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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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)  
**May 10, 2006**

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**VIVUS, INC.**

(Exact name of registrant as specified in its charter)

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

**000-23490**  
(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))
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**Item 8.01. Other Events.**

On May 10, 2006, VIVUS, Inc. conducted a conference call during which members of its senior management team discussed emerging corporate developments and certain other information. A copy of the transcript of the conference call is attached hereto as Exhibit 99.1. The transcript contains an inadvertent reference to a written freedom to operate opinion on page 15 rather than the intended reference to a freedom to operate opinion.

The information in this Form 8-K and the exhibit attached hereto shall not be deemed to be "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. Corporate Development Conference Call on May 10, 2006, 10:30 a.m. EDT

## 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/ Leland F. Wilson

**Leland F. Wilson**

**President and Chief Executive Officer**

Date: **May 12, 2006**

3

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
<b>99.1</b>	Transcript of VIVUS, Inc. Corporate Development Conference Call on May 10, 2006, 10:30 a.m. EDT

4

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## VIVUS, INC.

**Moderator: Timothy Morris****May 10, 2006****9:30 am**

Operator: Welcome to the VIVUS, Inc. Corporate Development Conference Call.

Joining the call from VIVUS are Lee Wilson, Chief Executive Office; Peter Tam, Senior Vice President of Product and Corporate Development, and Dr. Wesley Day, Vice President of Clinical Development.

At this time all participants are on a listen-only mode.

Certain statements and comments made during the course of this conference call, including responses to questions, are 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,” “expect,” “project,” “believe,” “forecast,” “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 substantial competition, uncertainties of patent protection and litigation, uncertainties of government or third party payer reimbursement, reliance on sole source suppliers, limited sales and marketing effort and dependence upon third parties, risks related to the development of innovative products, and risks related to failure to obtain FDA clearances or approvals and non-compliance with FDA regulations.

And as with any pharmaceutical under development, there are significant risks in the development, regulatory approval, and commercialization of new products.

Head-to-head clinical trials between products being developed by VIVUS and approved products or other products in development have not been completed.

Comparisons made to other products and the results from their studies are based on published data. And while we believe the data and comparisons to be correct, there can be no assurance that the published results are in fact accurate or that a direct head-to-head comparison in a clinical trial format would not result in a different conclusion.

There are no guarantees that future clinical studies discussed in this call will be completed or successful, or that any product will receive regulatory approval for any indication, or prove to be commercially successful.

VIVUS does not undertake any obligation to update or revive any forward-looking statements.

2

Investors should read the risk factors set forth in VIVUS’ Form 10K for the year ended December 31, 2005, and periodic reports filed with the Securities and Exchange Commission.

Following the speakers’ prepared remarks we will hold a question and answer session. To ask a question, please press star followed by 1 on your touchtone phone. If anyone has difficulty carrying the conference, please press star-0 for operator assistance.

I will now turn the conference call over to Mr. Leland Wilson, President and CEO. Please go ahead, sir.

Leland Wilson: Thank you, and thank you for attending our conference call today on such short notice.

As we announced earlier this morning, VIVUS has an exciting new program to tell you about. But before I get to the particulars, I would like to say that this is more than just a new program. For VIVUS, it represents a seminal event in our history.

For those loyal shareholders who have been with us since the early days, we appreciate your patience. And for those newer shareholders, we believe the expansion of our development pipeline outside of sexual function represents a significant step in the natural growth of VIVUS as an emerging pharmaceutical company.

As mentioned in the year-end conference call, VIVUS’ development strategy is to focus on compounds and classes of compound that (1) have been proven safe and effective for other indication; (2) address major markets; (3) have

3

strong patent positions; and (4) offer patients real advantages of safety and efficacy over existing therapies.

Qnexa has all of these characteristics, and more. Today, we would like to discuss with you the truly outstanding results from the Qnexa Phase 2 Trial conducted at Duke University.

With me today to discuss Qnexa are Peter Tam, VIVUS' Senior Vice President of Product and Corporate Development. Peter was responsible for in-licensing Qnexa and has been our internal product champion for the project.

Dr. Wesley Day, VIVUS' Vice President of Clinical Development. Wes is a clinical pharmacologist who joined VIVUS last year after 12 years at Pfizer. Dr. Day has extensive experience in cardiovascular and metabolic disease drug development. In his career, Wes has worked on several international clinical programs and has overseen clinical and regulatory aspects for two large programs for which NDAs were submitted.

