

**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 11, 2008**

**VIVUS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation)

**001-33389**  
(Commission File Number)

**94-3136179**  
(IRS Employer  
Identification No.)

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

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

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

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

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

**Item 8.01. Other Events.**

On November 11, 2008, VIVUS, Inc. conducted a webcast presentation at the Rodman & Renshaw Annual Global Investment Conference. A copy of the transcript of the webcast presentation is attached hereto as Exhibit 99.1.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference into any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of VIVUS, Inc. webcast presentation on November 11, 2008, 12:15 p.m. ET.

## 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 13, 2008**

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of VIVUS, Inc. webcast presentation on November 11, 2008, 12:15 p.m. ET.

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**VIVUS at Rodman & Renshaw  
Annual Global Investment Conference**

**Leland Wilson, President and CEO**

Thank you, and thank you for having us today. Our CFO is here, Tim Morris, so I think many of you recognize him and you can thank him for having 40 slides for 20 minutes! We're going to try to go pretty quickly through some of these, and I see a lot of friendly faces in the audience that know the story, so anybody that has questions, I'll meet you out in the hall afterwards as we go through this.

Obviously, I may be making forward-looking statements so consult our Q, etc., for the risks associated.

Taking a 20,000 foot view of VIVUS, this slide captures part of the essence of VIVUS in that we have a product for treating both obesity and diabetes that is in phase 3 testing. As a matter of fact, we're going to have clinical data, phase 3 data, here in about four weeks. So we're right down to the cusp on this, so it's — that's very good by itself. The second one is that we have a program for diabetes. We're working with the FDA to define the phase 3 program. We also have a product called Luramist, which is a treatment of hypoactive sexual desire disorder, which we do have an SPA in place and are ready to begin or to find a partner for this so that we can begin phase 3 testing.

Avanafil — we have with us Dr. Chuck Bowden, who is here as well. He is the clinical head of our development program for avanafil, so you can ask him questions as well. This product is for treatment of erectile dysfunction. It is a PDE5 inhibitors with some very unique characteristics, which we'll go into and which will help us to differentiate some other products that are on the market today. And clearly, we have MUSE that's been on the market for some time, and I'm actually happy to say that MUSE sales are increasing but of small base.

I think that captures where we are, but in the world we live in today, we heard the term "cash is king," and for I think more luck than a lot of things, we have \$204 million in the bank, which puts us at a very strong position financially. We were fortunate enough to have a product which we were able to get NDA approval for called Evamist, and we were able to sell that product outright to K-V Pharmaceuticals for \$180 million. And thanks I think largely to the work of Tim and some of our investors who are in this room, we were able to raise \$65 million almost right before the economic disaster fell upon us. So we are in the very — relative to our brethren, in a strong financial position.

Okay, let's go after obesity, and again I'll speed through this. So we had one heck of a last 12-month period here. We were able to start our phase 3 program for treatment of obesity and enroll these patients very rapidly. Now, we're talking about 4,500 patients that we were able to put into the trial, and this trial was done under an SPA. In the diabetes program we were able to complete and present our phase 2 diabetes data, and we'll go over some of those results. Avanafil, we were able to bring in \$30 million funding. Our timing was excellent for that, so we'll be able to take avanafil through our phase 3 testing program, which is in place as we speak. And for Luramist, we got the SPA for the phase 3 program, and we have agreement with the FDA on the safety protocols, but the FDA is constantly reviewing what's required for safety, for cardiovascular safety, as many of you know, and so we're continuing to have discussions along those lines. And again, I'll mention that we were able to raise \$65 million here just recently.

Okay, I don't have to spend too much time on obesity. We all know that it's an epidemic, but I think what's important for people to understand is that the reality in the world is transitioning from the fact that it used to be thought that obesity was a cosmetic issue. I don't think anyone agrees now that it's just cosmetic. We do now believe that obesity is the cause of type 2 diabetes, for example. Obesity causes high blood pressure. Obesity causes dyslipidemia. Obesity causes liver disease such as NASH and NAFLD and you can go on down the list. Now that's not only — And that has been shown in a couple of really powerful studies that were published a year ago in the *New England Journal of Medicine*, which dealt with the use of lap-band surgeries to show that you could reduce the incidence of all these condition, including diabetes, if you just got the patients to lose weight. So it's a very powerful disease that has tremendous economic cost to our healthcare systems.

