

**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)  
**March 8, 2017**

**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.)

**900 E. HAMILTON AVENUE, SUITE 550  
CAMPBELL, CA 95008**  
(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 2.02. Results of Operations and Financial Condition**

On March 8, 2017, VIVUS, Inc., or the Company, conducted a conference call during which members of its senior management team discussed financial results for the fourth quarter and year ended December 31, 2016, a business update and certain other information. A copy of the transcript of the conference call is furnished herewith 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 Company'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. Fourth Quarter and Year Ended December 31, 2016 Earnings Conference Call on March 8, 2017, at 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/ John L. Slebir

John L. Slebir

Senior Vice President, Business Development and General Counsel

Date: March 13, 2017

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of VIVUS, Inc. Fourth Quarter and Year Ended December 31, 2016 Earnings Conference Call on March 8, 2017, at 1:30 p.m. PT.

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**VIVUS, Inc.****2016 Fourth Quarter and Full Year Financial Results and Business Update Teleconference****08-March-2017, 04:30pm EST/01:30pm PST****Operator:**

Good day, ladies and gentlemen, and welcome to the VIVUS 2016 Fourth Quarter and Full Year Financial Results and Business Update.

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. If anyone should require assistance during the conference, please press star then zero on your touchtone telephone. As a reminder, this conference is being recorded.

I would like to introduce your host for today's conference, Mr. Mark Oki, Chief Financial Officer. Sir, you may begin.

**Mark Oki, Chief Financial Officer:**

Thank you, Operator. Good afternoon everyone and welcome to today's teleconference. Joining me today is Seth Fischer, VIVUS' Chief Executive Officer. In addition, Dr. Santosh Varghese, VIVUS' Chief Medical Officer, will be available for the question-and-answer portion of this call. During this 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, estimate, expect, forecast, intend, likely, may, opportunity, plan, potential, predict 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 actual events to differ materially from those indicated by such forward-looking statements. Investors are advised to read the risk factors set forth in the VIVUS Form 10-K for the year ended December 31, 2016 as filed earlier today.

VIVUS does not undertake an obligation to update or revise any forward-looking statements made on this call.

I will now turn the call over to Seth Fischer, Chief Executive Officer, to provide a business update.

**Seth Fischer, Chief Executive Officer:**

Thank you, Mark. Good afternoon and thank you for joining us. On today's call, I will update you on our business strategy evaluation, provide an update on our avanafil efforts and our Qsymia commercialization activities.

VIVUS has a history and core strength of developing product candidates through clinical testing and FDA approval. We have put ourselves in position to be able to explore acquiring value-creating development stage assets as we shape the VIVUS business model.

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In January 2017, we entered into a worldwide license agreement with Selten Pharma, Inc. for tacrolimus and ascomycin for the treatment of pulmonary arterial hypertension, or PAH, and related vascular diseases.

PAH is a chronic life-threatening disease characterized by elevated blood pressure in the pulmonary arteries, those arteries between the heart and lungs, due to severe constriction of these blood vessels. These high pressures make it difficult for the heart to pump blood through the lungs to be oxygenated, ultimately leading to heart failure. The prevalence of PAH varies among specific populations, but it is estimated at between 15 to 50 cases per million adults and usually develops between the ages of 20 and 60, but can occur at any age with a mean age of diagnosis around 45 years.

According to a February 2016 LifeSci Capital analysis, in 2015 the worldwide and U.S. markets for PAH pharmaceutical treatments exceeded \$4.5 billion and \$2.7 billion, respectively. The current medical therapies for PAH aim to reduce symptoms and improve quality of life. All currently approved products treat the symptoms of PAH, but do not address the underlying disease. Currently, lung transplantation is the only option for patients who are not responsive to current medical therapy.

It is believed that bone morphogenic protein receptor 2, or BMPR2, signaling inhibits vascular smooth muscle proliferation. Reduced BMPR2 expression, including loss-of-function mutations in BMPR2, is prevalent in PAH patients and may contribute to smooth muscle proliferation in the pulmonary arteries. It is also believed that reduced BMPR2 expression increases the susceptibility of vascular endothelial cells to apoptosis. Studies have shown that low doses of tacrolimus have restored BMPR2 signaling. We believe that enhancements of BMPR2 signaling with tacrolimus may address a fundamental cause of PAH.