Dr. Day holds a PhD in Pharmacology and Toxicology, and an Emerson Fellowship from the University of Maryland in Baltimore, a BS with highest honors from the University of Texas at Pan American, and is a Diplomate of the American Board of Toxicology. He has been an adjunct assistant professor for the School of Pharmacy at the University Maryland at Baltimore since 1995, and has also been an adjunct assistant professor at Temple University.

Qnexa is a therapeutic we have been developing since 2001. While some of the early research conducted by the inventor, Dr. Thomas Najarian, was compelling, further work was required in formulation development, patent, as

4

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well as clinical and regulatory affairs. Our team, headed by Peter Tam and assisted by Dr. Najarian, planned and executed on the development strategy which leads us to today's announcement.

In November of 2004, we met with the FDA to discuss our development plan. With the FDA's blessing, we completed the Phase 2 program. And in March 2006, we again met with the FDA to discuss the Phase 2 results and agree upon the development plan through to the NDA. Pending final formulation work, we will begin the pivotal Phase 3 trials in 2007.

Lastly, we wanted to make sure we had sufficient funding to complete the work required to start the Phase 3 study. As we announced earlier today, we will raise \$12 million through the sale of 3,669,725 shares of common stock in a registered direct offering. This financing was led by OrbiMed Advisors, LLC. OrbiMed has over \$5 billion under management, and we consider them to be one of the preeminent healthcare investors on Wall Street.

Under a confidentiality agreement, OrbiMed performed extensive due diligence on Qnexa, the results of the Duke study, and our intellectual property position. We are pleased to add OrbiMed to our already prestigious shareholder list.

We signed stock purchase agreements with OrbiMed and one existing investor. This financing, which is subject to normal closing, is expected to close today, May 10.

Top-line results from the Phase 2 trial were presented in the press release. Peter Tam and Wes Day will discuss these results in more detail, but before they do, I would like to highlight why we are so excited about this potential product.

5

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In our 24-week Phase 2 trial with Qnexa, patients on average lost 20 pounds more than the placebo group. While a head-to-head trial with Sanofi-Aventis' rimonabant has not been completed, patients on average lost only about 10 pounds in their Phase 3 published result. We believe the results of the Duke study are therefore remarkable.

I'm sure many of you are thinking that VIVUS is a sexual function company, what expertise do they have in the obesity area? As a reminder, our core expertise is in our ability to work with the FDA to conduct successful clinical trials. VIVUS since our inception has had a remarkable rate of success in this area, having completed more than 20 successful human clinical trials with only one trial not meeting or exceeding both safety and efficacy expectation.

Within just the last year, we announced positive Phase 2 clinical trial results for Testosterone MDTs<sup>®</sup> and avanafil, and most recently we announced positive Phase 3 results for Evamist<sup>™</sup>.

To fortify our obesity expertise at VIVUS, we have brought on the inventor of Qnexa, Dr. Thomas Najarian, as Principal Scientist for the obesity program. Dr. Najarian is a board-certified specialist in internal medicine, a graduate of both MIT and Harvard Medical School, and a former faculty member of the Harvard Medical School. He was the former Medical Director and Vice President at Interneuron Pharmaceuticals, now Indevus Pharmaceuticals, a company whose primary focus was on the treatment of obesity and obesity-related illnesses.

Dr. Najarian has authored many scientific publications in such journals as The New England Journal of Medicine, The Lancet, Technology Review and Circulation.

6

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He's the holder several US and international patents. Most importantly, Dr. Najarian has 25 years of experience in treating obesity.

Lastly, we have planned and organized an analyst day to be held on May 18 in New York City from 12:00 to 2:30 pm at the Four Seasons Hotel. We are bringing in external experts and principal investigators to discuss all of our investigational products including Qnexa. Dr. Najarian will be on hand to discuss the results from the Phase 2 study; Dr. James Buster will be present to discuss the Phase 3 results from the Evamist trials; and Dr. Marc Gittelman will be available to discuss the ALISTA<sup>TM</sup> and avanafil clinical trial results. These experts along with members of VIVUS' management team will be available to meet with analysts and portfolio managers.

The addition of Qnexa should help expand our coverage universe and our potential shareholder base. This will give many potential investors who have not been introduced to the company in the past a chance to meet first hand with management.

I will now turn the call over to Peter Tam to discuss the results of the Phase 2 trial and to tell us more about Qnexa. Peter?

Peter Tam:

Thank you, Lee.

I'm very excited today to finally to be able to tell you about this product, which we believe has the potential to be a breakthrough treatment for obesity.

I've been working at VIVUS for over 12 years and was responsible for in-licensing Qnexa from the inventor, Dr. Thomas Najarian.