What is Qnexa? It's a combination — it's a low dose, proprietary, novel combination of two products that are on the market today: phentermine and topiramate. And I put the doses up there at 15mg. Phentermine is approved up to 37.5 mg, and Topiramate at 92 mg and is approved up to 400 mg. Now, this is our top dose in clinical testing, so it's a small fraction of the actual approved doses that are on the market today. Phentermine has a substantial safety history on the marketplace, as well as topiramate. I draw your attention to the bottom here for expediency. Both phentermine and topiramate have more than one million years of patient experience in the marketplace just over the last five years. Topiramate, as many of you know, is one of the top selling drugs in the pharmaceutical industry, and phentermine has been on the market since 1948, I believe. So an excellent track record for safety during that time.

I'm not going to spend a lot of time on this because most of you have seen this data — this is our famous Duke Study data, which was kind of revolutionary and at the time was thought to be too good to be true, which we replicated now in multi-center studies across the United States. This was a 200-patient study. Typical demographics here for weight loss patients, but I want to draw to you attention that we were able to have 92% of the patients complete the study on Qnexa. That's opposed to 62% on placebo, so a very high completion rate, which is the indication in the case of the treatment of obesity, that's two issues. One is the safety — they tolerated the drug well; the second one is they were interested in staying on the drug because clearly the placebo was well tolerated as well, but they weren't interested in staying on the program. So here's a good measure of efficacy. But even more importantly, this I think is the data that came out of this — in just the six-month period of time that the patients were treated, we were able to achieve 25.1 pound loss on average from our treatment group. This is compared to 4.8 pounds in the placebo group.

Looking at it another way, this is percentage of patients who were able to lose 5%, 10% and 15%. I have never seen any other product that had a 15% category up there. In that case, we had 20% of the population of that study who were able to lose 15% or more of their body weight. Pretty amazing!

The second point that I'll draw your attention to is that you'll see on the right-hand side here an indication of the synergistic effect of phentermine and topiramate working together. At these low doses, you're able to achieve weight loss which is far greater than what you would predict from the individual agents by themselves. So for example, I'll draw your attention here to the 10% weight loss. If you do on a placebo-subtracted basis, you'll see that the Qnexa loss, the percentage of patients that achieved 10% weight loss far exceeds the combination of the two, and you can see that even more profoundly in the 15% rate. So there's magic that goes on when these two work. I'm likening this to a sieve that when you're trying to lose weight, you've got to block enough

holes in the sieve to make an impact on how much water gets through. And so we're blocking enough holes through the dual mechanism of both phentermine and topiramate here to cause this rather profound weight loss.

Importantly, I think, and interestingly from a medical standpoint, all of the cardiovascular risk factors are either pointing in the right direction or are showing statistically significant in this group of relatively normal patients, that is normal from blood pressure, normal from a lipid standpoint, etc. We were still able to show a statistically significant drop in systolic and diastolic blood pressure, a dramatic drop in triglycerides, in total cholesterol and waist circumference. So in this day of treating diabetic patients, for example, where it's not known — well, it is known that just treating the symptom of diabetes, that is the HbA1c, does not lead to greater morbidity, or mortality or reduce morbidity and mortality, or life expectancy. It's profound to show that we have the kinds of endpoints here that are indicative of the potential for a decreased mortality for this kind of a product.

So just in summary again, 10.7% weight loss; significant improvement of cardiovascular risks; 92% completion rate, and well tolerated. The side effects we see are paresthesia, which is tingling on the periphery such as the tip of the nose, the ears and the fingertips. It is in the label for topiramate. Increased urinary frequency, which deals with weight loss, and headache 10%.

