# 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) May 3, 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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

### Item 2.02. Results of Operations and Financial Condition

On May 3, 2017, VIVUS, Inc., or the Company, conducted a conference call during which members of its senior management team discussed financial results for the first quarter ended March 31, 2017, 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.

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# 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

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# EXHIBIT INDEX

Description

Number Transcript of VIVUS, Inc. First Quarter Ended March 31, 2017 Earnings Conference Call on May 3, 2017, at 1:30 p.m. PT. 99.1

Date: May 8, 2017

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### VIVUS, Inc. 2017 First Quarter Financial Results and Business Update Teleconference 03-May-2017, 04:30pm EST/01:30pm PST

## Operator

Good day, ladies and gentlemen, and welcome to the VIVUS 2017 First Quarter Financial Results and Business Update Teleconference. (*Operator Instructions*)

As a reminder, this teleconference is being recorded.

And now, I'll turn the program over to Mr. Mark Oki, Chief Financial Officer.

## Mark K. Oki - VIVUS, Inc. — 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 on March 8, 2017 and as amended by Form 10-K/A filed on April 26, 2017, as well as periodic reports filed with the Securities and Exchange Commission. 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 to provide a business update.

## Seth H. Z. Fischer - VIVUS, Inc. — Chief Executive Officer

Thank you, Mark, and 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 as well as our Qsymia commercialization activities.

VIVUS has a history and core strength of development 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 reshape the VIVUS business model.

We are working closely with Aquilo Partners to identify and evaluate potential product development candidates. Our goal is to add one or two clinical stage product candidates to our pipeline by the end of 2017, which could come in the form of a license, a co-development agreement, a merger or acquisition, or some other form.

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. 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.

Stanford completed a randomized double-blind Phase 2a trial with tacrolimus in 23 Class 1 and 2 PAH patients titrated to 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. We have assumed full responsibility for the development and commercialization of the licensed compounds.

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.

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.

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 Metuchen Pharmaceuticals, our commercial alliance partner in the U.S., Canada, South America and India, 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.

In March of this year, the commercial rights for avanafil in Africa, the Middle East, Turkey and the Commonwealth of Independent States, including Russia, were returned to us by Sanofi. To avoid adverse impacts to the regulatory approval applications in process, specifically in Russia and certain Middle East countries, Sanofi will provide transition services to assist us in the regulatory process. We are excited to have this asset back from Sanofi and are in the process of finding a commercial partner who can fully exploit the commercial potential of avanafil in these territories as well as in 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.

Now let me provide a Qsymia commercial update.

In the first quarter of 2017, the U.S. anti-obesity pharmaceutical market increased by 8%, when compared to the fourth quarter of 2016, while the branded anti-obesity segment, including Qsymia, increased by 14%. These increases were due to the seasonality of the anti-obesity market and the significantly higher promotional spending in the branded anti-obesity sector, primarily by our competitors, which began in December of 2016. We believe this additional noise in the marketplace may have driven growth in the total branded anti-obesity market, including Qsymia.

Our Qsymia digital campaign has leveraged the increase in consumer and patient interest in the branded anti-obesity category during the first quarter of 2017. Qsymia website traffic and Savings Card downloads have increased significantly, achieving volume not seen since the first quarter of 2015 at the height of the branded market. Currently, 90% of all new Savings Cards acquired online are patients who are new to the Qsymia brand. We believe this is due to our highly targeted digital strategy and exposure to the Qsymia efficacy message on the brand website when patients are the most motivated to start a weight loss effort.

In July 2016, 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

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claim terms and adopted a compromised 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've discussed in the past, we have a post-marketing requirement for Qsymia to perform a cardiovascular outcomes trial, or CVOT. To date, there have been no indications throughout the Qsymia clinical development program nor a 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 dialogue with FDA 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. 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 first quarter of 2017. I also refer you to the financial results and recent business updates included in our press release issued earlier today and our quarterly report on Form 10-Q filed earlier today.

### Mark K. Oki - VIVUS, Inc. — Chief Financial Officer

Thank you, Seth.

Total revenue was \$27 million and \$15.3 million for the first quarters of 2017 and 2016, respectively. Qsymia net product revenue was approximately \$17.6 million and \$12.4 million for the first quarters of 2017 and 2016, respectively.

In the first quarter of 2017, we changed our revenue recognition methodology for Qsymia sales from a sell-through model to a sell-in model. This change resulted in the recognition of \$7.3 million of net revenue for product that was shipped to wholesalers prior to January 1, 2017. During the first quarter of 2017 and 2016, approximately 102,000 and 116,000 Qsymia prescriptions were disbursed, respectively. Net revenue per prescription, excluding free trial offers, was approximately \$122 and \$125 for the first quarters of 2017 and 2016, respectively.

Beginning in the first quarter of 2017, due to the change in our revenue recognition methodology for Qsymia, revenue recognized is based on units shipped into the wholesaler rather than the number of prescriptions filled in the period. In the first quarter of 2017, we shipped approximately 89,000 units of Qsymia to the wholesalers. The change to the sell-in revenue recognition model could result in higher volatility of Qsymia sales compared to those historically reported.

