# 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 3, 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 August 3, 2017, VIVUS, Inc., or the Company, issued a press release regarding its financial results for the second quarter ended June 30, 2017, a business update and certain other information. The full text of the press release concerning the foregoing 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 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 | Press Release issued by VIVUS, Inc. dated August 3, 2017. |



**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 3, 2017



**EXHIBIT INDEX**

| Number | Description |
|---|---|
| 99.1 | Press Release issued by VIVUS, Inc. dated August 3, 2017. |

**VIVUS REPORTS SECOND QUARTER 2017 FINANCIAL RESULTS**

CAMPBELL, CA., August 3, 2017 - VIVUS, Inc. (NASDAQ: VVUS; the "Company"), a biopharmaceutical company committed to the development and commercialization of innovative therapies focusing on treatments for patients with serious unmet medical needs, today reported financial results for the quarter ended June 30, 2017 and provided a business update.

"During the second quarter, we made important progress in ramping up development of tacrolimus, our lead clinical candidate, which we believe has significant potential in treating pulmonary arterial hypertension, and we remain on track to hold a pre-IND meeting with FDA in the second half of this year," said Seth H. Z. Fischer, VIVUS' Chief Executive Officer. "VIVUS is dedicated to addressing the urgent therapeutic needs of patients with serious medical conditions and life-limiting diseases. We continue to evaluate opportunities to obtain additional product candidates that have the potential to radically improve patient care and outcomes."

**Recent Business Highlights and Upcoming Events**

- In May 2017, VIVUS announced the appointment of Thomas B. King to its board of directors.
- In July 2017, VIVUS announced a settlement agreement with Actavis Laboratories FL (Actavis) resolving patent litigation related to Qsymia®. The litigation resulted from the submission by Actavis of an Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration seeking approval to market generic versions of Qsymia. The settlement agreement permits Actavis to begin selling a generic version of Qsymia on December 1, 2024, or earlier under certain circumstances. In the event of a launch earlier than December 1, 2024, VIVUS will receive a royalty on Actavis' sales of the generic version of Qsymia.
- Seth H. Z. Fischer, VIVUS' Chief Executive Officer, will present at the 2017 Wells Fargo Healthcare Conference, taking place September 6th and 7th in Boston, MA. Mr. Fischer's presentation will be accessible via webcast and accessible in the events and presentations section of the Company's investor relations website, or by clicking here.

**Financial Results**

Total revenue, net for the second quarters of 2017 and 2016, was $11.2 million and $13.8 million, respectively. Revenue consisted of the following:

| | Three Months Ended June 30, | |
|---|---|---|
| | 2017 | 2016 |
| Qsymia, net product revenue | $ 8,518 | $ 12,749 |
| STENDRA/SPEDRA supply revenue | 2,119 | — |
| STENDRA/SPEDRA royalty revenue | 590 | 1,027 |
| Total revenue | $ 11,227 | $ 13,776 |



Beginning in the first quarter of 2017, with 48 months of returns experience, VIVUS believes that it has sufficient data and experience from selling Qsymia to reliably estimate expected returns. As a result, VIVUS changed its revenue recognition methodology for Qsymia sales from a "sell-through" methodology to a "sell-in" methodology.

Approximately 105,000 and 116,000 Qsymia prescriptions were dispensed in the second quarters of 2017 and 2016, respectively. In the second quarter of 2017, VIVUS shipped approximately 83,000 units of Qsymia to the wholesalers as wholesalers reduced their Qsymia inventory levels. VIVUS recognized approximately $2.3 million less Qsymia 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.

Total cost of goods sold was $3.6 million and $2.6 million in the second 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 $1.0 million and $1.1 million in the second quarters of 2017 and 2016, respectively. Research and development expenses were impacted by a decrease in efforts surrounding our Qsymia regulatory requirements partially offset by development efforts of tacrolimus for the treatment of pulmonary arterial hypertension.

General and administrative expense was $6.2 million and $7.7 million for the second quarters of 2017 and 2016, respectively, while selling and marketing expense for the commercialization of Qsymia totaled $5.4 million and $6.0 million in the second quarters of 2017 and 2016, respectively. The decreases were due to the continued cost control initiative and the result of the realignment of our sales force, and refinement of our marketing and promotional programs.

Net loss for the second quarter of 2017 was $13.4 million, as compared to $11.4 million in the second quarter of 2016. Cash, cash equivalents and available-for-sale securities were $251.5 million at June 30, 2017.

