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)

August 1, 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 August 1, 2011, VIVUS, Inc. conducted a conference call during which members of its senior management team discussed financial results for the second quarter and six months ended June 30, 2011 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 otherwise subject to the liabilities of that Section, 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. Second Quarter 2011 Earnings Conference Call on August 1, 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.

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

Date: August 4, 2011

EXHIBIT INDEX

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. Second Quarter 2011 Earnings Conference Call on August 1, 2011, 1:30 p.m. PT.

Thomson StreetEvents

Conference Call Transcript
VVUS - Q2 2011 Vivus Inc Earnings Conference Call
Event Date/Time: Aug 01, 2011 / 08:30PM GMT

FINAL TRANSCRIPT

Aug 01, 2011 / 08:30PM GMT, VVUS - Q2 2011 Vivus Inc Earnings Conference Call

CORPORATE PARTICIPANTS

Tim Morris
VIVUS, Inc. - SVP Finance and CFO

Leland Wilson
VIVUS, Inc. - CEO

Peter Tam
VIVUS, Inc. - President

CONFERENCE CALL PARTICIPANTS

Cory Kasimov
JPMorgan Chase & Co. - Analyst

Jason Butler
JMP Securities - Analyst

Tazeen Ahmad
BofA Merrill Lynch - Analyst

Scott Henry
Roth Capital Partners - Analyst

Thomas Wei
Jefferies & Company - Analyst

PRESENTATION

Operator

Good day, ladies and gentlemen. Welcome to the VIVUS second-quarter 2011 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.

(Operator Instructions)

As a reminder, this conference call is being recorded. I would now like turn the conference over to your host, Tim Morris. You may begin.

Tim Morris — ***VIVUS, Inc. - SVP Finance and CFO***

Thank you, operator. 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 statements may be identified by the use of forward-looking words, such as anticipate, believe, plan, 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 and continued dialogue with the FDA relating to matters raised in the Company's — in the FDA's complete response letter; the timing and results of the retrospective observational study of fetal outcomes in infants born to mothers exposed to topiramate during pregnancy; the updated interpretation of and agreement with the information VIVUS submitted and may submit relating to teratogenicity and cardiovascular safety; the FDA's interpretation of the data from our SEQUEL study; the FDA or EMA's request, if any, to conduct additional prospective or retrospective observational studies, or to provide further analysis of clinical trial data; changes in the regulatory environment and requirements for product development in our fields; substantial competition; the impact on future sales based on specific indication and 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 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 no guarantees that our response to the FDA's CRL or the CHMP's 120-day questions, FDA's requests stemming from the end-of-review meeting or the results of the retrospective observational study will be sufficient to satisfy the FDA or CHMP safety concerns, and that the FDA and foreign authorities 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 forward-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 Commission. I will now turn the call over to Mr. Leland Wilson, CEO of VIVUS.

Leland Wilson — *VIVUS, Inc.* - *CEO*

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 our two lead investigational development candidates, avanafil and QNEXA. I will provide an update on avanafil, including our business development strategy. Peter will provide an update on QNEXA, including our progress on FORTRESS and the recently announced results of an additional retrospective analysis of topiramate exposure *in utero* recently accepted for presentation at the IEC this month. And, lastly, Peter will provide an update on the QNEXA MAA.

The highlight of the second quarter clearly was the submission of the NDA for avanafil, our investigational drug for the treatment of ED. The filing of the NDA represents the culmination of years of work and dedication from the avanafil development team. Congratulations to VIVUS employees, our dedicated and loyal consultants, and our partner, Mitsubishi Tanabe Pharmaceutical Corporation. The avanafil NDA is the fourth NDA filed in our Company's 20-year history. We expect the NDA to be accepted within 60 days of filing, and we expect a standard 10-month review.

The avanafil team will now turn its attention to the preparation and filing of the marketing authorization application in the EU. The filing of the MAA in the EU is expected in the first half of 2012. As a reminder, the avanafil trials included more than 1,300 patients and included diabetic patients, radical prostatectomy patients, and patients with general ED. Avanafil hit every primary end point in all phase 3 — all three phase 3 studies. The efficacy rate as high as 80% were achieved.

