

**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 8, 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))

**Item 2.02. Results of Operations and Financial Condition**

On March 8, 2017, VIVUS, Inc., or the Company, issued a press release regarding its financial results for the fourth quarter and year ended December 31, 2016, 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 8, 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: March 8, 2017

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## EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
99.1	Press Release issued by VIVUS, Inc. dated March 8, 2017.

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## VIVUS REPORTS FOURTH QUARTER AND FULL YEAR 2016 FINANCIAL RESULTS

### Strong Cash Position Enables Strategic Initiative to Acquire New Product Pipeline

CAMPBELL, CA., March 8, 2017 - VIVUS, Inc. (NASDAQ: VVUS; the “Company”), a biopharmaceutical company developing and commercializing innovative, next-generation therapies to address unmet medical needs in human health, today reported its financial results for the quarter and year ended December 31, 2016 and provided a business update. Net income for the 2016 fourth quarter and full year was \$56.6 million and \$23.3 million, respectively, as compared to a net loss of \$12.2 million and \$93.1 million in 2015, respectively. Cash, cash equivalents and available-for-sale securities were \$269.5 million at December 31, 2016.

“Over the last six months, we have made significant strides to reshape VIVUS’ business model,” said Seth H. Z. Fischer, VIVUS Chief Executive Officer. “We have strengthened our balance sheet, with the \$70 million received from the license of U.S, Canada, South America and India STENDRA commercial rights to Metuchen; secured our STENDRA U.S. intellectual property rights with a settlement with Hetero; and began the process of building our product candidate pipeline with the addition of tacrolimus for the treatment of Pulmonary Arterial Hypertension.”

Mr. Fischer continued, “We are excited to take this momentum forward by utilizing our strong cash position for the acquisition and development of a new product pipeline to drive value creation for our stockholders while addressing the unmet needs of patients.”

### Business Update

- 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 March 2017, we engaged Aquilo Partners to assist us with our strategic process in identifying, evaluating and acquiring new product pipeline programs.
- 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.

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- In December 2016, VIVUS relocated its corporate headquarters from Mountain View, CA to 900 East Hamilton Avenue, Suite 550, Campbell, CA 95008 in our continued cost control efforts.

### Financial Results

Total revenue, net for the quarter and year ended December 31, 2016 was \$81.8 million and \$124.3 million, respectively, compared to \$15.3 million and \$95.4 million in the same periods in 2015, respectively. Revenue consisted of the following:

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Qsymia, net product revenue	\$ 11,046	\$ 13,970	\$ 48,501	\$ 54,622
License and milestone revenue	69,400	—	69,400	11,574
STENDRA/SPEDRA supply revenue	765	23	2,291	26,674
STENDRA/SPEDRA royalty revenue	594	1,350	4,066	2,560
Total revenue	\$ 81,805	\$ 15,343	\$ 124,258	\$ 95,430

Approximately 100,000 and 442,000 Qsymia prescriptions were dispensed in the quarter and year ended December 31, 2016, respectively, compared to 132,000 and 566,000 in the same periods in 2015, respectively. In the fourth quarter of 2016, we recognized a one-time up-front license fee of \$69.4 million for the licensing of the commercial rights to STENDRA in the U.S., Canada, South America and India to Metuchen Pharmaceuticals LLC.

Total cost of goods sold, excluding inventory impairment, was \$2.2 million and \$10.6 million in the quarter and year ended December 31, 2016, respectively, compared to \$2.6 million and \$34.2 million in the same periods of 2015, 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 \$9.3 million and \$30.6 million for the quarter and year ended December 31, 2016, respectively, compared to \$5.1 million and \$26.4 million in the same periods in 2015, respectively. The increase was primarily due to consulting expenses associated with our business strategy review, non-recurring costs associated with the closing of the Metuchen license agreement and legal expenses related to the defense of our intellectual property.

Selling and marketing expense for the commercialization of Qsymia totaled \$3.8 million and \$21.8 million in the quarter and year ended December 31, 2016, respectively, compared to \$8.6 million and \$53.0 million in the same periods in 2015, 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 \$1.8 million and \$5.6 million in the quarter and year ended December 31, 2016, respectively, compared to \$3.3 million and \$10.1 million in the same periods in 2015, respectively. The decrease was due to the timing of the performance of Qsymia post-marketing required clinical trials.

### **Note to Investors**

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the quarter and year ended December 31, 2016 financial results today, March 8, 2017, beginning at

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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/wqto3kub> The audience passcode is 660 570 48. 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/m<sup>2</sup> or greater (obese) or 27 kg/m<sup>2</sup> 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<sup>®</sup> (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 (MAOIs); 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<sup>®</sup> (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<sup>™</sup>, 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.

