would point out is the change in mean heart rate in our clinical program was about one-and-a-half beats per minute, which is considered very small. In addition to that, you've seen a number of analyses that we presented at the Adcom, such things as rate pressure product. We all know that our drug has a significant decrease in both diastolic and systolic blood pressure, a rate pressure product quotient indicates that — a beneficial risk profile for the drug.

We will do additional studies such as looking at anybody that's had a serious adverse event in the clinical program and what their heart rate is. And just to give you a little flavor of the kind of data that we're looking at here. So, any other comments from Wes or Tim?

Wesley Day: So I'd just like to emphasize that cardiovascular risk is not necessarily a pure function of a small increase in heart rate that was consistent across the two years, about one-and-a-half beats, but it's also a function of the benefits that we see. And part of the analysis will clearly be a balance in both our clinical data as well as an assessment of the literature — a balance of the risk and improved risk that comes with a small change in the heart rate in the presence of many cardiovascular surrogate benefits that we're seeing within the program, as well as continued in the second year of treatment in SEQUEL.

Adam Cutler: OK, great. So just one last question, if that's all right. Is it still your expectation that all three doses would be approved, or is there the possibility that maybe only the low and mid dose get approved?

Leland Wilson: It's our expectation that all three will be approved.

Adam Cutler: OK, great. Thank you.

Operator: Thank you. Or next question in our queue comes from Cory Kasimov with J.P. Morgan. Please go ahead.

Cory Kasimov: Hey, good morning, guys; thanks for taking the questions. First I want to follow up on this discussion of cardiovascular risk and see if perhaps you can kind of go into a little bit more detail regarding the disclosure you made in the SEQUEL press release last month on the relative risk of major adverse cardiovascular or neurovascular events across the entire development program. And I'm wondering how those results might compare to what you had already submitted to the FDA. And then I have a couple of follow-ups after that.

Leland Wilson: OK. Peter, do you want to take that one?

Peter Tam: Sure. The data that we presented during the SEQUEL press release demonstrated that the odds ratio was, I believe was 0.59, suggesting that the serious cardiovascular and neurovascular events on drug were lower than those observed in the placebo group. These events were fairly rare, as we observed in the SEQUEL trial. They are actually expected of this patient population, given the fact that these are patients at entry had co-morbidities — a minimum of two co-morbidities.

So we're not seeing anything, you know, out of the ordinary, but we certainly are comforted by the fact that we did not see an increase in serious cardiovascular adverse events, in spite of the presence of a slight increase in heart rate.

Cory Kasimov: And that's kind of in line with what you already submitted to the FDA, or is it better than, worse than?

Peter Tam: These data have not been submitted to the FDA formally, and that's why they need to be part of our formal submission to the FDA.

Cory Kasimov: OK, OK.

Leland Wilson: And yes they are in line with previous data — very consistent.

Cory Kasimov: OK, and do you plan on requesting a Type A meeting with the agency prior to submission of your response?

Leland Wilson: No, we do not. We believe the request is clear and we will prepare our response and submit it. If the FDA has any questions at that time, we may — we reserve the right to request a meeting at that point. But we think it is — the direction is pretty clear for us right now.

Cory Kasimov: OK, great. And then lastly, what do you believe is going to be the best way to monitor the teratogenic risk in a post-approval setting?

Leland Wilson: Well, I'll take a shot at it. But clearly a registry is required, and so — and obviously part of the REMS program. We will work as diligently as possible to get all pregnancies reported into the REMS program. And clearly, as we

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move through this, this is a kind of a living document that we will be looking for any signals that occur.

And as I said earlier, we do not expect them because of the fact that the existing North American registry has been ongoing now for 15 years, and has not at this point shown a signal either that it is a teratogen or it's not a teratogen.

Cory Kasimov: All right, great. Thanks for taking the questions.

Leland Wilson: You bet, Cory.

Operator: Thank you, sir. Our next question in our queue is Jason Butler with JMP Securities. Please go ahead.

Jason Butler: Hi, guys. Thanks for taking the question. I just wanted to follow up a little bit on the REMS. You've obviously had an ongoing dialog since the Advisory Committee in July; what do you think the FDA's sticking points are on the requirements for REMS and what is it looking to see, not just for teratogenicity but for other aspects of the REMS? And thanks.

Leland Wilson: Jason, yes. Well first I would say that we haven't gotten into what I would call deep discussions about our latest proposal for REMS at this point. I think that appropriately occurs after the FDA makes their approval decision, and at that point we expect to get into the thicket here as far as REMS are concerned.

