

**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)

August 4, 2016

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.)

**351 EAST EVELYN AVENUE
MOUNTAIN VIEW, CA 94041**
(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 August 4, 2016, VIVUS, Inc., or the Company, conducted a conference call during which members of its senior management team discussed financial results for the second quarter ended June 30, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Transcript of VIVUS, Inc. Second Quarter Ended June 30, 2016 Earnings Conference Call on August 4, 2016, 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: August 9, 2016

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EXHIBIT INDEX

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VIVUS, Inc.
2016 Second Quarter Financial Results and Business Update Teleconference
4-August-2016, 04:30pm EST/01:30pm PST

Operator:

Good day, ladies and gentlemen, and welcome to the VIVUS 2016 Second Quarter Financial Results and Business Update Teleconference.

At this time, all participants are in listen-only mode. Later, we will conduct a question-and-answer session and instructions will follow at that time. If anyone should require operator assistance during the call, you may press star then zero on your touchtone telephone. As a reminder, this teleconference is being recorded. And now I'll turn the program over to Mr. Mark Oki, Chief Financial Officer.

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. During the 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, 2015 as filed on March 9, 2016, and as amended by the Form 10-K/A filed on April 22, 2016, and periodic reports filed with the Securities and Exchange Commission such as in the VIVUS Form 10-Q filed earlier today.

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

I will now turn the call over to Seth Fischer to provide a business update.

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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 Qsymia commercialization activities, and provide some perspective on the obesity pharmacotherapy market.

In January, we engaged an advisor to assist us in an evaluation of our business strategy, most importantly, the disposition of the commercialization rights for STENDRA. In late 2015, Auxilium/Endo notified us of their intention of returning STENDRA to us effective June 30, 2016. We recently announced that we and Endo agreed to delay the transition of STENDRA back to us until August 31, 2016.

We have worked closely with Endo and our consultants to understand STENDRA's commercialization history, the competitive landscape in the erectile dysfunction, or ED, market, how STENDRA's clinical profile fits into this landscape, and the market potential of STENDRA when actively promoted.

We learned that the ED market is promotionally sensitive and when STENDRA is actively promoted, supported by digital and print advertising, STENDRA was able to significantly increase its market share. However, when the promotion ends, it quickly loses any gains made.

In interviews with healthcare providers that treat ED, we learned that STENDRA's 15-minute of onset, the high selectivity of STENDRA resulting in lower side effects, the ability to be taken with food and drink, and STENDRA's lower pricing uniquely addresses unmet needs among the patients being treated with competitive products.

We believe that STENDRA's proven responsiveness to active promotion demonstrates its revenue potential and when commercialized through an efficient sales and marketing program, can deliver significant value to the organization. We are concurrently preparing to commercialize STENDRA in the U.S. while maintaining discussions to license or sell STENDRA's U.S. commercialization rights. On September 1, when the U.S. commercial rights are returned to us, we or a third party will assume STENDRA's promotion activities from Auxilium.

Our business strategy review has also outlined the importance of building a diverse company with a pipeline portfolio. As a result, we are exploring opportunities to drive stockholder value through identifying both commercial and development stage products that leverage our know-how and infrastructure.

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We continue to work closely with Menarini, our commercial alliance partner in Europe, and Sanofi, our commercial alliance partner in the Middle East, Africa 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 25 countries within the Menarini territory. Menarini has also secured the commercial rights from Mitsubishi Tanabe for certain parts of Asia.

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

On June 30, 2016, we received notice from Hetero USA Inc. that it has filed an Abbreviated New Drug Application, or ANDA, with the FDA for generic versions of all strengths of STENDRA tablets. The notice from Hetero included a paragraph IV certification with respect to all of the patents listed for STENDRA in the FDA's Orange Book on the date of the Company's receipt of the notice. A paragraph IV certification is a certification by a generic applicant that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product.

On June 27th, under provisions of the Hatch-Waxman Act, we filed a patent infringement suit against Hetero. With this filing, a stay of approval of up to 30 months will be imposed by the FDA on Hetero's ANDA. We intend to vigorously enforce our intellectual property rights, but we cannot predict the outcome of this matter.

In the second quarter of 2016, the U.S. anti-obesity pharmaceutical market grew by 6% when compared to the first quarter of 2016, largely fueled by phentermine generics. During this same period, the U.S. branded anti-obesity segment, including Qsymia, remained flat.