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VIVUS has granted an exclusive license to Sanofi to commercialize avanafil in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia.

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](http://www.Stendra.com).

### **Important Safety Information**

STENDRA<sup>®</sup> (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<sup>®</sup>), indinavir (Crixivan<sup>®</sup>), saquinavir (Fortavase<sup>®</sup> or Invirase<sup>®</sup>) or atazanavir (Reyataz<sup>®</sup>); some types of oral antifungal medicines, such as ketoconazole (Nizoral<sup>®</sup>), and itraconazole (Sporanox<sup>®</sup>); or some types of antibiotics, such as clarithromycin (Biaxin<sup>®</sup>), telithromycin (Ketek<sup>®</sup>), 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**

A biopharmaceutical company developing and commercializing innovative, next-generation therapies to address unmet medical needs in human health. For more information about the company, please visit [www.vivus.com](http://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; risks and uncertainties related to our ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to retail distribution, the broadening of payor reimbursement, the expansion of Qsymia's primary care presence, and the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia; risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA® (avanafil) or SPEDRA™ (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 Mexico and Central America; risks and uncertainties related to our ability to minimize expenses that are not essential to expanding the use of STENDRA/SPEDRA and Qsymia or that are not related to our strategic process to obtain product pipeline programs; risks and uncertainties related to our ability to protect our intellectual property and litigation in which we are involved or may become involved; risks and uncertainties related to our ability to continue to identify, acquire and develop product pipeline programs; risks and uncertainties related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; and risks and uncertainties related to our ability to demonstrate through clinical testing the quality, safety and efficacy of product pipeline programs. 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 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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**VIVUS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(In thousands, except per share data)**  
**(Unaudited)**

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
Revenue:				
Net product revenue	\$ 11,046	\$ 13,970	\$ 48,501	\$ 54,622
License and milestone revenue	69,400	—	69,400	11,574
Supply revenue	765	23	2,291	26,674
Royalty revenue	594	1,350	4,066	2,560
Total revenue	81,805	15,343	124,258	95,430
Operating expenses:				
Cost of goods sold	2,186	2,626	10,602	34,157
Selling, general and administrative	13,125	13,657	52,379	79,387
Research and development	1,771	3,277	5,592	10,102
Inventory impairment and other non-recurring charges	—	—	—	32,061
Total operating expenses	17,082	19,560	68,573	155,707

Income (loss) from operations	64,723	(4,217)	55,685	(60,277)
Interest expense and other expense, net	8,104	7,976	32,313	32,827
Income (loss) before income taxes	56,619	(12,193)	23,372	(93,104)
Provision for (benefit from) income taxes	56	(10)	70	3
Net income (loss)	<u>\$ 56,563</u>	<u>\$ (12,183)</u>	<u>\$ 23,302</u>	<u>\$ (93,107)</u>
Basic net income (loss) per share	<u>\$ 0.54</u>	<u>\$ (0.12)</u>	<u>\$ 0.22</u>	<u>\$ (0.90)</u>
Diluted net income (loss) per share	<u>\$ 0.54</u>	<u>\$ (0.12)</u>	<u>\$ 0.22</u>	<u>\$ (0.90)</u>
Shares used in per share computation:				
Basic	<u>104,852</u>	<u>104,046</u>	<u>104,385</u>	<u>103,926</u>
Diluted	<u>105,338</u>	<u>104,046</u>	<u>104,969</u>	<u>103,926</u>

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

	December 31, 2016 (Unaudited)	December 31, 2015*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 84,783	\$ 95,395
Available-for-sale securities	184,736	146,168
Accounts receivable, net	9,478	8,997
Inventories	16,186	13,602
Prepaid expenses and other assets	8,251	9,430
Total current assets	303,434	273,592
Property and equipment, net	788	994
Non-current assets	1,554	2,616
Total assets	<u>\$ 305,776</u>	<u>\$ 277,202</u>
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 4,707	\$ 7,060
Accrued and other liabilities	15,686	15,891
Deferred revenue	19,174	22,142
Current portion of long-term debt	8,708	14,356
Total current liabilities	48,275	59,449
Long-term debt, net of current portion	232,610	217,034
Deferred revenue, net of current portion	6,449	6,508
Non-current accrued and other liabilities	257	1,296
Total liabilities	287,591	284,287
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	831,855	829,532
Accumulated other comprehensive (loss) income	(616)	(261)
Accumulated deficit	(813,054)	(836,356)
Total stockholders' equity (deficit)	18,185	(7,085)
Total liabilities and stockholders' equity (deficit)	<u>\$ 305,776</u>	<u>\$ 277,202</u>

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