Worldwide, sales of PDE5 inhibitor drugs approached $5.4 billion in 2010. In the United States alone, sales were about $2.5 billion, a 5% increase over the prior year. Levitra, the second to market following Viagra, with little differentiation, sold in excess of $500 million worth worldwide in 2010. With efficacy observed in all phase 3 studies in as little as 15 minutes, and low reported rates of common side effects, we believe avanafil can capture a meaningful portion of this market.

We are actively seeking a partnership deal for avanafil. Avanafil makes perfect sense for a partner who already covers the PCP market. It is an easy additional product because the market is established, target prescribers can be easily identified, and avanafil provides unique benefits. The results of our long-term avanafil study were presented at the AUA meeting in May. The radical prostatectomy results were presented in June, and the results from the diabetes study will be presented in the European Association for the study of diabetes this September in Lisbon. Results of TA-301, or REVIVE, have been submitted and accepted for publication in a major medical journal. We will continue to build awareness for avanafil with medical professionals and support the FDA review of the NDA throughout 2011. I will now turn the call over to Peter for an update on QNEXA

Peter Tam — *VIVUS, Inc.* - *President*

Thanks, Lee. We continue to make progress on several fronts towards the approval of QNEXA in the US and in Europe. In Europe, as part of the European regulatory review process for an MAA, the initial feedback from the CHMP is the 120-day list of questions, which is a compilation of questions from reviewers representing different disciplines from member countries in Europe.

We have received the 120-day questions from the CHMP. Questions for QNEXA MAA cover a broad range of topics, such as, issues relating to phentermine, which include historical concerns regarding its potential association with valvulopathy and pulmonary hypertension; comments relating to heart rate and limited long-term safety data in high risk patients; and known and suspected affects of topiramate, which includes CNS

effects and teratogenic potential. The CHMP also had questions about our proposed risk management plan for QNEXA. The 120-day questions are consistent with the issues previously raised by the FDA.

We are in the process of preparing our response to these questions, and as part of this preparation, we will be meeting with our rapporteur to seek clarification and solicit their input before we submit our response to the 120-day questions to the CHMP.

As part of the risk-benefit assessment, the CHMP also discussed the importance of weight loss and beneficial effects QNEXA provides in patients with obesity. Specifically, in the benefit-risk assessment, the CHMP recognized that there are obese patients who do not respond to lifestyle interventions and that obesity is considered a risk factor for cardiovascular disease. CHMP also pointed out that the beneficial effects of QNEXA, with respect to weight loss, being greater compared to previous and current treatments, are considered to be of high clinical importance.

We anticipate submitting our response to the 120-day questions in the fourth quarter of this year. The CHMP will have 60 days to consider our response and will provide their feedback along with a list of any remaining or outstanding questions at day 180. Because this is an ongoing exchange, and we are only at the clarification stage with the CHMP, we will provide more details after the receipt of the day 180 response. The day 180 response is expected in the first quarter of next year.

With regard to FORTRESS, the study is progressing as planned and we anticipate the results in the fourth quarter of 2011. Since the last call, we have received input to the FORTRESS protocol, and have selected four US data sites, or databases, for inclusion in the study. In addition to the epidemiologists from the individual data sites, we have engaged several very experienced epidemiologists who will consolidate the results from each of the databases. The data sites are in the data preparation and programming phase, and will move to the data extraction phase shortly.

Similar to a prospective clinical study, we remain blinded to the results until the data are integrated and analyzed. The FORTRESS study, we believe, will be the largest retrospective study of fetal outcomes and topiramate exposure ever conducted and will provide us with a definitive path forward for the resubmission of the QNEXA NDA.

In July 2011, this year, the top-line results of an additional retrospective study of medical claims data on oral clefts and major congenital malformations associated with topiramate exposure during pregnancy were accepted for presentation at the International Epilepsy Congress, or IEC, meeting in Rome, and the abstract was made available. This study was conducted using medical claims and pharmacy prescription data from the Wolters Kluwer Pharma Solutions Patient Longitudinal Database. This study identified 778 mother-infant dyads exposed to topiramate, regardless of dose, within 10 months prior to giving birth. It compared the incidence rate of oral cleft and major congenital malformation in topiramate-exposed dyads to two control groups. One comprised of 3,431 dyads exposed to other antiepileptic drugs during pregnancy, and the second cohort of 2,307 dyads with a diagnosis of epilepsy, but no exposure to topiramate during pregnancy. Dyads exposed to known teratogens were excluded from all cohorts.