On June 3rd, we launched our upgraded Qsymia Patient Savings Offer to bring more new patients into the brand and support their weight loss effort for the long term. In the new program, all new patients are eligible to receive a \$95 benefit at their first prescription of Qsymia. It may be used for a 14-Day Free Trial of the Starting Dose or \$95 savings for a 30-day supply of any dose. A subsequent monthly savings of \$65 will continue for an extended savings benefit up to 36 months.

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Our digital campaign is designed to direct informed consumers to productive Qsymia writers. Our enhanced web-based strategies continue to deliver clear and compelling communications to potential patients when they are the most motivated to start a weight-loss effort. In the second quarter of 2016, the Qsymia site has seen a 22% increase in repeat visitors versus the same period of 2015. Repeat visitors prove to be highly motivated to initiate Qsymia therapy as one in five download the Qsymia Savings Offer in preparation for starting their weight-loss effort after visit to a physician.

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 Actavis and Teva. The lawsuits were filed in response to ANDAs filed by both Actavis and Teva. In these applications, Actavis and Teva seek to market and sell a generic version of the currently approved doses of Qsymia capsules prior to the expiration of U.S. Patents listed in the FDA's Orange Book. There are 10 VIVUS patents asserted in the litigation, the last of which expires in 2029. VIVUS filed the lawsuits on the basis that Actavis' and Teva's proposed generic products infringe the VIVUS patents. 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 Actavis will be expert discovery. The Teva case remains in fact discovery. No trial date has 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.

Representatives from VIVUS met with FDA in May 2015 to discuss alternative strategies for obtaining CV outcomes data that would be substantially more feasible, and ensure timely collection of data to better inform on the CV safety of Qsymia. As a part of addressing the FDA comments from this meeting, we are now working with cardiovascular and epidemiology experts in exploring alternate solutions to demonstrate the long-term cardiovascular safety of Qsymia. This current effort is focused on the conduct of a retrospective observational study to evaluate 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, VIVUS is committed to working with FDA to reach a resolution. There is no assurance, however, that FDA will accept any measures short of those specified in the CVOT to satisfy this requirement. As for the EU, even if FDA were to accept alternatives to a traditional CVOT, there would be no assurance that EMA would accept the same.

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I will now turn the call back to Mark to discuss our financial results for the quarter ended June 30, 2016. 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 Oki, Chief Financial Officer:

Thank you Seth. Total revenue was \$13.8 million in the second quarter of 2016, compared to \$23.0 million in the second quarter of 2015.

Qsymia net product revenue was \$12.7 million and \$14.0 million for the second quarters of 2016 and 2015, respectively. These amounts represent approximately 116,000 and 152,000 prescriptions for the second quarters of 2016 and 2015, respectively, of which approximately 63.9% and 64.0% represent either a free or discounted offer, respectively. Net revenue per prescription, excluding free trial offers, was approximately \$126 and \$114 for the second quarters of 2016 and 2015, respectively.

As a reminder, we record revenue for sales of Qsymia on a sell-through model, whereby revenue is recognized when a prescription is dispensed to a patient. As of June 30, 2016, our deferred revenue related to gross sales of Qsymia was \$18.0 million, which represents product shipped to the wholesalers but not yet dispensed to patients.

Avanafil supply revenue was nil and \$8.1 million for the second quarters of 2016 and 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 currently has a 48-month expiration date.

Royalty revenue earned on our partners' net sales of avanafil was approximately \$1.0 million and \$0.9 million in the second quarters of 2016 and 2015, respectively. As Seth mentioned previously, U.S. and Canadian STENDRA commercial rights will return to us on September 1, 2016. As a result, we will not receive royalty revenue from the U.S. for STENDRA moving forward without entering into a new licensing agreement.

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Total cost of goods sold was \$2.6 million and \$9.9 million for the second quarters of 2016 and 2015, respectively. Gross margin percentages (as a percentage of net Qsymia product revenue and net avanafil supply revenue) were 79.2% and 55.4% for the second quarters of 2016 and 2015. The change in gross margin percentages were primarily due to the sales mix between Qsymia and avanafil during the periods.