I would say that the FDA has found our submission interesting, in their words, and we think it is a very complete REMS program for both pregnancies and suicidal depression and ideation and things that FDA didn't raise in their letter as well. So I think we're in pretty good shape and we'll just have to wait and see.

Jason Butler: OK great. And then just one follow-up on teratogenicity. Is there any new data that you have or might have that addresses the clinical risk of teratogenicity? Are you just talking about new analyses of data that you and the FDA have already got on hand?

Leland Wilson: Well you heard our Adcom, Jason, that the presentation regarding our analyses of the teratogenic risk in women that are taking anti-epilepsy drugs and those who have epilepsy without taking antileptic drugs, which showed that there was no difference between active and placebo in that analyses. That one is being formally submitted; hopefully it will be published reasonably soon and will be submitted to the agency.

There are a number of other analyses that we are doing as well as far as teratogenicity is concerned.

Jason Butler: Great, thank you very much.

Leland Wilson: You bet.

Operator: Thank you, sir. Our next question in our queue is Christopher James with MLV. Please go ahead.

Christopher James: Hi, good morning guys. Most of my questions have been answered. I hate to harp on the teratogenicity question, but it seems to me that it just simply can't be answered with the existing data; it seems like the only real data to support topiramate as a potential teratogen are in women who, you know, stayed on the drug throughout the pregnancy.

My question is how does the FDA view, you know, all these women of childbearing age that are taking even higher doses of topiramate for migraine headaches?

Leland Wilson: Wes?

Wesley Day: So, clearly the migraine headache population has significant overlap with the obesity population, and we view that as very favorable towards an assessment of the teratogenic risk because there are four existing registries, with over 400 reported pregnancies. And out of these 400 pregnancies, based on a control population, there's a relative risk that's right at one.

So with this extensive use of topiramate and an overlapping population, it's hard to conceive that there's a large teratogenic risk, and I would question whether, you know, there's even a small teratogenic risk.

On the non-clinical side, there's been a lot of discussion about the pre-clinical data for topiramate and the signals that have been demonstrated in animals. While working with teratologists and a close assessment of available information that we have on the reproductive risks suggests that much of the conclusions around changes in the reproductive risk in animals is a function of weight loss. And one of the areas that we're targeting carefully as part of our analysis will be demonstration and a close understanding of the relationship between weight loss in the maternal animals versus the actual changes in the fetus that aren't related to weight loss. So we think there's some important points to be made there.

We'd also like to emphasize that we do support Category X for Qnexa. Topiramate is currently a Category C, which is a lower level of risk and oversight. With our REMS program that we have in place, as well as a Category X, we believe that the risk will be manageable, and with an effective, well-controlled pregnancy registry, we believe it'll be just a matter of time before we'll be able to absolutely quantify what the true risk of teratogenic signal in humans is.

Christopher James: Great. Thanks for taking my questions and congrats.

Operator: Thank you, sir. Our next question in our queue is Chris Hamblett with Cowen & Company. Your line is now open.

Chris Hamblett: Hey, thanks for taking my questions, guys. Just following up again on teratogenicity. You mentioned registry. Are you proposing, or is it your expectation that you will have a patient certification program similar to iPledge for Accutane? That's the first question. And the second one is on the cardiovascular risk assessment side. Is there a way to compare the SEQUEL patients with those in the SCOUT trial for cardiovascular profiles?

Leland Wilson: OK, the first thing I would say is that Category X is something that we are behind for two reasons. First, we do not have a clear assessment based upon

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the North American registry of whether or not topiramate at high doses is a teratogen or not. And clearly, as Wes has said, the data — the pre-clinical data in animals is at best confusing at this point. One thing that it is clear to both us and the FDA, that is weight loss during pregnancy is not acceptable, and therefore we believe that Qnexa will be a Category X.

Now just what does Category X mean? That means it has implications for our REMS program. It is a strong signal to doctors that care needs to be taken. And so we are going to just do a bang-up job, and that's our pledge to the agency that only patients that — that patients are completely advised of the need to take birth control pills and contraception methods. They would be advised as soon as they become pregnant or know that they've become pregnant to go off the medication, et cetera.

So that REMS program is going to be very thorough, and we think adequate to control any possible risks that there may be.

Chris Hamblett: And then on the cardiovascular risk, SCOUT versus SEQUEL?

Leland Wilson: Wes or Peter?