As part of the agreement, Selten assigned to us its license to a group of patents owned by the Board of Trustees of Stanford University. We are responsible for future financial obligations to Stanford under that license.

We have assumed full responsibility for the development and commercialization of the licensed compounds. Selten received an upfront payment of \$1.0 million and will receive additional milestone payments based on global development status and future sales milestones, as well as tiered royalty payments on future sales of these compounds. The total potential milestone payments are \$39 million.

Stanford completed a randomized, double-blind Phase 2a trial with 23 class 1 and 2 PAH patients titrated to our target blood levels. All target blood levels were well tolerated with no drug related serious adverse events, nephrotoxicity or incident diabetes. In addition, Stanford provided tacrolimus for compassionate use in three class 3 or 4 PAH patients. The compassionate use demonstrated reduced rates of hospitalizations and functional class improvements were observed.

For 2017, our goals for this program will be to develop or in-license a proprietary formulation for tacrolimus and have a pre-IND meeting with FDA to obtain an IND and identify a potential clinical pathway to approval. In addition, we are focused on identifying additional product candidates to build our product pipeline.

Now moving onto avanafil, we believe that our collaboration partners are well positioned to take advantage of STENDRA's 15-minute of onset, high selectivity, resulting in lower side effects, and ability to be taken with food and drink, that uniquely addresses unmet needs among the patients being treated with competitive products.

We continue to work closely with Menarini, our commercial alliance partner in Europe, Australia and New Zealand, and Sanofi, our commercial alliance partner in Africa, the Middle East, Turkey and the CIS countries to ensure the supply of avanafil and provide assistance with their clinical, regulatory and commercial efforts. SPEDRA, as avanafil is known in the EU and other parts of the world, is available in Europe at retail pharmacies in approximately 30 countries within the Menarini territory. Menarini has also secured the commercial rights from Mitsubishi Tanabe Pharma Corporation for certain parts of Asia.

On September 30, 2016, we entered into a license and commercialization agreement and a commercial supply agreement with Metuchen Pharmaceuticals LLC. Metuchen received an exclusive license to develop, commercialize and promote STENDRA in the United States, Canada, South America and India for which we received an upfront license fee of \$70 million. We will not benefit from royalties on future sales in the Metuchen territories, but will be reimbursed for payments made to cover royalty and milestone obligations to Mitsubishi Tanabe based on U.S. sales. Metuchen will obtain STENDRA exclusively from us, however, Metuchen may elect to transfer the control of the supply chain for STENDRA for its territory to itself or its designee by assigning to Metuchen our agreements with the contract manufacturer.

We are exploring our options to maximize the value of STENDRA commercial rights to territories we have yet to partner, specifically Mexico and Central America.

On January 3, 2017, we entered into a settlement agreement with Hetero of the lawsuit brought by us in response to Hetero's filing of an Abbreviated New Drug Application, or ANDA. Under the settlement agreement, we granted Hetero a license to manufacture and commercialize the generic version of STENDRA described in its ANDA filing in the United States effective no sooner than October 29, 2024. The Settlement Agreement provides for a full settlement of all claims that were asserted in the suit, subject to the Court's acceptance of the stipulation of dismissal. As required by law, the Settlement Agreement will be submitted to the U.S. Federal Trade Commission and U.S. Department of Justice.

Now let's move on to an update on Qsymia. In the fourth quarter of 2016, the U.S. anti-obesity pharmaceutical market declined by 7% when compared to the third quarter of 2016, while the branded anti-obesity segment, including Qsymia, declined by 10%.

We are aware of significantly higher promotional spending in the branded anti-obesity sector beginning in December of 2016 and expect our commercial spending to increase in the first quarter of 2017 as compared to the fourth quarter of 2016 as well. We believe this additional noise in the market place may drive growth in the total branded anti-obesity market, including Qsymia.

On June 3, 2016, we launched our upgraded Qsymia Patient Savings Offer to bring more new patients into the — into brand and support their weight loss effort for the long term. Since its inception, nearly 50,000 unique patients have enrolled in the new savings program, 80% of which have gone on to the pharmacy to obtain their Qsymia prescription. Among all patients currently using the savings program, 63% have continued onto two or more refills with the average number of refills at three prescriptions.