Okay, so phase 3 trials. We're going to spend a fair amount of time talking about these, but we put these through an SPA process and we initiated the trials in December of '07 — 4,500 patients enrolled, and we're testing three different doses here. What we call the full strength, which is actually as I said earlier a fairly low dose compared to the approved products out there; a mid-dose, which is half of that; and then the low dose, which is a half of that. So we're talking about three very low doses of these two products going into the phase 3 clinical program. Co-primary endpoints dictated by the FDA — percent of weight loss at 56 weeks and percent of subjects achieving a 5% weight loss.

These are the three studies. The 301 study we call the EQUATE study. This is a study which is a multi-factorial study designed to show that both phentermine plus topiramate, that is Qnexa, is superior than either phentermine or topiramate alone. That data will be available in just approximately four or five weeks from now, so it's going to be available in December. So that's a 700-patient study in patients that have a BMI between 30 and 45. That's the first of the phase 3 data that will be upon us.

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The other two studies, the data will be available in June of next year — June/July time frame midyear, and in our world and in people in this room's world, that is (unintelligible). Just to give you a kind of perception of the work that's going on right now, we're writing the NDA for submission based upon this phase 3 data that's going to be coming here. So we're in that wonderful process of having the consultants on board to put this NDA together.

The EQUIP study is a study looking at morbidly obese patients. These are all gastric bypass eligible patients, the real tough ones that are out there that have a real severe problem with their weight, have been unable to make anything work in their lives, and so we're looking into that. We're testing that in both the full and the low dose, 1,250 patients.

And the CONQUER study, your 303 study, we're looking at overweight patients which have two or more co-morbidities, such as hypertension, dyslipidemia, etc. So again, a 4,500 patient phase 3 program. Results are coming out very, very rapidly, so it's a very exciting time for us.

Qnexa for diabetes — one of my very high interest areas because it's recognized that diabetes is an epidemic that's causing major cost to our healthcare system and it's a disastrous kind of situation. One-third of the people that are born in this century are going to have diabetes by the time they die, and we all know the kind of consequences from diabetes — the shorter life expectancy, and a very cruel death, too, for many of the cardiovascular problems that people have that have diabetes. And so this offers — and I want to get this concept across — this is not a treatment for a symptom of diabetes. This is a treatment for the cause of type 2 diabetes. Treating a symptom — it does treat the symptoms, such as HbA1c and also the symptoms of high blood pressure, symptoms of high cholesterol, all those kinds of symptoms are treated, but more importantly, it's a treatment for the cause, which is obesity, of type 2 diabetes. And it's a hard concept for a lot of people to get their hands around because they say the reason for type 2 diabetes is genetic component. Yes, well some people get diabetes at lower visceral fat levels than other people, and that's the genetic component. But if you have visceral fat, you are pre-disposed for diabetes. It's just that clear. And so reducing that visceral fat reduces the diabetes, and that's been shown again — prospectively and retrospectively done with gastric bypass studies, very large gastric bypass studies.

This is our 202 study, which we've released results for. It's a classic study done in type 2 diabetes in that the HbA1c's were about 8.6, fasting glucose was about 170, the weights were in the 216 area, but it's not classic from the standpoint that this was an all-comers study. To my knowledge, this is the first all-comers study ever done by a pharmaceutical company. Now, the difference between an all-comers study and one that is jury-rigged to get the best results is that you have patients that have severe diabetes. In this trial, we had — 60% of the patients had their diabetes for more than five years; many had it more than 10 years. And also 62% of the patients on Qnexa had two or more oral diabetic medications on board. So these are severe patients. They're not the Metformin-alone kind of fairly healthy patients with good beta cell function, etc., [unintelligible]. Now, with that, it's a parallel, placebo-design study, four-week titration and 24 weeks of treatment, and these are the results. I think I forgot to point out there that it's not really placebo we're comparing against here. The new FDA edict is that you compare against standard of care. Now, standard of care when you go onto a placebo-controlled trial here is that the