Peter Tam: Yes, the SEQUEL trial patient population, there probably are some overlapping characteristics between SEQUEL and SCOUT, but certainly is not quite as broad as SCOUT. So, you know, you guys can, you know, determine in terms of what the risk level might be, but there's some overlap that we can identify, based on the existence of co-morbidities, but certainly is not an exact population as those studied in SCOUT.

Chris Hamblett: OK, thank you.

Operator: Thank you. Our next question in our queue is Steve Yoo with Leerink Swann. Please go ahead.

Steve Yoo: I was wondering, could you give us the highlights of the presentation that was presented this past Saturday at the International Diabetes Obesity Forums Conference on the metabolic risk reduction generally associated with the

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amount of weight loss. Was there any new analysis that came out that might be of interest to the FDA on the CV risk?

Leland Wilson: Sure. Wes, do you want to take a shot?

Wesley Day: Sure. So I don't have the data in front of me, but we did present two abstracts that examined various categories of weight loss. One of the goals and interests that we've had is to understand and delineate the relationship between weight loss and improvement in various co-morbidities. As you know, at the end of two years we're seeing over 10 percent weight loss in both the mid and the full dose. So looking in these two abstracts we looked at categories ranging from under five, five to 10, and 10 to 15 percent. And essentially the findings were consistent with what has been expected, but not often shown in the literature, and that is is that greater weight loss equated with greater co-morbidity effects. And that's a theme that we're going to be analyzing and presenting at a number of meetings ranging from the diabetic glycemic endpoints to blood pressure endpoints as well as lipid endpoints.

What we have shown with Qnexa in one year and two year experiences are very consistent improvement and increase in HDL, decrease in triglycerides, on the level of 25 percent. We're seeing reductions in HbA1c that are maintained out at the end of two years. We're seeing weight loss maintained, visceral adiposity reduced. So all of these changes, we believe, are equated with significant reductions in weight loss, with over half the subjects at the end of two years demonstrating greater than 10 percent weight loss.

So those two abstracts were intended to correlate this weight loss with these greater improvements in co-morbidities and we were quite pleased to see that indeed Qnexa-related weight loss is certainly following with the themes of weight loss in general that have been shown by other studies such as the DPP study that was run several years ago.

Steve Yoo: OK, and let's see, going back to something that was raised a little earlier, can you give us more details on the relative risk of 0.59 in your full clinical trial experience? Can you give us numbers of events on both the drug and the placebo arm?

Peter Tam: We don't have those numbers in front to us, but these are, again, there's very few events. You know, again, you know, we do take comfort in the fact that these events were lower; these are primarily serious cardiovascular and neurovascular events, so these are, you know, MI, revasc as well as stroke events that we've included. So it's certainly a comfort, from our perspective.

Steve Yoo: Thank you very much for taking my questions.

Operator: Thank you, sir. Our next question in our queue is Thomas Wei with Jefferies. Please go ahead.

Thomas Wei: Hi. Thanks for taking my question and thanks for all the detail from the Complete Response Letter. I did want to ask, though, you know, presumably the letter contains a lot more than what you've described. In relation to the heart rate part of the clinical section, is there a specific set of data or specific analyses that the FDA has requested or recommended that you submit, or is it an open-ended statement that you just need to provide additional evidence?

Leland Wilson: OK first I would say, Thomas, that we're trying to be as absolutely as complete and present all the issues raised in the Complete Response Letter here as possible. And second, the communication was very clear and very precise about what we need to do. We understand — we believe strongly that we understand what needs to be done. So that's what we're going to do and hopefully get that submitted within six weeks.

Thomas Wei: So there are specific analyses there that the FDA has requested on heart rate and cardiovascular events?

Leland Wilson: No, not specific analyses.

Thomas Wei: Specific sets of data that they want submitted?

Leland Wilson: Well yes. With regard to SEQUEL, they want to see that data, as we expected. So that's part of it.

Thomas Wei: OK.

Leland Wilson: And also the sleep apnea study is part of the information that we are going to be providing and they're interested in as well.

Thomas Wei: But, there's no — it's not like they had led you to a particular set of analyses of that data; they just want to see what the overall data looks like on cardiovascular events?

Leland Wilson: Yes, that's correct. I mean, there's standard analyses, as you know, Thomas, that you need to do for all these parameters. And so we were doing those; that's what we will be doing. So comments from either Tim or Wes?

