
**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):

- ☐ 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))

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 ☐

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. ☐

Item 2.02. Results of Operations and Financial Condition

On May 3, 2017, VIVUS, Inc., or the Company, issued a press release regarding its financial results for the first quarter ended March 31, 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 May 3, 2017.

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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: May 3, 2017

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EXHIBIT INDEX

Number	Description
99.1	Press Release issued by VIVUS, Inc. dated May 3, 2017.

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VIVUS REPORTS 2017 FIRST QUARTER FINANCIAL RESULTS

VIVUS Focuses on its Strategic Initiative to Acquire New Product Pipeline

CAMPBELL, CA., May 3, 2017 - VIVUS, Inc. (NASDAQ:VVUS; the “Company”), a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs, today reported its financial results for the quarter ended March 31, 2017 and provided a business update. Net loss for the 2017 first quarter was \$1.1 million, as compared to a net loss of \$12.7 million in the first quarter of 2016. Cash, cash equivalents and available-for-sale securities were \$260.2 million at March 31, 2017.

“We continue our efforts to reshape VIVUS’ business model,” said Seth H. Z. Fischer, VIVUS’ Chief Executive Officer. “We have begun the formulation phase of our development program for tacrolimus as a treatment of Pulmonary Arterial Hypertension and expect to submit our request for a pre-IND meeting with FDA in the second half of 2017.”

Mr. Fischer continued, “In addition, we are evaluating other product development opportunities to utilize our cash resources, which could come in the form of a license, a co-development agreement, a merger or acquisition or other form.”

Business Update

- In March 2017, VIVUS reacquired the commercial rights for STENDRA in Africa, the Middle East, Turkey and the Commonwealth of Independent States, including Russia, from Sanofi.
- In March 2017, VIVUS engaged Aquilo Partners to assist us with our strategic process in identifying, evaluating and acquiring new product pipeline programs.
- In January 2017, VIVUS acquired exclusive, worldwide rights for the development and commercialization of tacrolimus and ascomycin for the treatment of Pulmonary Arterial Hypertension (PAH) and related vascular diseases from Selten Pharma, Inc. 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 January 2017, VIVUS granted a license to Hetero to manufacture and commercialize the generic version of STENDRA described in Hetero’s ANDA filing in the United States effective no earlier than October 29, 2024.
- In January 2017, VIVUS promoted Deborah Larsen to the newly created position of Chief Commercial Officer.

Financial Results

Total revenue, net for the first quarters of 2017 and 2016, was \$27.0 million and \$15.3 million, respectively. Revenue consisted of the following:

	Three Months Ended	
	March 31,	
	2017	2016
Qsymia, net product revenue	\$ 17,620	\$ 12,412
License and milestone revenue	5,000	—
STENDRA/SPEDRA supply revenue	3,812	1,526
STENDRA/SPEDRA royalty revenue	580	1,386
Total revenue	\$ 27,012	\$ 15,324

In the first quarter of 2017, we changed our revenue recognition methodology for Qsymia sales from a “sell-through” method to a “sell-in” method. This change resulted in the Company recognizing \$7.3 million of net product revenue related to units of Qsymia shipped prior to January 1, 2017.

Approximately 102,000 and 116,000 Qsymia prescriptions were dispensed in the first quarters of 2017 and 2016, respectively. Due to our switch to a “sell-in” model, revenue will be based on units shipped to the wholesaler rather than prescriptions dispensed in a given period. In the first quarter of 2017, we shipped approximately 89,000 units of Qsymia to the wholesalers. The “sell-in” 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 \$5.0 million payment for a license to certain clinical data.

Total cost of goods sold, excluding inventory impairment, was \$6.2 million and \$3.7 million in the first quarters of 2017 and 2016, respectively. The change in cost of goods sold was due to changes in net product and supply revenue in the respective periods and the sales mix between Qsymia and STENDRA/SPEDRA.

General and administrative expense was \$6.0 million and \$7.5 million for the first quarters of 2017 and 2016, respectively. The decrease was primarily due to VIVUS’ continued cost control efforts.