The results of the study found there were no statistically significant differences in oral clefts or major congenital malformation frequency between the topiramate-exposed and control groups. The complete results will be presented at the IEC meeting in Rome, Italy, on August 31, 2011, by Dr. Alison Pack, Associate Professor of Clinical Neurology, Department of Neurology of Columbia University Medical Center.

Additional analyses from this study have been submitted and accepted at upcoming medical meetings in the near future. This study, using the Wolters Kluwer Database, was conducted to provide an early assessment on the teratogenic potential of topiramate. This study and FORTRESS are, in general, similar in methodology and design. FORTRESS will include multiple databases as compared to the single database; therefore, the final number of dyads in FORTRESS will be greater.

In May 2011, the Journal of American Medical Association, JAMA, published the results of a study entitled, “Newer Generation Anti-epileptic Drugs and the Risk of Major Birth Defects.” The study was a population-based cohort study of over 800,000 liveborn infants in Denmark over 12 years. Individual level information on dispensed anti-epileptic drugs to mothers, birth defect diagnoses, and potential confounders were obtained from compulsory nationwide health registries.

The main outcome measures were prevalence odds ratios of any major birth defect diagnosed within the first year of life by fetal exposure to anti-epileptic drugs. The odds ratio for over 1,500 infants exposed to newer generation anti-epileptic drugs during the first trimester, as compared to over 19,000 infants not exposed to AEDs, was 0.99, with a 95% confidence interval crossing 1.0, and an upper bound of 1.36. The study concluded that among liveborn infants in Denmark, first trimester exposure to newer generation anti-epileptic drugs, including topiramate, compared with no exposure, was not associated with an increased risk of major birth defects. The Wolters Kluwer data, along with the Danish study, concluded that topiramate is not a major teratogen. Both studies further add to the growing base of evidence and provides comfort on the

teratogenic potential of topiramate. FORTRESS remains the definitive study for the assessment of topiramate teratogenicity, and we await those results in the fourth quarter of this year.

We would also like to point out that FDA has very recently updated the label for topiramate to reflect a lower-than-previously-reported relative risk of oral cleft. In March 2011, based on data from the North American Registry, the reported prevalence of oral cleft from topiramate exposure was 1.4%, as compared to a historical control of 0.07%. In July 2011, the label was revised and now includes the prevalence rate of 1.2%. The historical control was adjusted to 0.12%, which is more in line with the expected background rate in this general population. More importantly, the relative risk estimate was reduced from 21.3 to 9.6, lowering the risk by more than half.

Since this is an ongoing, voluntary registry that has only enrolled approximately half of the intended subjects, we expect these data from the North American Registry to continue to evolve and updated over time. With that, I will turn the call over to Tim to discuss financial results.

Tim Morris — ***VIVUS, Inc.*** - ***SVP Finance and CFO***

Thank you, Peter. For the second quarter ended June 30, 2011, VIVUS reported a net loss of $16.2 million, or $0.20 per share. This compares to a net loss of $22.8 million, or $0.28 per share for the second quarter last year. The net loss from continuing operations was $16.3 million, or $0.20 per share, as compared

to a net loss from continuing operations of $21.6 million, or $0.27 per share, during the second quarter of 2010. The lower net loss in 2011, as compared to 2010, primarily results from reduced R&D spending on QNEXA and avanafil as these products progress from the clinical stage to the approval stage. Included in the net loss for the second quarter of 2011 is a one-time accrual of a milestone payment of $4 million to be paid to Mitsubishi Tanabe upon the filing of the avanafil NDA. This milestone will be paid in the third quarter of 2011.

VIVUS had cash and cash equivalents of $121.6 million at the end of June. This compares to a $130.4 million at the end of December last year. The decrease in cash of $8.8 million is primarily due to cash used in operations offset by proceeds from the exercise of common stock options and ESPP purchases.

As relates to the rest of financials, I refer you to the press release for more information on the second and the first-half results.

On the investor relations front, we will participate in several investor conferences in September, including the Stifel Nicolaus conference in Boston and the UBS and JMP Healthcare conferences in New York City. With that, I would like to turn the call over to Leland before taking some questions.