Our digital campaign continues to provide potential patients with relevant and compelling Qsymia communications when they are the most motivated to start a weight loss effort. In the fourth quarter of 2016, consumers increasingly continued to seek out Qsymia brand and savings offer information. Quarter over quarter, organic traffic to the Qsymia website resulted in a 13% increase in consumers enrolling in the Savings Program.

On July 20th, the United States District Court for the District of New Jersey issued a claim construction, or Markman, ruling governing patent litigation brought by VIVUS against Teva and Dr. Reddy's. The lawsuits were filed in response to ANDAs filed by both Teva and Dr. Reddy's. In the ruling, the courts adopted VIVUS' proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to VIVUS for the final claim term. The next phase of the ongoing litigation with Teva will be expert discovery. The Dr. Reddy's case remains in fact discovery. Trial dates have not been scheduled in either case.

As we have discussed in the past, we have a post-marketing requirement for Qsymia to perform a cardiovascular outcome trial, or CVOT. To date, there have been no indications throughout the Qsymia clinical development program nor post-marketing experience of any increase in adverse cardiovascular events. Given this historical information, along with the established safety profiles of phentermine and topiramate, we continue to believe that Qsymia poses no true cardiovascular safety risk.

We have been in dialog with FDA, most recently in a face-to-face meeting, to discuss alternative strategies for obtaining cardiovascular, or CV, outcomes data that would be substantially more feasible and ensure timely collection of data to better inform on the CV safety of Qsymia. This current effort is focused on

providing FDA with additional CV safety data by conducting a retrospective observational study evaluating CV outcomes associated with Qsymia, phentermine and topiramate. Although we and consulted experts believe there is no overt signal for CV risk to justify the CVOT, we are committed to working with FDA to reach a resolution. There is no assurance, however, that FDA will accept any data or measures short of those specified in the CVOT to satisfy this requirement.

I will now turn the call back to Mark to discuss our financial results for the quarter and year ended December 31, 2016. I also refer you to the financial results and recent business updates included in our press release issued earlier today and our Annual Report on Form 10-K filed earlier today.

**Mark Oki, Chief Financial Officer:**

Thank you, Seth. Total revenue was \$81.8 million and \$124.3 million for the quarter and year ended December 31, 2016, respectively, and \$15.3 million and \$95.4 million during the same periods in 2015.

In the fourth quarter of 2016, we recognized revenue of \$69.4 million from the license of STENDRA to Metuchen in the U.S., Canada, South America and India.

Qsymia net product revenue was approximately \$11.0 million and \$48.5 million for the quarter and year ended December 31, 2016. These amounts represent approximately 100,000 and 442,000 prescriptions, respectively. Net revenue per prescription, excluding free trial offers, was approximately \$121 and \$124 for the 2016 fourth quarter and full year.

For 2015, Qsymia net product revenue was \$14.0 million and \$54.6 million for the fourth quarter and full year, respectively. These amounts represent approximately 132,000 and 566,000 prescriptions, respectively. Net revenue per prescription, excluding free trial offers, was approximately \$124 and \$117 for the 2015 fourth quarter and full year.

As a reminder, we record revenue for the sales of Qsymia on a sell-through model, whereby revenue is recognized when a prescription is dispensed to a patient. As of December 31, 2016, our deferred revenue related to gross sales of Qsymia was \$17.6 million, which represents product shipped to the wholesalers but not yet dispensed to patients.

Avanafil — avanafil supply revenue was \$765,000 and \$2.3 million for the quarter and year ended December 31, 2016, respectively, and \$23,000 and \$26.7 million during the same periods in 2015, respectively. The variations in supply revenue are a result of the timing of orders placed by our partners and may or may not reflect end user demand for STENDRA and SPEDRA. Avanafil tablets currently have a 48-month expiration date.

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Royalty revenue earned on our partners' net sales of avanafil was \$594,000 and \$4.1 million for the quarter and year ended December 31, 2016, respectively, and \$1.4 million and \$2.6 million for the quarter and year ended December 31, 2015. Full year 2015 results were impacted by a change in estimates made by Endo upon their purchase of Auxilium, reducing 2015 full year royalty revenue by \$1.2 million. Beginning in the fourth quarter of 2016, we no longer receive royalty revenue from net sales of STENDRA in the U.S. as a result of our licensing agreement with Metuchen.

