UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported)
November 7, 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 November 7, 2011, VIVUS, Inc. conducted a conference call during which members of its senior management team discussed financial results for the third quarter ended September 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. Third Quarter 2011 Earnings Conference Call on November 7, 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: November 10, 2011

EXHIBIT INDEX

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. Third Quarter 2011 Earnings Conference Call on November 7, 2011, 1:30 p.m. PT.

VIVUS, INC.
Q3 2011 Earnings Release Conference Call
November 7, 2011
4:30 p.m. ET

Operator

Good day, ladies and gentlemen, and welcome to the VIVUS third 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 is being recorded. I will now introduce our host for today, Mr. Tim Morris, Chief Financial Officer. Sir, please go ahead.

Tim Morris - ***VIVUS Inc - SVP Finance, CFO***

Thank you, Karen. Before we get started, I would like to remind you that during the course of 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, forecast, estimate, expect, intend, likely, may, plan, potential, predict, opportunity, and should, 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 and actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the response from the FDA to our re-submission of the NDA for Qnexa for the treatment of obesity, including weight loss and maintenance of weight loss recommended for obese patients or overweight patients with weight related co-morbidities such as hypertension, type II diabetes, dyslipidemia or central adiposity with a contraindication that excludes the use of Qnexa by women of childbearing potential; the timing and results of our FORTRESS study; the reliability of the medical claims healthcare database used in the FORTRESS study; the FDA's interpretation of and agreement with the information we submitted relating to teratogenicity and cardiovascular safety; the FDA's interpretation of the data from our SEQUEL study and sleep apnea study that we may be required to conduct additional perspective or retrospective observational studies or to provide further analysis of clinical trial data; our response to questions and requests for additional information including additional preclinical studies from the EMA and CHMP for the MAA of Qnexa; the result of external studies to assess the teratogenic risk of topiramate; the results of REMS or cardiovascular outcomes for obesity advisory meetings; the outcome of a second advisory committee meeting for Qnexa; the impact, if any, of the agreement by one of our competitors with an obesity compound to conduct or complete a cardiovascular outcome study pre-approval; impact on future sales based on specific indications and contraindications contained in the label and the extent of the REMS distribution and patient access program; the FDA's response to the NDA filed for avanafil; our ability to successfully commercialize or establish a marketing partnership for avanafil or our partner's ability to obtain regulatory approval to manufacture and adequately supply avanafil for commercial use; our history of losses and variable quarterly results; substantial competition; risk related to failure to protect our intellectual property and litigation in which we may become involved; uncertainty of government or third party payer reimbursement; our reliance on sole source suppliers; our

limited sales and marketing efforts and our reliance on third parties; failure to continue to develop innovative investigational candidates and drugs; risk related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA regulations; our ability to demonstrate through clinical testing the safety and efficacy of our investigational drug candidates; our dependence on the performance of our collaborative partners; the timing and initiation and completion of clinical studies and submission to the FDA or foreign authorities; the volatility and liquidity of the financial markets; our liquidity and capital resources and our expected future revenues, operations and expenditures.

As with any pharmaceutical in development, there are significant risks in the development and regulatory approval and commercialization of new products. There are no guarantees that our responses to the FDA's CRL or the CHMP's 120 day questions, the FDA's request stemming from the end of the review meeting or the results of the FORTRESS study will be sufficient to satisfy the FDA's and CHMP's safety concerns and that FDA or 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, Qnexa and avanafil. First, I will provide an update on Qnexa and comment on the recent re-filing of the NDA. Next, Peter will follow with an update on avanafil including the timeline for filing in Europe. Tim will follow with an update on cash and a revised guidance for year end. And lastly, I will take your questions.

Since our last call, the highlight was the re-submission of the NDA for Qnexa, our investigational drug for the treatment of obesity. Shortly after Labor Day, we held a conference call with the FDA to discuss our re-submission strategy. During the call, we agreed with the FDA to re-submit the Qnexa NDA and include a contraindication that excludes women of childbearing potential and a REMS.