Leland Wilson — ***VIVUS, Inc.*** - ***CEO***

Thanks Tim. Again, the filing of the avanafil NDA is the major corporate accomplishment for VIVUS. For QNEXA, we are encouraged by the conclusion of the Danish study and the IEC data that shows topiramate is not a major teratogen. But, we also realize FORTRESS is a definitive study for the purposes of refiling the QNEXA NDA.

Lastly, we are encouraged that the FDA is making progress in its thinking about pharmacotherapy for obesity. The recent meeting between the obesity advocacy groups and senior FDA officials suggests that the FDA is looking for ways to make available new treatment options for obese patients. In the last two months, the FDA has approved two new versions of Phentermine, an extended release and an oral dissolve formulation, which was approved by the Metabolic Endocrine Division. With that, I like to turn the call back over to the operator for questions and answers.

QUESTION AND ANSWER

Operator

Thank you.

(Operator Instructions)

Cory Kasimov, JPMorgan.

Cory Kasimov — ***JPMorgan Chase & Co.*** - ***Analyst***

Hey. Good afternoon, guys. Thank you for taking the question. First of all, just to try to get a better understanding of what would define success in the FORTRESS trial. If you were to get a similar odds ratio result in your analysis as to what was published for the Danish study in JAMA, as well as the recent Wolters Kluwer update, do you believe that is sufficient to satisfy the FDA, given that you will have more dyads in your analysis?

Leland Wilson — ***VIVUS, Inc.*** - ***CEO***

I will take a shot, Cory, and ask Peter to comment as well. Yes, those results show that the topiramate was not a contributor as a teratogen, a major contributor. So, yes, that's a fairly conclusive result, and I think similar results would be very welcomed here.

Cory Kasimov — ***JPMorgan Chase & Co.*** - ***Analyst***

Has the FDA given you strict guidance in terms of — and I think you said in the past it has not — strict guidance with regards to what the point estimate they would be comfortable with is?

Leland Wilson — ***VIVUS, Inc.*** - ***CEO***

No, they have not, nor do we expect them to until this study is completed, and the big problem with that is we just don't know how many dyads we're able to acquire in the four databases, and until we actually have those nailed down, it's very, very difficult to put an odds ratio to them.

Cory Kasimov — ***JPMorgan Chase & Co.*** - ***Analyst***

Okay. And then just one quick question also on avanafil just to be clear on the BD front. Are you trying to partner the product and subsequently participate in long-term upside there, or are you looking to sell the asset outright, or are both options on the table?

Leland Wilson — ***VIVUS, Inc.*** - ***CEO***

All options are on the table. I have a preference, Cory, as I said before, that I would like to sell the product outright. We do not intend to have a PCP sales force, and I think there's more profit if a company can come in and take over the asset and sell it. But we are open to all options at this point.

Cory Kasimov — ***JPMorgan Chase & Co.*** - ***Analyst***

All right. Thank you.

Operator

Jason Butler, JMP Securities.

Jason Butler — *JMP Securities - Analyst*

Hello. Thanks for taking the questions. First of all, could you in some way weight the focus of CHMP, in terms of phentermine and the cardiovascular questions and topiramate and the teratogenic potential questions?

Leland Wilson — *VIVUS, Inc. - CEO*

I will take a shot and then ask Peter to comment as well. You know, it's pretty clear that the CHMP is looking at the issues around QNEXA very similarly to what the FDA looked at. They are almost the exact same issues, as Peter has said. So, they're going through the process much like we went through last fall with the FDA and providing information to them so that they can move their decision process on down the line.

So, the issues — what is different is, clearly, that Phentermine is not on the market in Europe, so, they don't have the visibility and comfort, perhaps, that the FDA has. As I commented, they just recently approved two new versions for it. But we are — in our response to them that we are preparing, are giving them all of the data from the US marketplace that we can get our hands on as well.

Just, as a punch line, I think the FDA is very comfortable with the phentermine profile. They've been through this, and it's just an effort that we need to go through with the European Union to get them as well.

Jason Butler — *JMP Securities - Analyst*

Okay. Great. On the Wolters Kluwer data, can you talk about the control groups and how they compare to what we'll see from the FORTRESS trial? For example, I think you talked about — in FORTRESS potentially having a positive control group, whereas in this data set you said there was no — any exposure to major teratogens were excluded. So, just an idea of the similarities and differences in the control groups.