In the first quarter of 2017, we also recognized revenue related to a one-time \$5 million payment for a license to certain clinical data.

Avanafil supply revenue was \$3.8 million and \$1.5 million for the first quarters of 2017 and 2016, respectively. The variations in supply revenue are a result of the timing of orders placed by our partners that may or may not reflect end-user demand for STENDRA and SPEDRA. Avanafil tablets currently have a 48-month expiration date.

Royalty revenue earned on our partners' net sales of avanafil was \$580,000 and \$1.4 million for the first quarters of 2017 and 2016, respectively. As a reminder, 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 was \$6.2 million and \$3.7 million for the first quarters of 2017 and 2016, respectively. Qsymia gross margin percentages were 85% and 83% for the first quarters of 2017 and 2016, respectively.

Total selling and marketing expense was \$5.5 million and \$7.6 million for the first quarters of 2017 and 2016, respectively. The decrease in 2017 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 \$6 million and \$7.5 million for the first quarters of 2017 and 2016, respectively. Going forward, our general and administrative expense will fluctuate based on activity within our business strategy review and litigation activity.

Total research and development expense was \$2.2 million and \$1 million for the first quarters of 2017 and 2016, respectively. Research and development expenses in 2017 included a \$1 million expense from the upfront payment made to Selten for tacrolimus and ascomycin. We expect our research and development expenses to increase in 2017 as we continue to support our Qsymia post-marketing requirements and continue development of tacrolimus for PAH. Research and development expenses could increase significantly should we add product candidates to our portfolio.

Cash, cash equivalents and available-for-sale securities totaled \$260.2 million at March 31, 2017, as compared to \$269.5 million at December 31, 2016. The decrease was primarily due to losses from operations and debt servicing requirements.

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

## Seth H. Z. Fischer - VIVUS, Inc. — 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.

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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?

### **Question and Answer Session**

**Operator** (Operator Instructions)

Your first question comes from the line of Harold Weber from Aegis Capital. Your line is open.

## Harold Weber, Aegis Capital

I have a question for you in regard to STENDRA. What are we doing to try to let's say raise the consciousness of this product versus the competitors — Viagra, Cialis, just like that? I mean, this product is a very fine product. I happened to go to a physician and he recommended it versus the others, but it doesn't seem like it's getting much uptake, and I'm trying to understand why and what we could do about it. I think that there's a very large market for it.

## Seth H. Z. Fischer - VIVUS, Inc. — Chief Executive Officer

Well, thank you. The — STENDRA, as you know, in the U.S., we licensed to Metuchen Pharmaceuticals, so they're really responsible for all the sales and marketing of the product. And as you know, they took it over from Endo and are currently really ramping up all their resources to better market the product for the future.

## Harold Weber, Aegis Capital

So, you think that they are, at this point, making a serious commitment to start marketing the product more substantially, more nationally?

# Seth H. Z. Fischer - VIVUS, Inc. — Chief Executive Officer

Yes, Metuchen, I can tell you, is very dedicated to the success of the product.

# Harold Weber, Aegis Capital

I mean, this product, I think should be making us a crap load of money. And so far, it's just not — I just don't see it. And the medical community from what I hear is very pleased with it, so I would think the uptake should be a lot better.

#### Seth H. Z. Fischer - VIVUS, Inc. — Chief Executive Officer

Yes, and there's been a number of different transitions with the product over the last several years, but we're very confident in Metuchen's ability to really boost the product in the future.

#### Harold Weber, Aegis Capital

And as far as selling the licensing overseas, what's your — where are we holding with that?

#### Seth H. Z. Fischer - VIVUS, Inc. — Chief Executive Officer

Well, we just recently received the rights back. Menarini has the rights in Europe. The rest of the world rights we're currently in the process of looking for the proper partner for that product.

#### Harold Weber, Aegis Capital

Do you believe that at some time in the not too distant future we're going to have another partner for the rest of the countries that are not covered presently?

#### Seth H. Z. Fischer - VIVUS, Inc. — Chief Executive Officer

Yes, right now, we're early in that process, so we're entertaining different parties.

#### Harold Weber, Aegis Capital

Okay, and in regard to the new biologicals we're trying to bring to the market, any idea about that and what kind of expenses we're going to incur on this this year?

### Seth H. Z. Fischer - VIVUS, Inc. — Chief Executive Officer

This year — This year expenses should be minimal. But the most important thing is to really understand the trial design, which will be important in our meeting, our IND meeting, which will happen later this year.

#### Harold Weber, Aegis Capital

OK, thanks, Seth.

# Seth H. Z. Fischer - VIVUS, Inc. — Chief Executive Officer

Thank you.

#### Operator

There are no further questions in the queue at this time. I'll turn the call back over to Seth Fischer, Chief Executive Officer.

## Seth H. Z. Fischer - VIVUS, Inc. — Chief Executive Officer

Well, thank you again for all of you attending today, and we look forward to keeping you updated in the future. Have a good evening.

## Operator

This concludes today's business update teleconference. You may now disconnect.