**Additional Information**

The Company will not host a conference call for the quarter ended June 30, 2017 and will resume quarterly conference calls surrounding financial results for the quarter ended September 30, 2017. The Company's financial statements and related footnotes will be available in its Quarterly Report on Form 10-Q for the three and six months ended June 30, 2017, which was filed with the U.S. Securities and Exchange Commission earlier today.

**About Qsymia**

Qsymia is approved in the U.S. and is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of 30 $kg/m^2$ or greater (obese) or 27 $kg/m^2$ or greater (overweight) in the presence of at least one weight-related medical condition such as high blood pressure, type 2 diabetes, or high cholesterol.

The effect of Qsymia on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established.



**Important Safety Information**

Qsymia® (phentermine and topiramate extended-release) capsules CIV is contraindicated in pregnancy; in patients with glaucoma; in hyperthyroidism; in patients receiving treatment or within 14 days following treatment with monoamine oxidase inhibitors; or in patients with hypersensitivity to sympathomimetic amines, topiramate, or any of the inactive ingredients in Qsymia.

Qsymia can cause fetal harm. Females of reproductive potential should have a negative pregnancy test before treatment and monthly thereafter and use effective contraception consistently during Qsymia therapy. If a patient becomes pregnant while taking Qsymia, treatment should be discontinued immediately, and the patient should be informed of the potential hazard to the fetus.

The most commonly observed side effects in controlled clinical studies, 5% or greater and at least 1.5 times placebo, include paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth.

**About Avanafil**

STENDRA® (avanafil) is approved in the U.S. by the FDA for the treatment of erectile dysfunction. Metuchen Pharmaceuticals LLC has exclusive marketing rights to STENDRA in the U.S., Canada, South America and India.

STENDRA is available through retail and mail order pharmacies.

SPEDRA™, the trade name for avanafil in the EU, is approved by the EMA for the treatment of erectile dysfunction in the EU. VIVUS has granted an exclusive license to the Menarini Group through its subsidiary Berlin-Chemie AG to commercialize and promote SPEDRA for the treatment of erectile dysfunction in over 40 European countries plus Australia and New Zealand.

Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation (MTPC). VIVUS owns worldwide development and commercial rights to avanafil for the treatment of sexual dysfunction, with the exception of certain Asian-Pacific Rim countries. VIVUS is in discussions with other parties for the commercialization rights to its remaining territories.

For more information about STENDRA, please visit www.STENDRA.com.

**Important Safety Information**

STENDRA® (avanafil) is prescribed to treat erectile dysfunction (ED).

Do not take STENDRA if you take nitrates, often prescribed for chest pain, as this may cause a sudden, unsafe drop in blood pressure.

Discuss your general health status with your healthcare provider to ensure that you are healthy enough to engage in sexual activity. If you experience chest pain, nausea, or any other discomforts during sex, seek immediate medical help.



STENDRA may affect the way other medicines work. Tell your healthcare provider if you take any of the following; medicines called HIV protease inhibitors, such as ritonavir (Norvir®), indinavir (Crixivan®), saquinavir (Fortavase® or Invirase®) or atazanavir (Reyataz®); some types of oral antifungal

medicines, such as ketoconazole (Nizoral®), and itraconazole (Sporanox®); or some types of antibiotics, such as clarithromycin (Biaxin®), telithromycin (Ketek®), or erythromycin.

In the rare event of an erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including STENDRA) reported a sudden decrease or loss of vision. It is not possible to determine whether these events are related directly to these medicines or to other factors. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including STENDRA, and call a doctor right away.

Sudden decrease or loss of hearing has been rarely reported in people taking PDE5 inhibitors, including STENDRA. It is not possible to determine whether these events are related directly to the PDE5 inhibitors or to other factors. If you experience sudden decrease or loss of hearing, stop taking STENDRA and contact a doctor right away. If you have prostate problems or high blood pressure for which you take medicines called alpha blockers or other anti-hypertensives, your doctor may start you on a lower dose of STENDRA.

Drinking too much alcohol when taking STENDRA may lead to headache, dizziness, and lower blood pressure.

STENDRA in combination with other treatments for ED is not recommended.

STENDRA does not protect against sexually transmitted diseases, including HIV.

The most common side effects of STENDRA are headache, flushing, runny nose and congestion.

Please see full patient prescribing information for STENDRA (50 mg, 100 mg, 200 mg) tablets.

