UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)
November 7, 2017

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 November 7, 2017, VIVUS, Inc., or the Company, conducted a conference call during which members of its senior management team discussed financial results for the third quarter ended September 30, 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.

Exhibit No.	Description
99.1	Transcript of VIVUS, Inc. Third Quarter Ended September 30, 2017 Earnings Conference Call on November 7, 2017, at 1:30 p.m. PT.

EXHIBIT INDEX

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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

Date: November 13, 2017

VIVUS, Inc.
2017 Third Quarter Financial Results and Business Update Teleconference
07-November-2017, 04:30 ET/01:30 PT

Operator

Good afternoon and welcome to the VIVUS third quarter 2017 financial results conference call. Today's call is being recorded. For introductions and opening remarks, I'd like to turn the call over to Mark Oki, VIVUS' Chief Financial Officer. Please go ahead.

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

Thank you, operator. Good afternoon everyone, and welcome to today's teleconference. Joining me on the call today are Seth Fischer, VIVUS' Chief Executive Officer, and Dr. Santosh Varghese, VIVUS' Chief Medical Officer, who will be participating in the question-and-answer portion of this call.

Before we get started, I would like to remind everyone that during this conference call, we may 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 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 thank you all for joining us. During today's call, I will provide an update on recent developments with our product development pipeline as well as our portfolio of marketed products. Mark will then review our financial results for the third quarter of 2017, after which we will be happy to take questions.

I will begin with an update on tacrolimus, an exciting pipeline opportunity that we are developing for the treatment of pulmonary arterial hypertension, or PAH. 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 PAH therapies treat the symptoms of the disease, but do not address the underlying disease. Currently, lung transplantation is the only option for patients who are not responsive to current medical therapy, and new therapies that address the underlying cause of disease are urgently needed. VIVUS licensed tacrolimus from Selten Pharma in January 2017, and we are developing a proprietary formulation of tacrolimus for the treatment of PAH.

We believe that our proprietary formulation of tacrolimus will have substantial clinical and commercial potential in PAH. Additionally, the previous approval of tacrolimus in other indications by the U.S. Food and Drug Administration, or FDA, provides a significant body of safety data that we believe will help to decrease the risk of developing this molecule for the treatment of PAH.

As background, the FDA approved tacrolimus in 1994 for use in lowering the risk of organ rejection in patients undergoing kidney transplant, and it is currently indicated for use in additional organ transplant settings and to treat atopic dermatitis. Tacrolimus has been shown to increase signaling through the bone morphogenetic protein receptor 2 (BMPR2) pathway, which is down-regulated in PAH patients. Consequently, if successful, tacrolimus would provide a wholly new mechanism of action that could address the underlying molecular cause of this debilitating and progressive disease.

There is also promising clinical data that support the potential of tacrolimus in the treatment of PAH. The results of a completed study were published in September in the *European Respiratory Journal*. The study was a randomized, double-blind, Phase 2a trial with tacrolimus in 23 Class 1 and 2 PAH patients titrated to target blood levels. The study was conducted in a population of patients who were highly treated, with approximately 50% of subjects on triple PAH therapy and 25% on dual therapy.

Patients in the tacrolimus arms of the study were started on 1.5 mg of oral tacrolimus and then had their doses adjusted to achieve one of three tacrolimus target blood levels. Investigators noted that even the high level of tacrolimus in this study is not typically targeted for immunosuppression, as it has only mild immunosuppressive effects. The primary objective of the study was to demonstrate the safety and tolerability of tacrolimus and to demonstrate the feasibility of targeting different low-dose tacrolimus ranges. Adverse events, vital signs, serum creatinine, hemoglobin and white blood cell counts were used to assess safety and tolerability.

Key findings from the study were as follows:

- Blood draw results suggest a favorable and narrow range of bioavailability with low-level tacrolimus in PAH patients.
- All doses of tacrolimus were well tolerated. Nausea and/or diarrhea was the most common side effect, occurring in 11 patients, most of which were in the medium or high-dose tacrolimus arms.