Selling and marketing expense for the commercialization of Qsymia totaled \$5.5 million and \$7.6 million in the first quarters of 2017 and 2016, respectively. The total decrease was the result of the realignment of our sales force, refinement of our marketing and promotional programs, and continued cost control initiatives.

Research and development expense was \$2.2 million and \$1.0 million in the first quarters of 2017 and 2016, respectively. The increase was due primarily to the license fees paid to Selten for the development of tacrolimus and ascomycin for the treatment of PAH.

Note to Investors

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the quarter ended March 31, 2017 financial results and to provide a business update today, May 3, 2017, beginning at 4:30PM Eastern Time. Investors may listen to this call by dialing toll-free (877) 359-2916 in the U.S. and (224) 357-2386 from outside the U.S. The webcast link is: <http://edge.media-server.com/m/p/76esnfqz>. The audience passcode is 9384 6816. A webcast replay will be available for 30 days and may be accessed at <http://ir.vivus.com/>.

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/m² or greater (obese) or 27 kg/m² 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 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, including the former Sanofi territories; risks and uncertainties related to Sanofi Chimie's ability to undertake manufacturing of the avanafil active pharmaceutical ingredient and Sanofi Winthrop Industrie's ability to undertake manufacturing of the tablets for avanafil; risks and uncertainties related to our ability to manage the supply chain for STENDRA/SPEDRA for our collaborators; risks and uncertainties related to the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand; 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.
Mark Oki
Chief Financial Officer
oki@vivus.com
650-934-5200

Investor Relations: The Trout Group
Brian Korb
Managing Director
bkorb@troutgroup.com
646-378-2923

VIVUS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (In thousands, except per share data) (Unaudited)

	Three Months Ended March 31,	
	2017	2016
Revenue:		
Net product revenue	\$ 17,620	\$ 12,412
License and milestone revenue	5,000	—
Supply revenue	3,812	1,526
Royalty revenue	580	1,386
Total revenue	27,012	15,324
Operating expenses:		
Cost of goods sold	6,167	3,704
Selling, general and administrative	11,431	15,122
Research and development	2,180	1,029
Total operating expenses	19,778	19,855
Income (loss) from operations	7,234	(4,531)

Interest expense and other expense, net	8,302	8,161
Loss before income taxes	(1,068)	(12,692)
(Benefit from) provision for income taxes	(12)	16
Net loss	<u>\$ (1,056)</u>	<u>\$ (12,708)</u>
Basic and diluted net loss per share	<u>\$ (0.01)</u>	<u>\$ (0.12)</u>
Shares used in per share computation:		
Basic and diluted	<u>105,479</u>	<u>104,071</u>

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

	March 31, 2017 (Unaudited)	December 31, 2016*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 67,753	\$ 84,783
Available-for-sale securities	192,477	184,736
Accounts receivable, net	11,443	9,478
Inventories	17,190	16,186
Prepaid expenses and other assets	4,505	8,251
Total current assets	<u>293,368</u>	<u>303,434</u>
Property and equipment, net	738	788
Non-current assets	1,379	1,554
Total assets	<u>\$ 295,485</u>	<u>\$ 305,776</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,907	\$ 4,707
Accrued and other liabilities	20,313	15,686
Deferred revenue	1,505	19,174
Current portion of long-term debt	9,311	8,708
Total current liabilities	<u>36,036</u>	<u>48,275</u>
Long-term debt, net of current portion	234,866	232,610
Deferred revenue, net of current portion	6,232	6,449
Non-current accrued and other liabilities	370	257
Total liabilities	<u>277,504</u>	<u>287,591</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	832,582	831,855
Accumulated other comprehensive (loss) income	(491)	(616)
Accumulated deficit	(814,110)	(813,054)
Total stockholders' equity	<u>17,981</u>	<u>18,185</u>
Total liabilities and stockholders' equity	<u>\$ 295,485</u>	<u>\$ 305,776</u>

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