On October 17, we resubmitted that Qnexa NDA. The FDA has accepted the NDA for filing and designated the filing as a class 2 re-submission with an expected 6-month review cycle. The PDUFA date is April 17, 2012. The FDA indicated that an advisory committee of the Endocrine and Metabolic Division will meet to specifically discuss the Qnexa NDA in the first quarter of 2012.

The Qnexa NDA re-submission includes the results from the original full clinical trial population and the results from a subgroup that excludes women of childbearing potential. The NDA seeks approval for the treatment of obesity, including weight loss and maintenance of weight loss for obese patients with a BMI equal to or greater than 30, or overweight patients with a BMI equal to or greater than 27 with at least one weight-related co-morbidity. The proposed label includes a contraindication for women of childbearing potential.

The proposed pregnancy category is X. It is our belief that new weight loss medications will carry a category X classification since weight loss is not advised during pregnancy regardless of the maternal BMI. The re-submission also includes a proposed Risk Evaluation and Mitigation Strategy. The re-submission also addresses two other items requested in the Complete Response Letter from the FDA, the results of the two-year SEQUEL study and a review showing that the increase in mean heart rate seen in Qnexa trials does not increase major adverse cardiovascular events.

SEQUEL data has been presented previously but was not available for either the original submission or for the first AdCom. SEQUEL data showed that over two years patients treated with Qnexa achieved and maintained double-digit weight loss. Tolerability remained high, and there were no new or unexpected side effects during the two years. To date, we know of no other pharmacotherapy that has been able to achieve double-digit weight loss over a two-year period. A manuscript of the results of the SEQUEL study has been prepared and submitted for review.

On the question of heart rate, the re-submission includes several new analyses that address this topic. We also included data from OB-204 sleep apnea trial and data from the SEQUEL study. The agency has publicly expressed concern in the past about the potential for increased cardiovascular risk associated with certain obesity drugs that increase blood pressure. In all Qnexa, studies we see a consistent reduction in blood pressure, both systolic and diastolic. The degree of reduction is greater in the high risk patients, such as those with hypertension. It is our belief that the small increase in heart rate seen in the presence of a consistent reduction in blood pressure does not increase the risk of MACE events. Moreover, our entire clinical program, we do not see an increase in MACE events. In fact, when we examined serious cardiovascular and neurovascular events, we actually saw a statistically significant reduction compared to placebo.

In Europe we held a productive clarification meeting with our Rapporteur and Co-rapporteur in September. Our response to the 120-day questions from the CHMP is nearly complete. We are on track to file a response in the fourth quarter of this year. We anticipate the CHMP will issue their 180-day opinion in the first quarter of 2012.

Additional analyses from the Qnexa studies continue to be of interest to the medical community. As we reported last week, the results of the 56-week EQUIP study were published in *Obesity*, the peer-review journal of The Obesity Society. Additional analyses of results of Qnexa studies have recently been presented at medical meetings. Quality of life data showing improvement observed with Qnexa treatment was presented at the American Association of Diabetes Educators meeting. Multiple abstracts were presented at the EASD Annual Meeting highlighting the long-term beneficial effects of Qnexa treatment in metabolically impaired patients with pre-diabetes, diabetes and metabolic syndrome. Finally, several abstracts were presented at the annual Scientific Meeting of the Obesity Society. The presentations highlighted the long-term beneficial effects of Qnexa treatment. For example, Qnexa patients had significant improvement in liver function and reductions in medications used for diabetes, high blood pressure and high cholesterol.

The medical community continues to discuss weight loss as a treatment for type 2 diabetes. In this light, I am pleased to announce that additional analysis from the CONQUER study was selected for a podium presentation at the International Diabetes Foundation at the World Diabetes Congress in Dubai to be held in December.

Earlier this year, the IDF came out with a position statement supporting bariatric surgery as a means to resolve diabetes. Weight loss surgery uses excess weight loss as an endpoint as compared to weight loss, which is used in the pharmaceutical trials. Excess weight loss is reported as a percentage of weight over and above a healthy BMI, which is considered to be 25. Published studies of lap band patients report excess weight loss in diabetics over a one-year ranging from 32% to 38%. In contrast, from the CONQUER study, diabetic patients with

baseline BMI greater than 35 experienced a 33% reduction in excess body weight. We also see a consistent reduction in progression to diabetes in at-risk patients. Dr. Nancy Bohannon will present these results in December in Dubai.