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placebo patients get the best care that the doctor normally gives for their patients. They use the full armamentarium of anti-diabetic meds. The reason these patients come on these trials to a great extent is because they get healthcare and in many cases the healthcare is not available to them, and so they come into this trial, they get their meds and they get their diabetes under control. And so that's the reason for them being there. In spite of that, we were able to achieve a very excellent lowering of HbA1c of 1.2% and beat placebo dramatically, which was .6% lower on the standard care in that clinical practice. Additionally, we were able to lower the fasting plasma glucose dramatically, as you can see here. Important on both of these slides, they continue to decrease beyond the six-month period. So we're anxious to see the results of the study which is the extension to this 202 study — we call it 230 — we'll see the results of that again in December of this year. So that one-year data on diabetic patients will be available here in just a very short period of time.

This is the weight in this group. Everybody's done studies, everybody knows it's difficult to lower weight in diabetic patients because one, they have to eat on a regular basis in order to keep their blood glucose in a normal range; and the second one is mainly the drugs that they are using actually cause an increase in weight, like SFU's, and insulin even causes them to gain weight by themselves. So this is a very dramatic reduction in weight in this patient population. And I can tell you again the number one desire of both patients and physicians in this marketplace is for a product that reduces weight. We see that in Byetta, which is weight neutral to possibly some weight loss that people are willing to take the injections in order to get the weight loss associated with it. Doctors are interested because they know that it — and it's always been standard of practice, lose weight before you go on medication. They know that diet and

exercise is the way normally to treat patients that have type 2 diabetes, but they – people just don't do it. And so this is an aid to the treatment of – the use of diet and exercise to treat these kinds of patients. Again, it continues beyond where we are here at six months. Looking at these percent achieving 5% weight, 61 versus 14, and again, all the cardiovascular markers are either pointing in the right direction or they are statistically significant in this group that is well controlled for their hypertension and their dyslipidemia and their triglycerides, etc.

We all know from the Rimonabant experience that the FDA is interested in depression and suicidality. For those of you who are not familiar with this, the FDA has directed that all clinical trials done in this area will use at every visit a scale called the PHQ9. It's a nine-question questionnaire which is validated to show a level of depression and suicidality in this patient population. And so the first trial for us to complete with this data in hand is the 202 data, and very relieved and very happy to show that we actually showed a statistically significant reduction in HbA1c – reduction in PHQ9. Now, this is really important because we all have the Rimonabant concerns about the approval process, etc. This is our first look. This is very powerful data because even though it's a fairly small study, patient data was collected at every visit throughout the study, so the data, the amount of data in this study is very strong and the results are absolutely excellent.

Okay, summary results then in the 202 study: 1.2% reduction in HbA1c, 8% weight loss, significant improvement in cardiovascular risk factors, safe and well tolerated. Again, 85% retention in this multi-center study, 10 sites across the United States. Drop out for AE's were similar in both placebo and active.

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This is the extension study I mentioned. It's a parallel-design study, just a roll-over of 202 patients in here. We have 130 patients enrolled and we're looking at the data for that as I said next month. So here the data is coming out in December. EQUATE obesity data and 230 data in December, and then we're going to have the pivotal trial data, both 302 and 303, in mid 2009, and we'll file the NDA for obesity in late 2009. So that's really upon us, and so we're very fortunate to be at this position with a product which we think has tremendous potential.

I want to say a few words about avanafil, and then I'll invite you to talk to Chuck after the presentation because he knows this better than I do by far. But the basic concept here is the market is large. It is a very dissatisfied market. There is a high degree of switching. The second point that I'll make is avanafil is different from any other PDE5 out there. I'll make that point in a couple ways.