7

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In conjunction with our internal development team, we initiated a Phase 2 study at Duke University to evaluate the safety and efficacy of Qnexa. I'm here today to give you a brief overview of the study design and results.

Qnexa is proprietary pharmaceutical treatment containing low doses of the active ingredients phentermine and topiramate. The Phase 2 study was a 4-arm, double-blind, randomized, placebo-controlled study comparing the safety and efficacy of Qnexa to phentermine, topiramate and placebo. This trial involved 200 obese subjects, 159 women and 41 men with an average age of 40 and with a mean body mass index of 38. Each subject in the study received daily doses consisting of Qnexa, placebo, or each one of the active ingredients separately. Patients were asked to follow a simply calorie restriction diet and were treated over a 24-week period in a double-blinded manner.

Primary study endpoints used in the study were those specified in the FDA's and EMEA's guidance documents for weight loss drugs. These endpoints are average weight loss and the proportion of patients losing 5% and 10% or more of their initial body weight.

Patients in the Qnexa treatment arm experienced on average 25.1 pounds of weight loss over a 24-week period. In fact, the intent-to-treat analysis showed that 50% of patients in the Qnexa arm achieved weight loss of 10% or more of their total body weight. Primary weight loss measures and secondary efficacy endpoints such as waist circumference and body mass index all showed that Qnexa was significantly better than placebo and the other two single agent treatment groups.

The three major findings from the study are as follows. One, Qnexa achieved significantly greater weight loss as compared to placebo in each of the product's active ingredients alone. Moreover, the weight loss effect of Qnexa

8

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was greater than the sum of both active single-agent comparators using the most rigorous clinically meaningful endpoint — that is the proportion of patients losing 10% or more of their body weight.

The second important finding from the study was that the weight loss with Qnexa had not plateaued by 24 weeks, as has been often observed with other obesity treatments in development.

Lastly, and perhaps the most surprising of all findings, is that the study completion rate for Qnexa was 92%, compared to 62% for placebo over this 24-week study period. The study completion was the highest for Qnexa compared to all three treatment arms of the study.

Qnexa was well-tolerated as evidenced by the fact that only four patients, representing 8%, dropped out of the Qnexa study arm versus 19 patients, or 38%, on placebo. Only one patient out of 50 or 2% in the Qnexa arm withdrew from the study early due to an adverse event which was considered mild in severity. The overall withdrawal associated with adverse event was higher for the other groups including placebo.

The most common side effect of Qnexa was a slight transient tingling of the extremities, also known as paresthesia. The paresthesia reported was mild and temporary.

It should be noted that while the side effects were minimal, larger Phase 3 studies are required to ensure that Qnexa is safe and well tolerated when used for an extended period of time.

9

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I would now like to pass the call over to Dr. Wesley Day, Vice President of Clinical Development, to tell you more about Qnexa and its mechanism of action. Wes?

Wesley Day:

Thank you, Peter.

My name is Dr. Wesley Day, and I joined VIVUS late last year after spending over 12 years with Pfizer. Over my career in pharmaceutical drug development, I have not seen such convincing results from a Phase 2 trial as we have seen in this Qnexa trial.

Obesity is the number one health threat facing Americans today. Currently approved therapies are inadequate, and dramatic increase in obesity rates among adults speaks to the urgent need for treatment that can address this growing epidemic. As a clinical pharmacologist, to me this treatment represents an excellent example of how the complementary pharmacology of a combination therapy can improve efficacy and reduce side effects.

I would like to go into a little more detail about Qnexa and what we believe is the basis for what makes this treatment so effective and well tolerated.

As Peter and Lee mentioned, Qnexa is a proprietary pharmaceutical treatment that incorporates the active ingredients from two currently approved products: phentermine and topiramate. Both products have demonstrated weight loss properties. Earlier research by Dr. Thomas Najarian demonstrated the promise of this potential product.

Under Peter Tam's leadership, VIVUS assumed responsibility for evolving this invention into a realistic therapeutic treatment with appropriate

10

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regulatory, clinical, and commercial development attributes, with the ultimate goal of being that this invention would one day become an approved product.

By combining the respective pharmacological activities of phentermine and topiramate, we believe Qnexa simultaneously addresses both of the two major causes of over-eating: excessive hunger and the inability to feel satisfied. Phentermine is an appetite suppressant working through noradrenergic, nonserotonergic mechanisms, and is currently approved as a short-term treatment for obesity. Topiramate has been approved for treatment of migraine headaches and seizure disorders. This product has not been approved for obesity treatment. However, weight loss effects of topiramate have been reported in the literature and are believed to be mediated through an improvement of satiety via a GABA-ergic mechanism.