Wesley Day: Yes, hi, this is Wes again. Yes, I just want to remind that, you know, we submitted the NDA in December last year, and we prepared many months for the Adcom and developed a number of analyses in support of cardiovascular risk and the heart rate changes. Some of those were presented at the Adcom, not all of them.

Subsequent to the Adcom we've performed additional analyses to quantify and assess the risk of cardiovascular. And what the FDA asked us, in essence, was provide the evidence that the heart rate doesn't increase cardiovascular risk. There's extensive evidence, but it's in many pieces, and it's been developed over time. So what this is essentially asking us to do is put all this evidence together in a clearly regulatory quality document with all the associated databases and send it to them so they can look at the whole gestalt of it.

Thomas Wei: And can you just, then, remind us; at that panel meeting itself, the latest update on the actual myocardial infarctions was four versus zero. What is the new number when you add in SEQUEL and the sleep apnea study?

Leland Wilson: Wes or Peter?

Peter Tam: Again, Thomas, it's what we've presented was the cardiovascular and neurovascular events. We looked at the whole thing in its entirety and these numbers are, you know, when you calculate the odds ratio, it comes out for the entire program as 0.59 with upper bound I believe at 1.06 or something like — I don't have the data in front of me, but that's what we have. There was

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nothing unexpected. I mean, these events distributed fairly equally across the doses. And those are the data that we have.

And just as a follow-up, Thomas, there isn't any — what we've shared with you in this conference call as well as the press release is pretty much everything that the FDA has asked for. There are no — we did not exclude any specific analyses that the FDA requested. What they requested is what we have in the press release here.

Thomas Wei: I guess the reason why I ask about the heart attack number is that you presented a very similar analysis of cardio and neurovascular events during the panel meeting and I think the hazard ratio there was 0.60. But the panel really focused in on the fact that the heart attack number wasn't balanced. And so I just wanted to get an understanding. Is that still the case or have the numbers actually skewed substantially from four versus zero to something better?

Leland Wilson: No, the numbers have not skewed substantially at all, and in fact the discussion at the panel meeting, as you remember, was about revascularizations, serious emergency revascularizations, and the balance against those four MIs which we saw in the one-year data

was fairly well balanced. We see no signal, again, in our entire clinical program for increased risk for cardiovascular events or neurovascular events such as stroke. None.

Thomas Wei: OK, and I'm sorry, just one last question. So when you add in SEQUEL, you know, you've done this new analysis of 0.59 with an upper bound that's just a little bit over one. I guess it's a very different confidence interval than what you showed for the one-year analysis. But this is only 672 extra patients for a year; it's a very small portion of your overall database. How could you have changed the confidence intervals so meaningfully off of such a small number of patients? Can you actually just go into how you redefined the cardio neurovascular analysis to get there?

Peter Tam: We didn't redefine it in any way that was different in the way we presented at the Adcom, Thomas. I don't have the Adcom slides in front of me, but I don't

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believe that the — that the confidence interval was substantially different, compared to what was presented for the SEQUEL data.

Thomas Wei: OK. Thank you.

Operator: Thank you. Our next questioner in our queue is Alan Carr with Needham and Company. Please go ahead.

Alan Carr: All right, thanks for taking my question. So just I guess to confirm, then, you said there's nothing else in this letter besides the five areas of concern that they've already raised. And part two to that is, you know, is that consistent with the discussions that you've had with the FDA since the Advisory Committee?

Leland Wilson: Yes, they are — very consistent.

Alan Carr: And then apparently the letter you said mentions that clinical trials might be required if your response is inadequate. Is there any more detail around that in terms of what sort of trials like I might specifically be interested in?

Leland Wilson: No discussion about that. Kind of very standard language that if the response does not meet their needs, they reserve the right to request additional clinical data.

Alan Carr: OK. Thanks very much; appreciate you taking the question.

Leland Wilson: You bet.

Operator: Thank you. Our next question in our queue is Tong Michael with Wells Fargo. Please go ahead.

Tong Michael: Thanks. Most of my question's been answered. But I just want to go back to the teratogenicity aspect. Outside of the clinical package for Qnexa do you have any data or analysis that supports the notion that the presence of phentermine does not amplify the effect to topiramate?

Wesley Day: So we — this is Wes — we did run reproductive tox studies with the combination as part of our overall non-clinical package, and the findings from

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the segment two portion of that study were clean. There was no change in the signal; actually there were — they were totally clean, overall, for the combination. Thus, the conclusion is that the presence of phentermine didn't change, modify, or increase any signal of teratogenic risk.