Peter Tam — *VIVUS, Inc. - President*

Jason, this is Peter. Just to be clear, I'm not sure we've made a comment about having a positive control. However, obviously, those analyses could be run using, for example, the Wolters Kluwer database. The study, certainly, the big difference is that the FORTRESS study would be much larger. We certainly believe that it will be larger, even though we don't have the exact number of dyads, and given the fact that it is four databases that will be used to look at this.

We are going to be presenting more data going forward on the Wolters Kluwers data. There is a very rich source of data, looking at different patient population and looking at the background rate. These are very, very good data, and we are going to be providing more results going forward.

Jason Butler — *JMP Securities - Analyst*

That's great. Finally, have you had a chance to share the Wolters Kluwer data with the FDA yet, and if so, could you characterize their response to it?

Peter Tam — *VIVUS, Inc. - President*

We have shared those results with the FDA, but at this point, certainly, FDA is looking at the data. As we conduct additional analyses, and as these abstracts are presented, we will certainly provide those to the FDA.

Jason Butler — *JMP Securities - Analyst*

Okay. Great. Thank you.

Operator

Tazeen Ahmad, Bank of America.

Tazeen Ahmad — *BofA Merrill Lynch - Analyst*

Hi, guys. Thanks for taking my question. Can you give us a little bit of color on whether or not the EU regulators have indicated that they would like to see the results of the FORTRESS study? Do you plan — is your plan to not respond until Q4, officially, based on having the FORTRESS

study results in hand? And, depending on what the results show, would you be willing to change your EU filing to a more narrow indication similar to what your plan in the US might be?

Leland Wilson — *VIVUS, Inc. - CEO*

Okay. I will take pieces of that. The first one is, as Peter mentioned, the exact same issues were raised for the FDA. So, clearly, teratogenicity was raised. We believe the studies that are being completed and the FORTRESS study will be definitive in answering. I think it will be the most thoroughly investigated drug for teratogenicity in the history of the pharmaceutical industry.

We will wait until we have the FORTRESS data in order to present it to the EU. That is a key part of the timing in our response to the questions that CHMP has raised. You are very astute in picking that up.

Tazeen Ahmad — *BofA Merrill Lynch - Analyst*

And would you be willing to change your indication to a narrower indication if the results are not as ideal as you would expect?

Leland Wilson — *VIVUS, Inc. - CEO*

Well, yes, we would. And, as we've mentioned previously, we are prepared to submit, and we will be prepared to submit an NDA if the FORTRESS studies do not support our general position that we have right now that topiramate is not a major teratogen. But, we will be ready to submit that; and that, of course, then could easily be translated to a submission in the European Union.

I would say just a couple of words about that. Although, I don't think it is likely that we will submit a limited indication — the limited indication, if you stop and think about it a little bit, has a substantial number of patients — potential patients in that group. And that's because many women of the childbearing age are not of childbearing potential. They've been sterilized or, whatever reason, and a very significant population of men, similarly to women, is obese. So there's probably about 80 million people in the United States that qualify for the limited indication. That's a heck of a market right there by itself. But, again, I don't think that is the course we are going down, but we will be prepared, both in the US and in Europe if indeed that is the course we have to take.

Tazeen Ahmad — *BofA Merrill Lynch - Analyst*

Okay. And just one question on avanafil. I know you said all options are on the table. Would you be willing to do regional agreements with multiple companies?

Leland Wilson — *VIVUS, Inc. - CEO*

That's — all options are open. It's not my preference, but, we'll see how that all works out.

Tazeen Ahmad — *BofA Merrill Lynch - Analyst*

Okay. Thanks.

Operator

Scott Henry, Roth Capital.

Scott Henry — *Roth Capital Partners - Analyst*

Thank you. I just had a couple of financial questions, if I could get them in. First, given all the moving parts, are you still comfortable with the $100 million in cash at the end of the year?

Tim Morris — *VIVUS, Inc. - SVP Finance and CFO*

Yes, Scott, this is Tim. We haven't changed our guidance on that.

Scott Henry — *Roth Capital Partners - Analyst*

Okay. Excellent. And, with regards to R&D spend, if I pull the $4 million payment out of Q2, it gets around $7 million. Should we expect that to continue or decrease significantly from that number going forward?

Tim Morris — *VIVUS, Inc. - SVP Finance and CFO*

Yes. We tend not to give quarter-to-quarter guidance, but I would say your methodology is probably correct.