Two other important obesity items recently made headlines. First, in September we saw the results of patient advocacy efforts. Efforts led in part by the Obesity Care Continuum resulted in a request from the Senate Appropriations Committee for the FDA to respond within six months as to their plans to approve new obesity therapy. We view this as significant and believe this request is unprecedented. We are encouraged by this request and applaud the efforts of the OCC and other patient advocacy groups.

The second item making headlines was a result of the pharmacoeconomic study that quantified the cost of obesity to government healthcare systems. In his keynote at the annual Obesity and Wellness Congress, Kenneth E. Thorp, Ph.D. reported a 10% weight loss in patients age 60 to 64 may be able to provide Medicare savings of $8 billion over 10 years and $35 billion over the average patient's lifetime. If left untreated, patients develop serious medical condition such as diabetes, costing taxpayers billions of dollars over the patient's lifetime.

With the re-submission complete, our team is focused on preparing for the upcoming Advisory Committee meeting in the first quarter of 2012. Anticipating an approval in the second quarter of 2012, the commercial group is preparing for the launch of Qnexa in the second half of 2012. The initial marketing focus will be on those overweight and obese patients that are currently seeking treatment for their co-morbidities. We will target approximately 25,000 physicians that write a significant portion of these medications for cardiometabolic diseases. Current plans include a 150-person sales force calling on these targeted physicians. In the coming months, we will continue to update you on the commercial plans for Qnexa.

I will now turn the call over to Peter to update you on the progress with avanafil.

Peter Tam - ***VIVUS Inc*** - ***President***

Thanks, Lee. The avanafil highlight in the third quarter was the acceptance of the avanafil NDA, our investigational drug candidate for the treatment of erectile dysfunction. The target date for the FDA to complete its review of the avanafil NDA is April 29, 2012. In previously announced results from the pivotal phase 3 trials, patients treated with avanafil achieved significant improvement in erectile function compared to placebo. We think that the most unique feature out of all of these results is that avanafil was shown to be effective in as early as 15 minutes in patients who attempted sex early and that the high specificity of the avanafil for the PDE5 isozymes translates to a very well tolerated safety profile. These attributes are observed consistently in every one of our phase 3 studies. Whether you have ED due to general vascular impairment, diabetes or even radical prostatectomy for prostate cancer, the effect of avanafil was consistently and clinically meaningful.

On the scientific communication front, in November, three avanafil abstracts will be presented at the Society for Sexual Medicine North America annual meeting and in December three abstracts will be presented at the European Society for Sexual Medicine meeting in Milan.

On the European regulatory front, the Marketing Authorization Application, or MAA, for avanafil is being prepared. We have received authorization that avanafil is confirmed for filing under the centralized procedure. In addition, we have received a pediatric waiver, and a Rapporteur and Co-rapporteur have been appointed. We plan to file the MAA under the centralized procedure with the EMA in the first quarter of 2012.

So far, 2011 has been a great year and we have made a tremendous amount of progress. We feel that we are in a great position of having two late-stage products in Qnexa and avanafil under regulatory review and potential approvals both in April. While there remains a lot of work that needs to be done for both of these investigational products, we are very much looking forward to 2012 as we expect it will be a transforming year for VIVUS.

I will now turn the call over to Tim to discuss financial results.

Tim Morris - ***VIVUS Inc - SVP Finance, CFO***

Thank you, Peter. For the third quarter we reported net loss of $8.6 million, or $0.10 per share, as compared to a net loss of $18 million or $0.22 per share in the third quarter last year. Net loss for the first nine months of 2011 was $34.7 million, or $0.42 per share, as compared to the net loss of $59.6 million, or $0.74 per share, for 2010. The lower net loss for both periods in 2011 as compared to 2010 primarily results from reduced research and development spending on Qnexa and avanafil as these projects progress from the clinical trial stage to the regulatory review stage. For more details on the financial results, please refer to the press release and the related filings with the SEC.