- Four patients experienced fluid retention/edema, which was mild to moderate in intensity and transient in duration, resolving without limitation of or changes to diuretic regimens.
- One patient experienced hemoptysis as a serious adverse event that was determined to be most likely not related to tacrolimus.
- No side effects associated with immunosuppressive doses of tacrolimus were observed during the study period, nor were cardiovascular events, worsening of PAH symptoms or hospitalization of PAH.
- Dose-dependent increases in BMPR2 were observed, although these changes did not reach statistical significance in this small sample population.

The study investigators concluded that these results support the evaluation of tacrolimus in a Phase 2b efficacy study in PAH patients, and we are working to advance our proprietary formulation of tacrolimus into the clinic. Toward that end, we held a pre-IND meeting with the FDA in October. During the meeting, The FDA addressed VIVUS' questions related to preclinical, nonclinical and clinical data and planned design of clinical trials of tacrolimus in class III and IV PAH patients, and clarified the requirements needed to file an IND to initiate a clinical trial in this indication. VIVUS is on track to file this IND in the first half of 2018. As discussed with the FDA, VIVUS currently intends to design and conduct clinical trials that could qualify for Fast Track and/or Breakthrough Therapy designation.

Now let me provide an update on our marketed products.

During the third quarter, we achieved several important objectives related to Qsymia, our prescription product for weight management.

In July and August 2017, we announced settlement agreements with Actavis Laboratories and Dr. Reddy's Laboratories, and Dr. Reddy's Laboratories, Inc. resolving patent litigation related to Qsymia. The litigation resulted from the submissions of Abbreviated New Drug Applications, or ANDA, by Actavis and Dr. Reddy's seeking approval to market generic versions of Qsymia. The settlement agreements permit Actavis and Dr. Reddy's to begin selling a generic version of Qsymia on December 1, 2024 and June 1, 2025, respectively, or earlier under certain circumstances. In the event of a launch earlier than these dates, VIVUS will receive a royalty on net sales of the generic version of Qsymia.

We are pleased to have concluded all patent litigation that we have brought in the context of generic availability of Qsymia. We believe that the settlements related to this ligation underscore the strength of our intellectual property around Qsymia and demonstrate our commitment to defending our existing patents for all our products and technologies.

In September 2017, we announced an agreement under which Alvogen Malta Operations will market Qsymia in South Korea for the treatment of chronic weight management or weight-related conditions. Alvogen will be solely responsible for obtaining and maintaining regulatory approvals and for all sales and marketing activities in South Korea. VIVUS received a $2.5 million upfront payment and is eligible to receive addition to future milestone payments. In addition, VIVUS will receive royalties on Alvogen's net sales of Qsymia.

Alvogen has manufacturing centers in South Korea and hundreds of products on the market in Asia, and Alvogen has the expertise and relationships that we believe will be essential for making Qsymia a success in South Korea. Our agreement with Alvogen supports our ongoing efforts to maximize the value of our current assets, and we look forward to engaging in a strategic partnership with Alvogen to realize the Qsymia opportunity in South Korea.

As for STENDRA/SPEDRA, we are in discussions to license the commercial rights to avanafil in Russia and the CIS countries, the Middle East and North Africa as well as Mexico and Central America territories. We are also working with Sanofi to obtain regulatory approval to commercialize avanafil in Russia, Saudi Arabia and other countries within CIS and MENA.

Going forward, we intend to continue our efforts to make the most effective use of our capital resources to realize additional value from our marketed products, seek additional marketed products, and expand our product development pipeline. We will evaluate a variety of deal structures that have the potential to create long-term value for our stockholders, including licensing agreements, asset purchases, co-development and/or co-promotion agreements, and potential M&A activity.

Tacrolimus is an example of the type of pipeline expansion opportunities that we are seeking. As a company with demonstrated clinical development and commercialization expertise, our strategy is to identify and develop high-potential molecules that have compelling safety and promising efficacy data, and transform them into proprietary products that enable significant advances in patient care and outcomes. We continue to have a goal of adding a product candidate by end of this year.