Tong Michael: And was that analysis part of the original NDA submission?

Wesley Day: Yes it was.

Tong Michael: OK and then just to confirm, so the CRL does not mention cognitive effects, like memory loss or suicidality?

Leland Wilson: That's correct.

Tong Michael: Great. Thank you very much.

Operator: Thank you. Our next question in our queue is Andy Schopick with Nutmeg Securities. Please go ahead.

Andy Schopick: Thank you and good morning. Well, I guess this is going to be spun a whole lot of different ways. Let me ask you this question. Given the events that have occurred relating to weight loss drug formulations since your panel meeting was held — what is your take on the prospects for a climate that would allow approval for a weight loss formulation provided it meets the FDA requirements and concerns? Is anything different, from your perspective, in view of what's happened in recent months?

Leland Wilson: Not really. You know, the business of drug approval, approvals, as you know, has not gotten any easier over the years. And I think we are at probably the all-time most difficult time to get drugs approved completely. But it is — still breaks down to an assessment of the risks and benefits, as you know.

Now, the issues that have changed over the years, not over the recent past but over the years, has been an appreciation for the risk associated with obesity. Everyone at the FDA now is clearly up to date and knows that obesity, for example, is the primary cause of

type II diabetes, which is rampant. And it is

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a primary cause of hypertension, dyslipidemia, et cetera, including early death and survival and the costs and expenses et cetera that go with it.

So the FDA has really grown to appreciate the benefits of a weight loss drug. Now having said that, they also appreciate that two-thirds of the population is overweight or obese, and that this is potentially a very high risk approval because of the potential exposure in a broad population.

And so that's why the strong interest in REMS, to make sure it's prudently prescribed to the appropriate patient population, that the launch does not end up in a runaway use, like other drugs that reach the market. We are a very big fan of that, that it's very important for us to be able to control the launch and get it to the right patients, and then to monitor any adverse events, particularly for teratogenicity and cardiovascular outcomes that occur post-approval.

So that's the only thing, I think, that's changed. They are a very prudent and conservative group, and I think in the end the right decision will be made. I am very confident of that; I've been doing this now for 30 years in some form or another as head of regulatory affairs in a pharmaceutical company. And eventually the right answer will surface. And we're all interested in the right answer.

Andy Schopick: Good luck. Thank you.

Leland Wilson: Yes.

Operator: Thank you, sir. Our next question in our queue is Bart Classen with Summer Street Research. Please go ahead.

Bart Classen: Thank you so much, gentlemen. There's been a lot of discussion today on teratogenesis. I was just curious, have you all reached the question with the FDA at any point about a fallback position of approval in men, not that we're expecting it's not an approvable drug with women, but I was just curious if that question has ever come up.

Leland Wilson: No, it hasn't, nor are we interested in that as well.

Bart Classen: OK. And you say that you believe you can file this in six weeks. I presume, then, you've pretty much prepared for these questions; you've been working on this since the advisory panel?

Leland Wilson: Yes, that's correct.

Bart Classen: All right, thank you so much, gentlemen. I wish you the best of luck.

Leland Wilson: Thank you.

Operator: Thank you, sir. Our next question in our queue is Jason Butler with JMP Securities. Please go ahead.

Jason Butler: Hi guys, thanks for taking the follow-up. I just wanted to touch on the sleep apnea study. Have you guys — is it correct that you guys had not submitted that as part of the original NDA? And then following on from that, is there any data in that trial that provides more acute clarity on the heart rate question that the FDA hasn't seen before?

Wesley Day: Hi, this is Wes. Yes, the sleep apnea study included 45 subjects, so it was a small phase 2 study. But importantly, it was a very relevant population. These are patients with severe sleep apnea and obesity, average BMI of over 35. We did, in the process of performing the polysomnagraphy analyses that were part of the primary endpoint, as you recall, we saw a significant reduction in the number of sleep apneic events in the Qnexa-treated subjects. But as part of the sleep lab work we did record, you know, vitals. And one of the important findings that we had, and unfortunately was somewhat obscured through the presentation at the Advisory Committee — and this was not included in the original NDA submission — was that heart rate went down at night. And what we believe is going on here is that in general, where the heart rate is measured in a clinical trial, it's not long after the dose has been taken. So we see a small increase, and that increase is very consistent over two years. But in that sleep apnea study, where we were able to follow the heart rate over time, it was clear that the heart rate was being affected by essentially the Cmax, or the pharmacokinetic properties of the drug. So at night the heart rate actually went down.