At the end of September, we had cash, cash equivalent and available-for-sale securities of $155.3 million. This includes the net proceeds of $45.3 million from the registered direct offering of our common stock. The offering was a direct result of a reverse inquiry from an existing shareholder. With the additional proceeds, we are revising our year-end cash guidance up from $100 million to $140 million.

On the investor relations front, we will participate in several investor conferences in the fourth quarter and into the early part of 2012. This week we will present at the Credit Suisse Healthcare conference in Phoenix; in December we will participate in the Deutsche Bank Biofest in Boston; and in January we will kick off the year with a presentation at JPMorgan Healthcare meeting in San Francisco, the predominant healthcare meeting on the West Coast.

With that, I will turn it back to Leland.

Leland Wilson - ***VIVUS Inc - CEO***

Thanks, Tim. Again, our re-filing of the Qnexa NDA is a major corporate accomplishment for VIVUS. We are encouraged by the cooperation of the FDA in agreeing to our filing strategy that includes a contraindication for women of childbearing potential. The clinical and regulatory teams are busy preparing for the AdCom, and commercial team is planning for the launch of Qnexa. This is an exciting time for VIVUS with two NDAs currently under review by the FDA.

With that, we will open it up to questions.

QUESTION AND ANSWER

Operator

(*Operator Instructions*)

Our first question comes from the line of Christopher James of MLV & Company.

Christopher James - ***McNicoll, Lewis & Vlak - Analyst***

Hi. Good afternoon and thanks for taking my question. Congrats on an excellent quarter and a great job with both Qnexa and avanafil. I start with the AdCom. When will the FDA inform you as to the timing and the date of that? Are there any rules in terms of the number of days they need to give you a heads up?

Peter Tam - ***VIVUS Inc - President***

Yes, Chris, this is Peter. The FDA has informed us that the AdCom will be held in the first quarter of next year, so once we get a tighter date on that, we will certainly let you know.

Christopher James - ***McNicoll, Lewis & Vlak - Analyst***

Sure. Thanks. With respect to the actual panel members, are there any rules around individuals that have been on the panels prior, meaning do you expect to see some of the same docs that came before you on previous panels?

Peter Tam - ***VIVUS Inc*** - ***President***

Yes. I think there will be panel members that were present at our last Advisory Committee meeting. We certainly expect that some of those members will be there for the second one. We also expect that there hopefully will be a greater representation of obesity experts at our AdCom. So we will see.

Christopher James - ***McNicoll, Lewis & Vlak*** - ***Analyst***

Great. And then do you expect, I know — I don't know if you can speculate, do you expect a full day, or do you expect a half-day panel?

Peter Tam - ***VIVUS Inc*** - ***President***

Right now we don't know. We certainly expect a full-day meeting.

Christopher James - ***McNicoll, Lewis & Vlak*** - ***Analyst***

Sure. Just moving on to the obesity, the new data that was published, the 14.4% weight loss. Can you comment on the heart rate increases in that cohort? Is that any different than previous cohorts?

Peter Tam - ***VIVUS Inc*** - ***President***

No. This is actually not real new data. When we share the EQUIP data along with the CONQUER data we presented those at the last AdCom, there really is no difference in terms of the heart rate profile. Again, there's a very slight increase in the heart rate in the presence of consistent reduction of blood pressure.

Christopher James - ***McNicoll, Lewis & Vlak*** - ***Analyst***

Right. And then with respect to the bariatric surgery, you mentioned lap band, have you shared these data with the surgeons and what are their thoughts on the data, competitive or complementary?