First, this slide will indicate down here in the bottom left the Tmax. That's the time to maximum plasma concentration for your drug. That is 35 minutes for avanafil versus 125 minutes for tadalafil and 60 minutes for sildenafil and vardenafil. In order to have sexual function, you have to have maximum levels of plasma concentration, or at least you have to have adequate levels in the blood stream. This is an indication that goes in much faster than any other product. The number one need and request by patients in the marketplace is for a faster acting product, because what happens – the reason why efficacy is variable is because they often do not wait that two hours or three hours or beyond in order for the efficacy to occur in this product. So, a very good differentiation because it is very rapid action. The second one is the half-life is one-and-a-half hours, which gives you three to four hours of window to have sexual activity and then the product is out of the body. The incidence of nuisance side effects with PDE5 inhibitors is very high: headaches, stuffy nose and red face. And so if you have Cialis on board, you've got a 36-hour headache or red face or whatever. This one gets in and gets out, but on a more serious note, the risk to patients that have erectile dysfunction is that they will have a major cardiovascular event. ED is thought to be the miner's canary for a major cardiovascular event, so you show up with the veins in your penis that are clogged, you are at risk by definition of a cardiovascular event. Nitrates are routinely used as first line therapy for the treatment of this. They are contra-indicated with patients that have sildenafil on board or any other PDE5 inhibitors. But that window of time when they can't use nitrates is much shorter for avanafil, and we have studies to show that in 8 hours after taking avanafil, there is no difference in the response, the vascular response to giving them a nitrate at that point. Again — So that's it.

We have the avanafil phase 2 study, and I'll speed through these pretty quickly. A classic parallel, placebo-controlled study here, four weeks, and I'll go right to the efficacy endpoint. The sexual questionnaire is the endpoint that we look to and the endpoints specifically are what we call SEP questions #2 and #3 out of this SEP profile, and we were able to show here in top line form that this product is as effective, if not more effective, than any other PDE5 inhibitor. Now, they're not on a controlled basis clinical trials, but these data are comparable to what was seen in the cohort of patients that other companies have studied. So it's important to understand that the efficacy is there for the product, and we would expect that because it is highly specific and a highly potent inhibitor of PDE5.

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The next product I'll talk about is testosterone. This product uses the same delivery system we had with Evamist, the product we sold to K-V, which was approved on the PDUFA date, which happens very rarely these days. And so it has – that delivery system has been validated, it has been shown to be preferential by patients that use these kinds of products over patches and gels, etc., and transdermal is the right way to deliver this for safety reasons. We have an SPA in place, and we are still continuing discussions regarding the safety, kind of protocol that's required for these drugs. The whole safety, cardiovascular safety screening program as many of you know is still in play because of the Advisory Panel that occurred this summer, and we've been directed by the FDA that they will have — further guidance is forthcoming. I'm not sure what that means, but my sense is that sooner rather than later we'll have guidance regarding what kind of cardiovascular safety studies will be required for not only this product but for all products in the pharmaceutical arena. The market forecast for this is quite high. It has been shown to be effective by Procter and Gamble in their product, and so we're looking to advance that product.

Now again, I'm over time, so just ever so quickly here, we have \$204 million in cash and securities; Qnexa and obesity data is due in December; extension study also in December; avanafil phase 3 trial initiation in the first quarter, and our pivotal data for obesity in mid-2009.

So, we've got the money. We can weather the storm of the market in order to be able to complete our obesity NDA and even take it through final NDA approval. Questions?

*Question and Answer Session*

*[Question from audience inaudible]*

Wilson: Everyday. Everyday. And the way the program will work is that you'll set a target for your body weight, it's a BMI target, and when you get to that target, you'll go on a lower or maintenance dose, a half dose typically of what you were on during the weight reduction program. And it's interesting – pardon me?

*[Question/comment from audience inaudible]*

Wilson: Well, we're working to show that right now, but we do have patients that have reached their goal in the major phase 3 program that's on hand right now, and that just does not happen. So patients that have struggled with weight, you know, some of these patients are over 300 pounds, and they come in and they've lost, you know, 70, 80, 90 pounds and so they've reached their goal and they want to know how, you know, what to do. So we actually encourage them to go on a maintenance dose and will show that they're able to maintain their weight on that, but you have to wait to see the data.

*[Question from audience inaudible]*

Wilson: That's a popular question. Any other questions? Okay, thank you. I apologize for going over. Appreciate it.

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