Total research and development expense was \$1.1 million and \$2.6 million for the second quarters of 2016 and 2015, respectively. The variance was primarily due to the timing of clinical projects to support our Qsymia post-marketing requirements. During the second quarter of 2016, we focused our efforts on the development and feasibility assessment of our Qsymia retrospective cohort study, the Qsymia adolescent pharmacokinetic/pharmacodynamics study, and the protocol development of our Qsymia adolescent efficacy and safety study.

Total selling and marketing expense was \$6.0 million and \$15.3 million for the second quarters of 2016 and 2015, respectively. The decrease in 2016 was due primarily to the realignment of our sales force, refinement of our marketing and promotional programs, and cost control initiatives implemented in 2015.

General and administrative expense was \$7.7 million and \$6.9 million for the second quarters of 2016 and 2015, respectively. The increase was primarily due to higher Qsymia litigation expenses.

Cash, cash equivalents and available-for-sale securities totaled \$220.2 million at June 30, 2016, as compared to \$241.6 million at December 31, 2015. The decrease was due primarily to cash used in operating activities and debt service requirements.

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

Seth Fischer, Chief Executive Officer:

Thank you, Mark.

We at VIVUS remain confident in our two approved products. STENDRA's 15-minute onset of action, high selectivity resulting in lower side effects, ability to be taken with food and drink, and STENDRA's lower pricing uniquely addresses unmet needs of ED patients.

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We are equally prepared to commercialize STENDRA ourselves, utilizing our existing infrastructure or licensing the rights to a third party, whichever provides the greatest benefits to patients, healthcare providers and our stockholders.

Obesity continues to be a healthcare epidemic in the U.S. and around the world. Qsymia provides patients and their healthcare providers with a proven first line once-a-day therapeutic option. Obese patients using the standard dose of Qsymia along with diet and exercise on average lose 10% of their body weight, 24 pounds and four inches off their waist. In the June 14, 2016 edition of JAMA, an article was published evaluating the efficacy and safety profiles of five currently marketed anti-obesity medications using a systematic review and meta-analysis. The study concluded that Qsymia was one of two therapies within the entire therapeutic class that was associated with the highest odds of achieving at least 5% weight loss. The publication again underscores Qsymia's strong efficacy and safety profile.

The areas of focus for VIVUS for the second half of 2016 are to: ensure a smooth transition of STENDRA from Endo; if we choose to self-commercialize, to integrate STENDRA into our current commercial infrastructure in an efficient and effective manner; maximize the value of the avanafil commercialization rights for Canada, Latin America and India; manage our avanafil alliances with Menarini and Sanofi to help ensure the commercial success of this important erectile dysfunction medication around the world; continue to compete effectively in the anti-obesity market by highlighting the benefits of Qsymia for this population; advance our efforts to address in a cost-effective manner the remaining Qsymia regulatory post-marketing requirements; evaluate potential in-licensing opportunities to build our portfolio of products and product candidates; and effectively manage our cost structure.

We are now happy to take your questions.

Question and Answer Session

Operator:

(Instructions). Our first question comes from the line of Jessica Fye with JP Morgan. Your line is now open

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Ryan on for Jessica Fye — JP Morgan:

Hey guys, this is Ryan on for Jess. Appreciate you taking the question. I guess given that we are approaching the transition date for STENDRA, can you talk a little bit more about — are you preparing the sale, your sales force to train to market the drug yourself, or how do we think about sort of the timelines for self-commercialization versus waiting for securing a partnership?

Seth Fischer, Chief Executive Officer:

We are moving down the path to commercialize the product on our own, but also running down a parallel path as part of a strategic process to look at bringing on a potential out-license partner, and those are both actually running parallel, so we are in fact training our own people along with running the other process.

Ryan in for Jessica Fye — JP Morgan:

OK, and can you give us any updates about the communication timelines for discussing with the FDA sort of the design for the CVOT study?

Seth Fischer, Chief Executive Officer:

So the discussions with FDA are actually ongoing, so they're not necessarily face-to-face. There's been correspondences going both ways between us and FDA over the last several months, and when we believe that there's something to further update the market on, we will definitely do that.

Ryan in for Jessica Fye — JP Morgan:

OK, thank you very much.

Operator:

Thank you and I'm not showing any further questions at this time. I would now like to hand the call back to Mr. Seth Fischer, Chief Executive Officer, for closing remarks.

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Seth Fischer, Chief Executive Officer:

Thank you, Operator, and thank you all for calling in today and we will look forward to updating you in the future.

Operator:

Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program and you may all disconnect. Everyone have a great day.

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