Peter Tam - ***VIVUS Inc*** - ***President***

We haven't really shared these data with bariatric surgeons. We certainly believe that Qnexa will be complementary to the common goal, which is to really help these patients lose weight. We just believe that Qnexa is a viable alternative for these patients. And in the EQUIP study when we enrolled patients that are eligible for gastric bypass surgery, as reported in the EQUIP study manuscript, the paper, we saw a 14.4% reduction. I think that compares favorably to the average weight loss achieved with lap band surgery, which recently has been reported to be about 18%. So we certainly look at it as a complementary alternative for those who need to achieve a significant amount of weight loss, and we believe that Qnexa provides that alternative for these patients.

Christopher James - ***McNicoll, Lewis & Vlak*** - ***Analyst***

Right. But would you say that they are pushing for this drug or has their tone changed over the course of the last year or so?

Lee Wilson - ***VIVUS Inc*** - ***VP, CAO***

This is Lee. I'll take a shot at that. Again, it's opinions here. My opinion is that we are not competitive in a typical competitive pharmaceutical marketing sense here. They are not our competitors. And I don't think that they view us as their competitors. With 80 million people or more walking around with this condition and gastric bypass, whether its lap band or not, only available for a very, very small percentage of the patients, this is not a competitive situation. I mean clearly, patients that are going to be available for both the pharmaceutical market and the bypass sector of this marketplace, and so we will see how it all comes out in the end. It is my hope that we will work together for the patients' benefit, and I think that is the opinion of the bypass surgeons as well.

Christopher James - ***McNicoll, Lewis & Vlak*** - ***Analyst***

Right. No, I was just trying to get at — if surgeons have significant more power in any decision making and perhaps if they're in your corner then you have a better chance. Finally, can you describe the tone of the FDA over the past few months discussing, with your talks with them. Has that changed? Can you compare and contrast how that is different?

Peter Tam - ***VIVUS Inc*** - ***President***

We have been obviously having dialogues with the Agency and we certainly find the tone of FDA to be collaborative. I think there is a certain sense that they certainly believe that this is a disease that merits therapy. They are looking very hard at Qnexa as a viable option to treat obese patients. I would characterize it as a positive collaborative and it has been very good.

Christopher James - ***McNicoll, Lewis & Vlak*** - ***Analyst***

Great. Thanks. Great job and I'll jump back in the queue.

Operator

Thank you, Sir. Our next question comes from the line of Steve Byrne of Banc of America.

Steve Byrne - ***BofA Merrill Lynch*** - ***Analyst***

Hi. With a focus on reimbursement coverage, can you discuss your level of effort and maybe to characterize the discussions you've had with managed care organizations and maybe self-insured large companies about the interest level in Qnexa and with the potential for covering it as a weight loss drug?

Lee Wilson ***VIVUS Inc*** - ***CEO***

Yes, this is Lee. That is a very complex question that would require a conference call on its own and I think you know that as well. So, yes, there are many issues regarding reimbursement for obesity products, and certainly we are working diligently to try to gain reimbursement both by the private insurers and by government Medicare or Medicaid reimbursement programs. So, I don't want to say too much more than that other than that we are busily working on that end and as we go forward, we will be able to report results to you that I think will make sense when we get to them.

Steve Byrne - ***BofA Merrill Lynch*** - ***Analyst***

Okay. You talked about pursuing a 150-rep sales force. Are you also considering a parallel path in discussions with potential partners to license the drug rather than selling it yourself?

Lee Wilson - ***VIVUS Inc*** -***CEO***

We are looking at potential partners for Europe and the rest of the world. We are not looking for a potential partner for the US market.

Steve Byrne - ***BofA Merrill Lynch*** - ***Analyst***

Okay, and then one question I had about you, the analysis of the pooled data, when you pull in the sleep apnea trials and so forth and you conclude a statistically significant reduction in MACE events. Can you comment on specific numbers of events that you have in those pooled data in the various arms, and how sensitive is it based on how you define the MACE event?