Qnexa may indeed be the first product to effectively address the primary control mechanisms of eating, hunger and satiation. As Peter has already discussed, the results of the Phase 2 study suggests that Qnexa is a highly efficacious new treatment for obesity, and the efficacy of Qnexa well exceeded that of the active single-agent comparators.

How the pharmacological mechanisms of Qnexa interact to produce the effects we have seen in this Phase 2 study are not completely understood. It is clear, however, that the clinical results for efficacy and tolerability are exciting, to say the least. Our primary challenge now is to address the needs of the new drug through effective formulation development and execution of a successful Phase 3 program.

The study at Duke University was performed using a twice-a-day administration of Qnexa. The company is currently developing a once-a-day formulation of this drug that it expects to use in its Phase 3 studies.

11

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As Lee mentioned before, we have met with the FDA several times over the course of development of Qnexa. The FDA has agreed to our overall development plan, and we expect to start Phase 3 in 2007.

We have planned our Phase 3 program and expect to complete necessary trials and requirements for the NDA submission in 2009.

Qnexa was well tolerated, and we are eager to advance this exciting treatment through Phase 3 clinical development and ultimately NDA approval.

I would now like to pass the call back to Peter Tam to discuss the IP position for Qnexa.

Peter Tam:

Thanks. Qnexa is a proprietary pharmaceutical treatment comprising of low doses of topiramate and phentermine. The US patent for Qnexa has been allowed by the US Patent Office, and the issue fee was paid in March of this year. The patent contains composition, product formulation, and method-of-use claims that protect Qnexa as a patented proprietary product for the treatment of obesity. The US patent expires in 2019.

The corresponding European patent with similar claims has been approved for grant. VIVUS is prosecuting worldwide patent coverage for Qnexa. Our patent and patent applications include composition, formulation, and method-of-use claims for combination therapy using a sympathomimetic agent such as phentermine, and an anticonvulsant such as topiramate for the treatment of obesity and other related disorders. Additional formulations and method-of-use patents and continuations-in-part have been filed. We believe we've put together a cogent patent strategy and a strong patent fence around Qnexa and

future generations of Qnexa to ensure exclusivity for many, many years to come.

I'd now like to turn the call back over to Lee for a closing statement.

Leland Wilson:

I want to thank all of you for attending the call today. As I said in the beginning, Qnexa represents a seminal event for VIVUS as we grow into a profitable pharmaceutical company. Results we have experienced with Qnexa are remarkable and are unparalleled to any Phase 2 trial results I have seen in my 35 years in the pharmaceutical drug development field.

Before closing, I would like to thank our investors for their support, and our employees for their quality work and for making VIVUS a very fun place to work.

As a reminder, we'll be holding an Analyst Day on May 18 in New York City from 12:00 to 2:30 pm at the Four Seasons Hotel. Seating is limited and we encourage attendees to RSVP as soon as possible. Information about the day can be found on our website.

Thank you. And we'll now open this up for questions.

Operator:

At this time, I would like to remind everyone, in order to ask a question, please press star then the number 1 on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

Your first question comes from Ilya Kravets.

Ilya Kravets:

Hi, guys. Congratulations on the news, and thanks for taking the call.

I have a couple of questions regarding the trial on Qnexa and the terms of the licensing agreement. Maybe starting with the drug, what are the doses of each separate drug that are present in Qnexa? And also for the trial, maybe you can give us the weighted baseline for these patients (unintelligible) give us the BMI score and the post-dosing rebound that was monitored and what you have so far.

Peter Tam:

Hi, Ilya, it's Peter.

Yeah, in terms of the doses in Qnexa, for competitive reasons we're not disclosing that right now. And your question in terms of the initial baseline weight, the average or the mean baseline weight for these patients entering their study was 230 pounds, about 230 pounds, and the BMI was 38. And in terms of post-dosing rebound effect, we did not look at that after the termination of the study.

Ilya Kravets:

Okay, great, and then just clarification on one of the points that you made. The efficacy that was seen with Qnexa, you said it was superior than each drug separately. Was it also statistically significantly superior to the combination, I mean if one was to add the benefit of each one?

Peter Tam:

Yeah. So the Qnexa was highly statistically significant over each of the single agents. We did not, however, test by adding the two individual effects to see whether or not that was statistically significant compared to Qnexa. But the goal here is to demonstrate that Qnexa is effective in a statistically significant manner over the single agent alone.