**About VIVUS**

VIVUS is a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs. For more information about the Company, please visit www.vivus.com.

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to potential change in our business strategy to enhance long-term stockholder value, including the evaluation of development opportunities; risks and uncertainties related to our ability to successfully commercialize Qsymia; risks and uncertainties related to our ability to successfully develop or acquire a proprietary formulation of tacrolimus as a precursor to the clinical development process; risks and uncertainties related to our ability to identify, acquire and develop new product pipeline candidates; risks and uncertainties related to our ability to develop a proprietary formulation and to demonstrate through clinical testing the quality, safety, and efficacy of our current or future investigational drug candidates; risks and uncertainties related to the timing, strategy, tactics and success of the commercialization of STENDRA (avanafil) by our sublicensees; risks and uncertainties related to our ability to



successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with MTPC in which we do not have a commercial collaboration; risks and uncertainties related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; and risks and uncertainties related to our ability to protect our intellectual property and litigation in which we are involved or may become involved. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should 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 the Form 10-K/A filed on April 26, 2017, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

**VIVUS, Inc.**
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**Investor Relations: Lazar Partners**
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**VIVUS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
**(In thousands, except per share data)**
**(Unaudited)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| Revenue: | | | | |
| Net product revenue | $ 8,518 | $ 12,749 | $ 26,138 | $ 25,161 |
| License and milestone revenue | — | — | 5,000 | — |
| Supply revenue | 2,119 | — | 5,931 | 1,526 |
| Royalty revenue | 590 | 1,027 | 1,170 | 2,413 |
| Total revenue | 11,227 | 13,776 | 38,239 | 29,100 |
| | | | | |
| Operating expenses: | | | | |
| Cost of goods sold | 3,570 | 2,647 | 9,737 | 6,351 |
| Research and development | 1,014 | 1,096 | 3,194 | 2,125 |
| Selling, general and administrative | 11,630 | 13,692 | 23,061 | 28,814 |
| Total operating expenses | 16,214 | 17,435 | 35,992 | 37,290 |
| | | | | |
| Income (loss) from operations | (4,987) | (3,659) | 2,247 | (8,190) |
| | | | | |
| Interest expense and other expense, net | 8,398 | 7,735 | 16,700 | 15,896 |
| Loss before income taxes | (13,385) | (11,394) | (14,453) | (24,086) |
| Provision for income taxes | 1 | 7 | (11) | 23 |
| Net loss | $ (13,386) | $ (11,401) | $ (14,442) | $ (24,109) |
| | | | | |
| Basic and diluted net loss per share | $ (0.13) | $ (0.11) | $ (0.14) | $ (0.23) |
| Shares used in per share computation: | | | | |
| Basic and diluted | 105,712 | 104,126 | 105,596 | 104,099 |



**VIVUS, INC.**
**CONDENSED CONSOLIDATED BALANCE SHEETS**
**(In thousands)**

| | June 30, 2017 (Unaudited) | December 31, 2016* |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 76,406 | $ 84,783 |
| Available-for-sale securities | 175,115 | 184,736 |
| Accounts receivable, net | 8,441 | 9,478 |
| Inventories | 15,628 | 16,186 |
| Prepaid expenses and other assets | 5,333 | 8,251 |
| Total current assets | 280,923 | 303,434 |
| Property and equipment, net | 670 | 788 |
| Non-current assets | 1,198 | 1,554 |
| Total assets | $ 282,791 | $ 305,776 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 4,384 | $ 4,707 |
| Accrued and other liabilities | 20,357 | 15,686 |
| Deferred revenue | 1,694 | 19,174 |
| Current portion of long-term debt | 24,601 | 8,708 |
| Total current liabilities | 51,036 | 48,275 |
| Long-term debt, net of current portion | 220,183 | 232,610 |
| Deferred revenue, net of current portion | 5,732 | 6,449 |
| Non-current accrued and other liabilities | 369 | 257 |
| Total liabilities | 277,320 | 287,591 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock and additional paid-in capital | 833,349 | 831,855 |
| Accumulated other comprehensive loss | (382) | (616) |
| Accumulated deficit | (827,496) | (813,054) |
| Total stockholders' equity | 5,471 | 18,185 |
| Total liabilities and stockholders' equity | $ 282,791 | $ 305,776 |

* The Condensed Consolidated Balance Sheets have been derived from the Company's audited financial statements at that date, as adjusted.