Peter Tam - ***VIVUS Inc*** - ***President***

So Steve, this is Peter. I just want to be clear. We looked at MACE events with respect to a very narrow all the way to a very broad definition. Our program wasn't intended to look specifically at MACE events from the very beginning of conception of the trials. So what we ended up doing was pulling all the studies, and this is appropriate because we want to make sure that everybody gets included in the safety analysis, so we included patients who are at high risk primarily because they have sleep apnea as well as obesity along with other co-morbid conditions. When you go to the broader definition of serious adverse cardiovascular and neurovascular events, and this would include strokes and so forth, these are all serious events, we actually saw a significant reduction on the basis of the hazard ratio having the upper 95% confidence interval ruling out one. So in that regard, we are certainly comfortable with the data, and those are the data we we're going to be presenting to the FDA.

Lee Wilson - ***VIVUS Inc*** -***CEO***

I would just comment in addition that all definitions that we have for MACE are less than 1, with a point estimate less than 1, and that data was presented at the original AdCom, so you can reference that data.

Steve Byrne - ***BofA Merrill Lynch*** - ***Analyst***

Okay. Thank you.

Operator

Thank you, Sir. Our next question comes from the line of Thomas Wei of Jefferies.

Thomas Wei - ***Jefferies & Company*** - ***Analyst***

Thanks for taking my question. Just to follow up on the answer that you just gave, so the submission of the cardiovascular and the neurovascular analysis was part of the original filing in the AdCom materials there, so could you go through in a little bit more detail what is the new evidence on heart rate that you are going to be highlighting in your re-filing?

Peter Tam - ***VIVUS Inc*** - ***President***

There is a series of arguments that we have prepared for FDA. We looked at heart rate in the presence of other endpoints, such as blood pressure, because it is important as the rate pressure product, which is something we presented at our AdCom. We looked at outliers who had high heart rate as a result of being on the study. We looked at their blood pressure and showed no

increased risk. Again, the rate pressure product is lower. So those results will be shared. We looked at different ways of cutting the data, MACE events as well, and along with SEQUEL results, because that certainly adds to the pool of experience on Qnexa. And again, we saw, as I mentioned before, a

significant reduction in the neurovascular and cardiovascular serious adverse events. So these are some of the arguments that we've prepared and have submitted to the FDA for their review.

Thomas Wei - ***Jefferies & Company*** - ***Analyst***

And maybe it would be helpful to know for the new proposed narrow indication that you are filing for, how many patients do you have in your safety database for Qnexa that fall into that definition?

Peter Tam - ***VIVUS Inc*** - ***President***

It is substantial and we haven't disclosed that number yet. The fact that we — If you can imagine, CONQUER was a study that enrolled patients with at least 2 co-morbidities. That in itself would have a tendency of pushing the patient's age a little bit higher. So it is a substantial body of experience from the CONQUER trial as well as the rest of the program. These MACE events, they actually look quite good even in that smaller population. So, again, we look forward to sharing these results with the rest of you as well as with the FDA.

Thomas Wei - ***Jefferies & Company*** - ***Analyst***

Can you say for the (inaudible) in your filing that do fall under that narrow indication, what does the average increase in heart rate look like relative to the overall population?

Peter Tam - ***VIVUS Inc*** - ***President***

It is consistent. It is not any different, not in a substantial way. So, again, we feel very comfortable with these additional analyses. Again, just want to remind you that the heart rate effect is small, and in the presence of a significant reduction in blood pressure, in particular in high-risk patients, we certainly feel comfortable with the results that we have compiled.

Thomas Wei - ***Jefferies & Company*** - ***Analyst***

And if I remember correctly, the original number on the overall heart rate increase were in the — were they in the 2-beat—per-minute range, so you are seeing symptoms similar to that in men and women of non-childbearing age?

Peter Tam - ***VIVUS Inc*** - ***President***

Yes. It's 1.6 beats for the top dose and 0.6 beat for the mid dose.

Thomas Wei - ***Jefferies & Company*** - ***Analyst***

Okay. Lastly, can you go over in a little more detail what the nature was of some of the critical 120-day questions you got at the EMA? Thanks.

Peter Tam - ***VIVUS Inc*** - ***President***

Yes. The 120-day questions that we got from the CHMP, they are essentially very much consistent with some of the questions raised by FDA as well as the Advisory Committee meeting. That is about the extent that I can share at this time. We are obviously working hard to get our responses in to the FDA this last quarter of the year. So we will be getting those in to CHMP very, very quickly.