Ilya Kravets:

Right. Okay, great. And then just one question on IP for Topamax. As far as you know, what is J&J's position on use patents for obesity, because they did try that product for obesity, and others who withdrew? So if – how big is the

chance of you infringing on it? Had there been any cross-licensing with J&J or anything of that sort?

Peter Tam:

The composition patent for Topamax expires around September of 2008, and we have not discussed any cross-licensing with J&J. We believe that we have the freedom to operate, and that by the time the product is available for commercialization, the composition patent will expire.

Ilya Kravets:

Right. So my question was for the use patent in obesity, as far as you know, you're not infringing at anything on that one?

Peter Tam:

Yeah. We are aware of the patent, and we are confident that we have the freedom to operate.

Leland Wilson:

Yes, Ilya, it's Lee. We actually have a written freedom to operate opinion.

Ilya Kravets:

Okay, wonderful. And just finally on that, the patent has been - the US patent has been issued and we can find it on I guess the PTO?

Peter Tam:

Yes. The patent – Just to be clear, Ilya, the patent has been allowed. It was allowed recently. We've paid the issue fee. We expect the issuance probably within the next month or so.

Ilya Kravets: Okay, great. Thank you very much, and once again congratulations.

Peter Tam: Thank you.

Operator: Your next question comes from Michael Tong.

15

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Michael Tong: Hi. Thanks for taking the question. The first question is, is there any liability or do you need to do additional safety studies for the use of phentermine in combination of other - in the presence of other active ingredients? Second question is, is there any ongoing follow-up studies on the Phase 2 to see whether you have reached the plateau for the weight loss, you know, post-24 weeks? And then finally, with the financing, Tim, can you remind us, you know, pro forma where your cash would be and what kind of burn would this Phase 3 program require?

Peter Tam: Yeah, Michael. There is some – You know, we talked to the FDA fairly extensively about both the pre-clinical as well as the clinical programs and we do have to do from combination safety studies in the animals, and these are short term studies. And with respect to clinical studies, the Phase 3 program will demonstrate the safety of this combination product over placebo. And in terms of your question about when will this drug plateau, we have not done a study long enough in a prospective manner to define when the plateauing phase will occur, so that's something that's going to have to be evaluated when we initiate our Phase 3 program.

Michael Tong: Okay. And as far as the cash position, Tim?

Timothy Morris: Yeah, Michael. If you just add the proceeds onto what we reported at the end of March, that puts our pro forma cash balance at around \$40 million. So we haven't changed our guidance yet. We will probably update people in our cash burn position during Analyst Day, but we're fairly comfortable with the proceeds that we have from this small financing and the cash that we have on hand. That will be sufficient to fund the study to the start of Phase 3. Again, we haven't given any guidance on the total cost of the program, but we're going to follow FDA guidelines there to have 1,500 enrolled for

16

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approximately one year. And I think we can also give some guidance on the total cost of the trial at the Analyst Day as well.

Michael Tong: Great. Thank you.

Operator: Your next question comes from Marc Robins.

Marc Robins: Lee, you bastard you. You know I have been punishing myself with this Merck trial.

I'm sorry, would you help me better understand the method of action of what these two drugs are doing so I can compare it to the Merck cannabinoid receptor inverse antagonist that I've been on?

Leland Wilson: Okay, Marc. Well thank you for the, I think, a compliment back...

Marc Robins: Yeah, it's a compliment.

Leland Wilson: All right. And yes, although I can answer your question, I think adequately, I'll turn it over to pharmacologist...

Marc Robins: And by the way since I've got calluses of being stuck as a guinea pig for Merck, I demand to be, you know, stuck as a guinea pig for VIVUS, so.

Leland Wilson: All right.

Marc Robins: Okay.

Leland Wilson: I'll let Wes handle, or Peter, whichever of you want.

17

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Marc Robins: Fair enough. I'm bigger than both, weight wise.

Peter Tam: Yeah, Mark, it's Peter. Good to see you recently.

Yeah, the interesting thing about this combination product Qnexa is the fact that it has two drugs and it works by two separate mechanisms of action. And we believe that the reason why people are overweight and obese is because there's a lack of control on both of these mechanisms that actually control feeding. The two major mechanisms that control feeding are hunger, you know, we get hunger and then we eat, and then we stop eating when we are full. That's why a lot of patients, they become obese because they cannot stop and they're constantly hungry and they tend to overeat a lot.