At this time, I'll turn the call over to Mark for a review of our third-quarter financial results.

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

Thank you, Seth.

Net loss for the third quarter of 2017 was $6.0 million, as compared to $9.2 million in the third quarter of 2016. Cash, cash equivalents and available-for-sale securities were $236.0 million at the end — at September 30, 2017.

Total revenue for the third quarters of 2017 and 2016 was $15.2 million and $13.4 million, respectively. Revenue consisted of the following:

Qsymia net product revenue was $10 million in the third quarter of 2017, compared to $12.3 million in the same period last year.

Beginning in the first quarter of 2017, with 48 months of returns experience, we believed that we had sufficient data and experience from selling Qsymia to reasonably estimate expected returns. As a result, we changed our revenue recognition methodology for Qsymia sales from a "sell-through" methodology to a "sell-in" methodology.

Approximately 97,000 and 109,000 Qsymia prescriptions were dispensed in the third quarters of 2017 and 2016, respectively. In the third quarter of 2017, we shipped approximately 92[1] units of Qsymia to the wholesalers. As wholesalers continued to reduce their Qsymia inventory levels, we recognized approximately $500,000 less Qsymia net revenue under the “sell-in” methodology than would have been recognized under the “sell-through” methodology. The “sell-in” methodology could continue to result in higher volatility of Qsymia sales as wholesalers adjust inventory levels compared to those historically reported.

As Seth mentioned, we entered into a license agreement with Alvogen for commercial rights to Qsymia in South Korea. We recognized $2.5 million of licensing revenue in the third quarter of 2017 related to this agreement.

STENDRA/SPEDRA supply revenue was $2.1 million in the third quarter 2017 compared to no revenue in the same period in 2016. Supply revenue is based on the timing of orders placed by our partners, Menarini and Metuchen, and may or may not represent actual demand for STENDRA/SPEDRA.

SPEDRA royalty revenue was $649,000 in the third quarter 2017 compared to $1.1 million in the same period in 2016. This decrease was the result of no longer earning royalties on U.S. sales of STENDRA beginning in the fourth quarter of 2016.

Total cost of goods sold was $3.5 million and $2.1 million in the third quarters of 2017 and 2016, respectively. The increase was primarily a result of higher STENDRA/SPEDRA supply revenue during the quarter.

Research and development expense was $0.9 million and $1.7 million in the third quarters of 2017 and 2016, respectively. Research and development expenses were impacted by a decrease in efforts surrounding our Qsymia post-marketing regulatory requirements partially offset by development efforts of tacrolimus for the treatment of PAH.

General and administrative expense was $5.6 million and $6.0 million for the third quarters of 2017 and 2016, respectively, while selling and marketing expense for the commercialization of Qsymia totaled $2.8 million and $4.4 million in the third quarters of 2017 and 2016, respectively. The decreases were due to continued cost control initiative and the result of the realignment of our sales force and refinement of our marketing and promotional programs.

[1] Speaker intended to say 92,000 units

That concludes my remarks today. Operator, you may now open the line for the question and answer period.

Operator

Thank you. [*Operator* instructions].

And if there are no further questions, I would like to turn the line back to Seth Fischer for closing remarks.

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

Thank you, Operator, and thank you for your time today. As always, we are pleased to share our progress with you and look forward to providing additional updates in the months ahead as we advance our development and commercial portfolios. We are particularly excited about the progress we are making in advancing tacrolimus into clinical development and with our potential opportunities to expand our development pipeline. Every day we strive to meet our goals of improving patient quality of life and giving healthcare providers new treatment options that are significant advances over current therapies. I believe that we are more strongly positioned than ever before to achieve this vision, and I know that we have the expertise, insight and dedication to create value for patients and our shareholders.

Thank you to everyone on the call for participating. Talk to you soon.

Operator

And that does conclude today’s call. All parties may now disconnect. Everyone have a great day.