And our assessment of heart rate and heart rate risk shows a reduction in heart rate overnight is one of the most important properties for the reduction of overall heart rate risk. So hopefully these points will be consolidated and made more clear in this document that we're generating as a result of the FDA's request, and there'll be a better picture of what these changes in heart rate really mean in the context of all of the improvements in the cardiovascular parameters that we've seen throughout the clinical program.

Jason Butler: OK, so just to clarify, were there any —acknowledging that it was a small trial — were there any patients in there that showed the kind of heart rate increases that the FDA was concerned about as the panel there, the kind of 10 to 20 beats lower per minute more, and was there any data that you could collect from this trial to ease their concerns that heart rate stayed up at these high levels for a prolonged period of time?

Wesley Day: Yes, I don't believe that was the case. Again, you're getting into kind of this categorical outlier type of analysis. And we've taken these analyses, in some cases at the Adcom and in many cases after the Adcom, we've taken them down to the individual subjects. And we don't believe that there's any reason to believe that there's going to be an additional risk imposed by this very small fraction of subjects that have a higher categorical increase. The sleep apnea study certainly didn't demonstrate that there was any additional risk here. And again, our challenge is, and the goal of this document we'll be submitting is to really put these changes in heart rate in the context of the overall picture going on with an obese, co-morbid patient.

Jason Butler: OK, great. Thanks.

Leland Wilson: Thank you. Well I think that's the end of the questions. I wanted to thank you for them. Obviously, we hope we were able to give you some color to that. I would comment — someone mentioned spin, a word that we are certainly not interested in here. It is not in our best interest to try to spin this in any way; we want to be very factual in our communications to you and try to be as close as we possibly can to the CRL that we received.

So having said that, I think there's some real clear points that I would like to make. First one is that all of you are familiar, I believe, with the work that we did in preparation for the Adcom. Not all that has been presented to the FDA; there were additional analyses that were certainly done and not presented there. So there's lot of additional work that we've already done, and that gives us some of the confidence that we can answer, particularly the cardiovascular issues. And so that's part of what's going to be presented.

Importantly here, we believe that we can answer and prepare our preparation in approximately six weeks. And so that will get us to a next response back to the FDA in approximately two weeks after that. So it's a relatively short timeline.

I want to say that yes, we were disappointed that we did not receive a CRL which just dealt with labeling, and — labeling and a REMS program, or even better, an approval at this point. But it seems to be a step which many companies are having to follow through. I think maybe I was overzealous because in light of the Adcom outcome, that additional steps could, and probably would be, required. And that's the case here.

And I want to say that this CRL response that we got from the FDA is just a step in the process towards approval, and one that we are confident in being able to meet. But again, there can be no guarantees that what we are doing is correct. But I think those of you who have worked with us now over a long period of time have gained some confidence that what we have done has been pretty right on in almost all circumstances. So we feel confident with that.

We certainly feel confident in the approvability of this drug. I think all of you understand the outstanding efficacy and I think Wes captured that extremely well. We have been very forthcoming in outlining the risk associated with this. It is great to hear from the FDA that we're not talking about cognitive function, we're not talking about suicidality or depression or a lot of other things; it's centered down to two areas.

And first I would just summarize, again, on teratogenicity. We don't know whether it's a teratogen or not at this point, and the only way you're going to

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find out is with registry data in the marketplace. And in order to get to that it's heavily dependent upon a REMS program, where we are working diligently to prevent and inform women about the risks of pregnancy. And so we think that is the way forward and I think a lot of you would agree with that.

In cardiovascular area here, we have demonstrated, as Peter said, in our overall program the risks are less than one, certainly favorable to placebo. We have said publicly that we believe in our long-term outcome studies that we will be able to show not only that there's no increased risk but we'll be able to show an improvement in morbidity and mortality in the cardiovascular outcome study, and we're hopeful to be able to do that post-approval. Clearly, the FDA did not ask for a cardiovascular outcome study prior to approval.

And so with that I would like to close and thank all of the investors here for their support and for the tremendous effort that has been put forward by the management team here and also all the employees at VIVUS. It's heartwarming to me that we are at this step and feel very proud of this accomplishment. But we have a long ways to go yet. Thank you very much.

Operator: Thank you, sir. Ladies and gentlemen, this does concludes today's conference. Thank you for your participation and have a wonderful day. Attendees you may now disconnect.

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