This compound or this product, Qnexa, affects both of these mechanisms. It can actually suppress appetite so people don't feel



hungry, and then they can stop eating very, very quickly after they get hungry, and a lot of patients in the trial actually mentioned that they feel full, you know after a short meal. So it works by both mechanisms and that's why we believe that this drug - this combination product is so effective.

Marc Robins: Well, the satiation seems to be similar to the drug that I'm on. And the thing that is worrisome, you spoke of tingling, but I've noted, and again this is a double-blind placebo so I'm only guessing that this will all be - I place money on it, is that it really has an emotional effect, the depressive effect on the subject. And I was wondering if you had witnessed or seen or had observed any of these in the patients at all, the trial patients at all.

Peter Tam: No, we didn't. I mean we used all sorts of measures to try to assess any depressive symptoms. We did not see anything in that regard. And as I want to remind you, Qnexa actually employs very low doses of these two drugs. So

18

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therapeutic windows demonstrated on the efficacy side is very large, in fact that we're using low doses bodes well for the safety aspect of it.

Marc Robins: The Phase 3 you said would be 1,500 patients for one year. That contrasted the 2,000 patients in two years from Merck, one year on the drug and then one year as follow-up. Any comment on why there might be a difference in the two studies?

Peter Tam: Yeah, the 1,500 patient is really the FDA's guidelines for anti-obesity treatment, that's 1,500 patients on active medication for one year. And in our negotiations and discussions with the FDA, the fact that this is a combination therapy using existing - low doses of existing approved drugs, they're comfortable with the one-year program.

Marc Robins: Okay, very good. Well, congratulations. Great news and keep up the good work. Thank you.

Peter Tam: Thanks, Marc.

Operator: Your next question comes from Jeff Goates.

Ian Sanderson: Hi, it's Ian Sanderson at Cowen and congratulations.

Leland Wilson: Thank you very much, Ian.

Ian Sanderson: Couple of questions, first on the out-licensing plans here, do you intend to run the Phase 3 trials yourself, or do you have some intention to potentially out-license this to a partner? Second, on the formulation issues, going from a BID to a QD dosing, you know, how challenging is that and is this a single-tablet combination as currently formulated?

19

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And then third, when might we see the full data from the Phase 2? Do you have some presentation plans here?

Leland Wilson: Okay. All right, so we're looking to each other to see which one will handle, which one of us. Peter, do you want to take one?

Peter Tam: Phase 3?

Leland Wilson: Okay.

Peter Tam: Or you want to - Yeah, so Phase 3 where we are is that, you know, we've not disclosed this data to any potential partners. You know, right now we have the recent round of financing that will help us get to the start of Phase 3, so anything can happen between now and then. But our plan given the exciting results, you know, we like to take this thing forward all the way through.

So that's one. But, it all depends on, you know, what partners offer up in terms of ways of licensing and co-development and so forth. So, you know, as a small company we're obviously open to these discussions.

Leland Wilson: BID to QD, Wes, do you want to take that one?

Wesley Day: We're not overly concerned with this hurdle. We have plans in place to develop a formulation which will address that, and there's no technical reason why we can't accomplish this goal.

Ian Sanderson: And is it currently a single tablet combination of these two?

20

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Leland Wilson: Yes, it's a twice-a-day capsule currently and we're going to make it a once-a-day.

Ian Sanderson: Okay.

Leland Wilson: And the last one is the release of data. You're going to get some more data at the Analyst Meeting, and then we will present this at

appropriate scientific forum, to be determined.

Ian Sanderson: Okay. And lastly, can you provide some perspective on why J&J halted its development of topiramate for obesity? Was it just low efficacy?

Peter Tam: No, you know, they've actually published several very good papers on Topamax for treating obesity. And, you know, my read of it is that they got good efficacy at higher doses, doses that also resulted in drop-out rate, high drop-rates as well as side effects. They've not been able to get the low doses to be, you know, effective with acceptable safety profile. What we've done here is that we've really broadened that therapeutic window by using low doses to achieve the efficacy that we've been able to achieve, and also escape the side effects that are related to the high doses of Topamax. The other interesting aspect of Topamax is that patients — and I don't know whether you've spoken with any patients on Topamax as an off-label treatment for obesity, patients continue to lose weight. That's one of the interesting characteristics of Topamax, and I think we're seeing that in our Phase 2 study.

Ian Sanderson: Thank you.

Operator: Your next question comes from Brant Jaouen.

Brant Jaouen: Hi, good morning guys.

21

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Peter Tam: Hey.

Brant Jaouen: A couple of quick questions for you. In your end of Phase 2 meeting, which I'm assuming was a meeting with the FDA in March, did you talk about bridging basically the safety data from the twice daily to the once daily? And, you know, what were their thoughts on this?