Scott Henry — *Roth Capital Partners - Analyst*

Okay. And then, the final question, with regards to an OUS filing for QNEXA, I typically think of a 12- to 18-month review period. Obviously, you have a lot more going on here in the 120-day and 180-day periods than would be typical. Do you expect that to extend the review period significantly?

Leland Wilson — *VIVUS, Inc. - CEO*

Well, as I mentioned, we're going to wait until we have the FORTRESS data before we answer the 120-day questions from the CHMP. That process then goes back through discussions and we end up with an 180-day set of questions that come out. And then, I think it's a couple months after that, you will get some response from them, which is really the first definitive response you have on any of issues that we have. It's much like our complete response letter that

we receive from the FDA. So there is some spots in there where we are slightly delayed, but our goal is to move as rapidly as we possibly can and, at this point, I see no reason to revise our estimates for 2012.

Scott Henry — *Roth Capital Partners - Analyst*

Okay. Thank you for taking the questions.

Operator

Thomas Wei, Jefferies.

Thomas Wei — *Jefferies & Company - Analyst*

Hello. Thanks. I had a question on the FORTRESS study and the Wolters Kluwer Database. Can you just confirm for me, is that database part of FORTRESS?

Peter Tam — *VIVUS, Inc. - President*

Tom, no, it is not.

Thomas Wei — *Jefferies & Company - Analyst*

On a relative basis, though, are you able to say how — for the other databases that you are looking at, how does the size compare to the size of the Wolters Kluwer Database?

Peter Tam — *VIVUS, Inc. - President*

It will be bigger. It will be more representative of the cross-sectional sampling of the patients in the US. So, it's going to be a very rich database.

Thomas Wei — *Jefferies & Company - Analyst*

And, I guess you are getting to part of what else I had wanted to ask. How are these other databases that you're using different from Wolters Kluwer, and, given the data that you do have from the Walters Kluwer Database, why wouldn't you include that as part of FORTRESS? Is there something about it that does not make it as good of a database as the other one?

Peter Tam — *VIVUS, Inc. - President*

No, I wouldn't say that. The FORTRESS study certainly is a study that we've worked diligently with the FDA on. It is a — what we called a definitive study. The Wolters Kluwer Database was meant to be a study for us to look at the data separate from the FORTRESS study to assess the teratogenic potential early.

We look at all of these as individual pieces of evidence. Some are generated by us, some are generated by others, some are generated outside of the US. All put together, they all provide a good comprehensive picture, which is really what the FDA is looking for in terms of a full assessment of the teratogenic potential, and we definitely intend to submit the Wolters Kluwer data to the FDA as part of a our resubmission for QNEXA.

Thomas Wei — *Jefferies & Company - Analyst*

And, just lastly, you had mentioned phentermine not been approved in Europe. Could you just remind me whether or not it had ever actually been filed for approval, and was it actually outright denied approval for a particular reason? Or, is there some other historical artifact for why phentermine is not actually marketed in Europe?

Leland Wilson — *VIVUS, Inc. - CEO*

Just a little history here. Back when the Fen-Phen issue broke both in the US and Europe, there was questions by both the European and American regulatory authorities. In Europe, there was not a sponsor interested in prosecuting the efforts. That is, their sales were just not adequate — for whatever reason, they made the decision that they just were not interested in prosecuting it. It was never formally taken off the market, but it was never supported thereafter.

In the United States, as you know, it became the largest selling drug for treatment of obesity in the United States and continues to this day, and scrips are increasing pretty dramatically, so I think that is the difference here. It's just the support that it received by its sponsor.

Thomas Wei — *Jefferies & Company - Analyst*

Thanks. That's very helpful.

Operator

Thank you. There are no further questions at this time. I will turn the call back over to Leland for closing remarks.

Leland Wilson — *VIVUS, Inc. - CEO*

Okay. Well again, thank you very much for your support. I really want to recognize our people here that have worked just extremely hard on the avanafil NDA. They continue to work hard on the MAA and, clearly, for QNEXA, there's just been a tremendous effort by a very small number

of people here that have really produced exceptional results. So, I want to recognize, because I know most of them are listening today, and I really appreciate their contributions, as I appreciate the support from our investor community as well. Thanks, again.

Operator

Ladies and gentlemen, this concludes today's conference. You may now disconnect. Good day.