Operator

Thank you. Our next question comes from the line of Simos Simeonidis with Cowen and Company.

Simos Simeonidis - ***Cowen and Company*** - ***Analyst***

Hi, guys. Thank you for taking the questions. It's been a little over a year since the CRL for Qnexa. Could you characterize for us or talk about any discussions you may have had with the Agency on a pre- or post-approval CV outcomes study? What is the latest or the status of these discussions?

Peter Tam - ***VIVUS Inc*** - ***President***

So, I think I've — one thing we have said, and remains true, is that in all of our discussions with the FDA, we've never talked about a pre-approval cardiovascular safety study. The question that we have in our CRL is to provide evidence to the FDA with regard to the elevations in heart rate and whether or not that increases the risk for MACE. We've done what I believe is a great job in terms of putting those arguments together. With respect to pre-approval, that's never been discussed.

Simos Simeonidis - ***Cowen and Company*** - ***Analyst***

And the same goes for a post-approval trial?

Peter Tam - ***VIVUS Inc*** - ***President***

That is something we actually want to conduct and we have talked to the FDA about this from the very beginning. That is something that we continue to work toward with the FDA on that design of the study.

Simos Simeonidis - ***Cowen and Company*** - ***Analyst***

But you don’t have any concrete feedback from them in terms of numbers and size of the trial?

Peter Tam - ***VIVUS Inc*** - ***President***

It’s too early at this stage.

Simos Simeonidis - ***Cowen and Company*** - ***Analyst***

Okay. You mentioned that you believe that the increase in heart rate that you have seen in the trials doesn’t increase the MACE events. In your discussions with the Agency in the past few months, do you believe that they, going through your data, they share that opinion?

Peter Tam - ***VIVUS Inc*** - ***President***

That’s really for the FDA to determine. We shared these arguments with them and they accepted those arguments, and that’s about the extent that we will get at least for now.

Simos Simeonidis - ***Cowen and Company*** - ***Analyst***

Okay. Thanks. One final question, this one on avanafil. Could you give us your current thoughts on partnership versus divestiture and the timing of such a potential transaction would it probably be after April 29th, or do you have partners that are maybe willing to do something before approval?

Lee Wilson - ***VIVUS Inc -CEO***

This is Lee. I don’t want to comment too much, but we are actively engaged in discussions with a number of people. The structure of that deal varies widely between potential partners or outright acquisitions, so we can’t comment specifically on what they were. And whether or not they’re going to get done before the approval process is anyone’s guess at this point, but I do feel very optimistic that we have adequate interest from an appropriate number of companies that we will be able to structure a deal which is favorable to all of us.

Simos Simeonidis - ***Cowen and Company*** - ***Analyst***

And, Lee, you are still then not planning on building a US sales force for avanafil if it were approved and let’s say there was no partner at that time?

Lee Wilson - ***VIVUS Inc -CEO***

No, we are not.

Simos Simeonidis - ***Cowen and Company*** - ***Analyst***

Okay. Thank you very much.

Operator

Thank you, Sir. That concludes our question-and-answer session. I’d like to turn the conference back to Leland Wilson for any final remarks.

Leland Wilson - ***VIVUS Inc*** - ***CEO***

Thanks, everybody. I appreciate your support and I think you all can feel the tenor of life around VIVUS here is increasing pretty dramatically. We are working on very positive things right now as far as the approval of both avanafil and Qnexa, and the AdCom, and the European submissions, et cetera, the partnering relationships, et cetera. So the tenor here has increased substantially over the last several months. It feels real good. We obviously are adding additional people. Many of you have commented that you have seen the ads that we have for people we are trying to bring on board. So, that is always a good time in companies and right now morale — I can’t remember it being as high as it is right now and we are all very positively inclined here as far as what we think about the future of VIVUS. Thank you. I appreciate your support. Thanks very much.

Operator

Ladies and gentlemen, thank you for your participation in today’s conference. This does conclude the program and you may now disconnect. Everyone have a good day.