Peter Tam: Yeah, the meeting we had technically not an end of Phase 2 but it was really in that spirit, and they took it as a Type C meeting that provided us with really end of Phase 2 type of guidance. And, you know, they saw the data, they were impressed with the data, and it will be used as part of the safety package as well as efficacy for Qnexa going forward.

Brant Jaouen: Okay. And how long in terms of - I know phentermine is only approved for short-term use in weight loss. Is your plan to try to get a longer term type indication? Or how do you position this product?

Peter Tam: Yeah, Qnexa is a going to be a long-term therapy similar to rimonabant and similar to Xenical. It's not going to be indicated for the short-term treatment of obesity.

Brant Jaouen: Okay. And I don't know if you guys mentioned this earlier, but in terms of the way that you acquired this product, can you kind of walk us through whether there are some future royalty milestone payments included there?

Peter Tam: Yeah, there's a small milestone payment to be paid upon approval of the product.

Brant Jaouen: Who's that paid to?

22

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Peter Tam: And also a small royalty stream going forward.

Brant Jaouen: Who is that paid to?

Peter Tam: That's paid to the inventor, Dr. Thomas Najarian.

Brant Jaouen: Okay. Who's also now going to be VIVUS employee?

Peter Tam: That's correct.

Brant Jaouen: Okay. Those are all my questions.

Leland Wilson: Thank you.

Peter Tam: Thanks.

Operator: Your next question comes from Andy Kierman.

Andy Kierman: Yes. Hi. This is Andy Kierman with UBS.

Peter Tam: Hi, Andy.

Andy Kierman: Hi. This question is for Lee Wilson. Lee, I have been a shareholder since 2000-2001, and my question kind of relates to shareholder value. This drug seems to fit with your expertise in developing new drugs. And it would appear to me our company's income statement is being used for research and development expenses, in the sense that if we develop these drugs and they bring them to fruition, a larger pharmaceutical company doesn't have to incur those expenses. It would also appear to me that we're too small to

commercialize these drugs. And my question for you I guess is at the end of the day, how do we make sure as VIVUS shareholders that we get adequately compensated in the event of partnership or a joint venture that would happen?

Leland Wilson: Well, I think VIVUS' track record in creating corporate deals is outstanding. I think we are even well recognized for the deals that we did both with J&J and with ASTRA for MUSE<sup>®</sup>, and one of the things that I am very proud of is our ability to negotiate sound corporate partnership.

Now, having said that, we look for - to achieve the best possible value for not only shareholders but employees as well for each of these products.

As you know, Andy, one of the challenges out there is that the bigger companies that have the money tend to make some of the rules here. So you have to be very good at negotiating sound deals. We have all seen many companies that have licensed their jewel technology out without enough payment coming back in to sustain their development program, and they ultimately end in an acquisition often by their partner company for what I would consider to be not adequate payments for the technology that they have. So it is - You got your finger right on the challenges that all companies have in becoming a full-pledged pharmaceutical company. It's one that I think we're very capable of managing.

Andy Kierman: Yeah, I mean I guess I would just add that with Evamist right around the corner that I just - I don't feel like the company's market cap is indicative of being fairly valued at this point.

Leland Wilson: We agree 100%. And so it's one of the reasons why we're having an Analyst Day so that people can talk to our investigators. I can tell you that patients are extremely excited about Evamist. You may know from previous conference

calls that I am the internal product champion for Evamist. This is a remarkable advancement in the delivery of estrogen. Estrogen as you know has gone through the ups and downs WHI, etc., and now the Nurses' study and all the information has gone out on the news, but I can tell you that after having come through all that, the estrogen market is again healthy, and the number of patients we believe is increasing, is going to increase rather dramatically over the next several years. So look for good things out of Evamist.

Leland Wilson: Next question please.

Operator: Yes. Your next question comes from Steve Brozak.

Steve Brozak: Hey, congratulations, gents. This is exciting news here.

Leland Wilson: Thanks, Steve.

Steve Brozak: I know that the numbers that you are talking about are really small, but have you seen any kind of physiological differences and response given the patient profiles and things like that? Anything that - any kinds of trends that you would look at that, you know, would offer you interesting information? I know that you haven't had enough time to cherry-pick the data yet, but I'm kind of curious about it.