Total cost of goods sold, excluding inventory impairment, was \$2.2 million and \$10.6 million for the quarter ended December 31, 2016, respectively, and \$2.6 million and \$34.2 million in the same periods in 2015. Gross margin percentages, as a percent of net Qsymia product revenue and net avanafil supply revenue, were 81% and 79% for the quarter and year ended December 31, 2016, respectively, and 81% and 58% during the same periods in 2015. The change in gross margin percentages were primarily due to the mix of sales between Qsymia and avanafil.

Total selling and marketing expense was \$3.8 million and \$21.8 million for the quarter and year ended December 31, 2016, respectively, and \$8.6 million and \$53.0 million during the same periods in 2015. The decrease in 2016 was primarily due to the realignment of our sales force, refinement of our marketing and promotional programs, and continued cost control initiatives.

General and administrative expense was \$9.3 million and \$30.6 million for the quarter and year ended December 31, 2016, respectively, and \$5.0 million and \$26.4 million during the same periods in 2015. In 2016, our general and administrative costs include Qsymia litigation expenses, one-time expenses related to the licensing of STENDRA to Metuchen, expenses related to our business strategy review and the move of our corporate headquarters to Campbell, California. Going forward, our general and administrative expenses will fluctuate based on activity within our business strategy — business strategy review and litigation activity.

Total research and development expense was \$1.8 million and \$5.6 million for the quarter and year ended December 31, 2016, respectively, and \$3.3 million and \$10.1 million during the same periods in 2015. The variance was primarily due to the timing of clinical projects to support our Qsymia post-marketing requirements. We expect that our research and development expenses to increase in 2017 as we continue to support Qsymia post-marketing requirements and begin development of tacrolimus. Research and development expenses could significantly increase should we add additional product candidates.

Cash, cash equivalents and available-for-sale securities totaled \$269.5 million at December 31, 2016, as compared to \$241.6 million at December 31, 2015. The increase was due primarily to cash received from Metuchen's licensing of STENDRA offset by the cash used in operating activities and debt service requirements.

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I will now turn the call to Seth for closing comments.

**Seth Fischer, Chief Executive Officer:**

Thank you, Mark.

For 2017, we are excited for the opportunity to utilize our strong cash position for the acquisition and development of a new product pipeline to drive value creation for our stockholders while addressing the unmet needs of patients. We have engaged Aquilo Partners to assist us in identifying, evaluating and acquiring pipeline products.

Additional areas of focus for VIVUS in 2017 are to advance our PAH development program, including the development of a proprietary formulation of tacrolimus and having a pre-IND meeting with FDA to obtain an IND and identify a potential clinical pathway to approval; continue to efficiently monetize Qsymia in the U.S. and seek to monetize Qsymia and avanafil outside of the U.S.; defend our Qsymia intellectual property rights; advance our efforts to address, in a cost-effective manner, the remaining Qsymia regulatory post-marketing requirements; address and potentially reduce our outstanding debt balances; and effectively manage our cost structure.

We will now take your questions.

**Operator:**

Thank you. [*Operator Instructions*]

And our first question comes from Caroline Palomeque from Wallach Beth Capital. Your line is open.

**Caroline Palomeque, Wallach Beth Capital:**

Hi, thanks for taking the question. Just wondering just about the commercial strategy going forward. You just hired a new Chief Commercial Officer, I'm just wondering what the new marketing or promotional strategy will be just the next — in the next quarter or two. Yes, that's my question?

**Seth Fischer, Chief Executive Officer:**

Yes. So just for background, Deborah Larsen has been with the company for now well over a year and she was just recently promoted to Chief Commercial Officer, so it's really a promotion. As far as the commercial strategy, I believe you're primarily talking about Qsymia. We will continue to commercialize the product and we believe that we've right-sized the organization for what we believe will allow us to continue to drive sales where there are key prescribers in the U.S. for the product as well as competitive prescribing.

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**Caroline Palomeque, Wallach Beth Capital:**

Okay. Thank you.

**Seth Fischer, Chief Executive Officer:**

Yep.

**Operator:**

[*Operator Instructions*]

And I'm showing no questions at this time.

**Seth Fischer, Chief Executive Officer:**

Well, thank you again for calling in today, and we look forward to updating you in the future.

**Operator:**

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the program. You may now disconnect. Everyone have a great day.

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