
**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)
March 13, 2018

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 March 13, 2018, VIVUS, Inc., or the Company, issued a press release regarding its financial results for the fourth quarter and year ended December 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued by VIVUS, Inc. dated March 13, 2018.

2

EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
99.1	Press Release issued by VIVUS, Inc. dated March 13, 2018.

3

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: March 13, 2018

4



VIVUS REPORTS FOURTH QUARTER 2017 FINANCIAL RESULTS

CAMPBELL, CA., March 13, 2018 — 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 and year ended December 31, 2017 and provided a business update.

“Throughout 2017, we executed on strategies intended to expand our pipeline and maximize our legacy assets. Achievements in these areas include advancing tacrolimus toward the clinic, with a phase 2 trial start scheduled for the second half of 2018, and our marketing agreement for Qsymia® in the Republic of Korea,” said Thomas B. King, VIVUS’ interim Chief Executive Officer. “We move into 2018 with continued efforts to monetize our current assets, identify additional assets to enhance our pipeline and financial resources, and ultimately create value for patients and stockholders.”

Recent Business Highlights

- **VIVUS Management Transition**

On December 31, 2017, VIVUS board member Thomas B. King was appointed to the role of CEO on an interim basis. VIVUS’ Board is working with an executive search firm to identify a permanent CEO with the passion and vision to help VIVUS succeed in the execution of its strategies.

- **Tacrolimus Hits Key Milestones**

In October 2017, the Company announced that it held a pre-IND meeting with the U.S. Food and Drug Administration (FDA) for its proprietary formulation of tacrolimus for the treatment of pulmonary arterial hypertension (PAH). The FDA addressed VIVUS’ questions related to preclinical, nonclinical and clinical data, 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.

2018 Strategic Objectives

- Continue to expand the Company’s clinical and commercial portfolios, with a particular emphasis on cash flow-generating assets
- Continue monetization of VIVUS’ legacy assets
- Recruit and hire a permanent CEO
- Initiate the tacrolimus Phase 2 clinical trial in the second half of 2018



Financial Results

Net loss for the fourth quarter of 2017 was \$10.1 million, as compared to net income of \$56.6 million in the fourth quarter of 2016. Cash, cash equivalents and available-for-sale securities were \$226.3 million at December 31, 2017.

Total revenue, net for the fourth quarters of 2017 and 2016, was \$11.9 million and \$81.8 million, respectively. The decrease was primarily a result of lower license and milestone revenue recognized in the fourth quarter of 2017 as compared to 2016. Revenue consisted of the following:

	Three Months Ended December 31,	
	2017	2016
Qsymia, net product revenue	\$ 8,934	\$ 11,046
License and milestone revenue	—	69,400
STENDRA/SPEDRA supply revenue	2,343	765
STENDRA/SPEDRA royalty revenue	664	594
Total revenue	\$ 11,941	\$ 81,805

Beginning in the first quarter of 2017, with 48 months of returns experience, VIVUS believed that it had 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 91,000 and 100,000 Qsymia prescriptions were dispensed in the fourth quarters of 2017 and 2016, respectively. In the fourth quarter of 2017, VIVUS shipped approximately 88,000 units of Qsymia to the wholesalers as wholesalers continued to reduce their Qsymia inventory levels. VIVUS recognized approximately \$0.3 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 \$3.9 million and \$2.2 million in the fourth quarters of 2017 and 2016, respectively. The increase was primarily a result of higher STENDRA/SPEDRA supply revenue during the fourth quarter of 2017.

Research and development expense was \$1.2 million and \$1.8 million in the fourth 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 PAH.

General and administrative expense was \$5.7 million and \$9.3 million for the fourth quarters of 2017 and 2016, respectively, while selling and marketing expense for the commercialization of Qsymia totaled \$3.0 million and \$3.8 million in the fourth 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.



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.

4



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, or our partner's, 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 the impact, if any, of changes to our senior management team. 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, 2017 as filed on March 13, 2018, 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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5



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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Revenue:				
Net product revenue	\$ 8,934	\$ 11,046	\$ 44,983	\$ 48,501
License and milestone revenue	—	69,400	7,500	69,400
Supply revenue	2,343	765	10,407	2,291
Royalty revenue	664	594	2,483	4,066
Total revenue	11,941	81,805	65,373	124,258
Operating expenses:				
Cost of goods sold	3,936	2,186	17,187	10,602
Research and development	1,204	1,771	5,263	5,592
Selling, general and administrative	8,681	13,125	40,130	52,379
Total operating expenses	13,821	17,082	62,580	68,573
(Loss) income from operations	(1,880)	64,723	2,793	55,685
Interest expense and other expense, net	8,190	8,104	33,302	32,313
(Loss) income before income taxes	(10,070)	56,619	(30,509)	23,372
Provision (benefit) for income taxes	5	56	2	70
Net (loss) income	<u>\$ (10,075)</u>	<u>\$ 56,563</u>	<u>\$ (30,511)</u>	<u>\$ 23,302</u>
Basic net (loss) income per share	<u>\$ (0.10)</u>	<u>\$ 0.54</u>	<u>\$ (0.29)</u>	<u>\$ 0.22</u>
Diluted net (loss) income per share	<u>\$ (0.10)</u>	<u>\$ 0.54</u>	<u>\$ (0.29)</u>	<u>\$ 0.22</u>
Shares used in per share computation:				
Basic	105,941	104,852	105,741	104,385
Diluted	105,941	105,338	105,741	104,969



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

	December 31, 2017 (Unaudited)	December 31, 2016*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 66,392	\$ 84,783
Available-for-sale securities	159,943	184,736
Accounts receivable, net	12,187	9,478
Inventories	17,712	16,186
Prepaid expenses and other assets	7,178	8,251
Total current assets	263,412	303,434
Property and equipment, net	542	788
Non-current assets	1,014	1,554
Total assets	<u>\$ 264,968</u>	<u>\$ 305,776</u>
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	\$ 10,072	\$ 4,707
Accrued and other liabilities	21,475	15,686
Deferred revenue	2,075	19,174
Current portion of long-term debt	5,147	8,708
Total current liabilities	38,769	48,275
Long-term debt, net of current portion	230,536	232,610

Deferred revenue, net of current portion	4,674	6,449
Non-current accrued and other liabilities	327	257
Total liabilities	274,306	287,591
Commitments and contingencies		
Stockholders' (deficit) equity:		
Common stock and additional paid-in capital	834,835	831,855
Accumulated other comprehensive loss	(608)	(616)
Accumulated deficit	(843,565)	(813,054)
Total stockholders' (deficit) equity	(9,338)	18,185
Total liabilities and stockholders' (deficit) equity	\$ 264,968	\$ 305,776

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