Peter Tam: No. I mean it is, you know, in the grand scheme of things in terms of getting a drug approved, this is a relatively small study and that's why it's a Phase 2 study. No, we looked at the data in terms of baseline characteristics. There is no predictor that we can see that would discriminate between a responder from a non-responder. What's interesting is that there are - there really aren't any non-responders in the Qnexa group. There are those who lost a

tremendous amount of weight, like about 70 pounds in a very short period of time, versus those who lost about 10 pounds. So, you know, the degree of weight loss varies from patient to patient. And in terms of whether there's a patient characteristic or baseline characteristic that would predict responders, that's something we're going to have to find out in larger studies.

Steve Brozak: Now, the patient pool that you're dealing with is one that probably is, you know, not in the healthiest of shapes to begin with. And, you know, in terms of other drugs that you're looking at that they may be on, what kind of interaction did you notice if any at all or was it, you know, a completely safe profile?

Leland Wilson: Yeah, you know, part of Dr. Najarian's earlier work with Qnexa or this combination treatment, he was able to treat patients with this. And interestingly, again these are, you know, observations from his patients, patients with what we call really metabolic syndrome - patients with diabetes, hypertension, dyslipidemia - they all have been able or many of them have been able to reduce, if not completely eliminate, those medications retreating these co-morbidities associated with obesity. One of the things that is quite exciting about this combination is that in particular, Topamax or topiramate, one of the components in Qnexa, has other pharmacologic effects with respect to treating hypertension, with respect to improving diabetes and so forth. So we're going to be looking at those co-morbidities going forward, because there's some exciting stuff going on here.

Steve Brozak: Wow, this comes as close to a silver bullet as you can ask for. Okay, congratulations again, gentlemen.

Leland Wilson: Thank you.

26

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Peter Tam: Thank you.

Operator: Your next question comes from Stuart Weisbrod.

Jeffrey Shatman: Hi, it's Jeffrey Shatman. How are you? A couple of questions. Maybe you covered it; I wasn't tuned in the whole time. But why release the intent-to-treat data and not the per-protocol?

Peter Tam: There are, you know, essentially three cuts of the data. There is the intent-to-treat, the modified intent-to-treat, and the completer. The most rigorous one is really the intent-to-treat analysis. And we're going to be disclosing more data at the Analyst Day, so I don't know what else to tell you. If there is a specific question you have with regard to other population, I'll be happy to take them.

Jeffrey Shatman: Also, do you have data on this drug alone without the benefit of diet?

Peter Tam: Not in this study. The 500-kilocalorie restriction diet is a typical diet that the FDA as well as the EMEA would like to see as part of their protocol. They want to see some behavioral modification as part of the studies, and that's what we incorporated. We didn't ask these patients to go on a severely calorie restricted diet. We didn't ask patients to go on an exercise program. We try to mimic the real world, and that is if somebody wants to lose weight, they going to have to try to eat a little bit less, and in terms of 500 calories, that's probably about a hamburger less a day. It's not a significant behavior modification. We just want to make the protocol mimic what's going to happen in the real world.

Jeffrey Shatman: But they could have done more severe diet restriction, right? I mean so...

Leland Wilson: Yes, yes.

27

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Peter Tam: Yeah. I mean that's why we do a placebo-controlled study. I mean the delta, the difference in weight loss between the placebo group and the Qnexa group is about 20 pounds, and if you look at the rimonabant Phase 3 study, their North American study as well as a European study, they only lost about 10 pounds over a one-year period. And in our six-month study, or 24 week study, we lost – you know, again, this is not a head-to-head study – we lost twice the weight in half the time. Jeff?

Operator: You're next question comes from Ilya Kravets.

Ilya Kravets: Hi, guys. I think you mentioned this but I missed it. The royalty payments and milestone payments related to Qnexa, can you just quickly go through that?

Peter Tam: There's a milestone associated with the complete - I'm sorry, not completion but the approval of the drugs, so that goes out to, you know, hopefully around 2010 is when we're expecting approval for this product. And then there's this small royalty stream, single digit, low single-digit royalty stream associated with this.

Ilya Kravets: Okay, great. Thank you.

Peter Tam: Uh-huh.

Operator: At this time, there are no further questions. I'll now turn the call over to Mr. Lee Wilson for any closing remarks.

Leland Wilson: Well, obviously some very good questions today and I thank you for that, and please join us for our Analyst Day session where we'll have time to go through this in greater detail. As I said earlier, rarely in a person's life do they get a chance to have a product which really is as exciting as Qnexa. And we

28

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are very blessed at VIVUS to have this. And thank you all for listening today and we look forward to working with you to bring this product forward.

Thanks a million.

Operator: Thank you. This concludes today's conference call. You may now disconnect.

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29

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