
**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 8, 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 May 8, 2018, VIVUS, Inc., or the Company, issued a press release regarding its financial results for the first quarter ended March 31, 2018, 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 May 8, 2018.
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EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
99.1	Press Release issued by VIVUS, Inc. dated May 8, 2018.
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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 8, 2018

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VIVUS REPORTS FIRST QUARTER 2018 FINANCIAL RESULTS

Company provides business update on PANCREAZE® acquisition, new Athyrium debt line and new management

Company to host conference call today at 4:30pm ET

CAMPBELL, CA — (Marketwire) — May 8, 2018 — VIVUS, Inc. (NASDAQ: VVUS) (the “Company”), a specialty pharmaceutical 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 March 31, 2018 and provided a business update.

“The acquisition of PANCREAZE®, a cash flow-positive asset, and the restructuring of a portion of our corporate debt are significant steps toward our goal of positioning VIVUS as a robust generator of value for stockholders and patients,” said John Amos, VIVUS’ new Chief Executive Officer. “Our new management team is energized and actively engaged in seeking additional product acquisitions that will leverage our commercialization expertise and strengthen our balance sheet. I am confident that we have the strategy, resources and employee talent to make VIVUS a leader in the specialty pharmaceutical market.”

Recent Business Highlights

• ***VIVUS Management Transition***

In April 2018, VIVUS announced the addition of John Amos as its new Chief Executive Officer and Board Member. The Company also announced the addition of Kenneth Suh as President and Chief Executive Officer of Willow Biopharma Inc. (now a wholly-owned subsidiary of VIVUS, Inc.), and Scott Oehrlein as the Company’s Chief Operations Officer to the senior leadership team. These three individuals each have strong track records of building successful cash-flow positive businesses through product acquisition and enhanced commercialization strategies and efficiencies. This leadership transition is a critical first step in executing VIVUS’ strategy to expand and optimize the management of the Company’s portfolio of commercial products and accomplishes one of the Company’s key goals outlined for 2018.

• ***VIVUS to Acquire PANCREAZE to Expand its Commercial Product Portfolio***

In May 2018, VIVUS announced that it had entered into an agreement with Janssen Pharmaceuticals, Inc., under which VIVUS will acquire all product rights for PANCREAZE® (pancrelipase) Delayed-Release Capsules in the United States and Canada. The transaction is expected to close, subject to governmental anti-trust reviews and other customary closing conditions, by the end of the second quarter of 2018.

Approved in 2010, PANCREAZE is a pancreatic enzyme preparation consisting of pancrelipase, an extract derived from porcine pancreatic glands, as well as other enzyme classes, including porcine-derived lipases, proteases and amylases. The pancreatic enzymes in PANCREAZE act like digestive enzymes physiologically secreted by the pancreas. PANCREAZE is specifically indicated for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions.



• ***VIVUS Enters into an Agreement to Restructure a Portion of its Convertible Notes and Establish a New Credit Line with Athyrium***

VIVUS entered into an agreement for a new \$120 million Senior Secured Note with investment funds managed by Athyrium Capital Management, LP (“Athyrium”). The agreement provides for \$110 million of notes to be issued by VIVUS concurrent with the closing of the PANCREAZE acquisition and subject to the satisfaction of other customary closing conditions. The remaining \$10 million will be available for issuance upon meeting certain financial thresholds or repurchasing the Company’s Convertible Notes at certain prices. Payments on the Senior Secured Notes will bear interest at 10.375% and will be interest-only for the first three years. Concurrently with the Senior Secured Notes issuance, VIVUS will repurchase Athyrium’s Convertible Notes, due in May 2020 with a face value of \$60 million, at a discount to par.

2018 Strategic Objectives

- Expand the Company’s growing commercial portfolio through the acquisition of additional cash-flow positive specialty pharmaceutical products that leverage the Company’s demonstrated commercialization capabilities.
- Continue monetizing VIVUS’ legacy assets through innovative sales and marketing strategies and potential expansion into additional markets.
- Further the development of tacrolimus, a potentially first-in-class therapy for the treatment of pulmonary arterial hypertension (PAH). VIVUS expects to file an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration for tacrolimus in the treatment of PAH and complete the development of its proprietary formulation of tacrolimus.



Financial Results

Net loss for the first quarter of 2018 was \$10.7 million, as compared to a net loss of \$1.1 million in the first quarter of 2017. Cash, cash equivalents and available-for-sale securities were \$209.1 million at March 31, 2018.

Revenue consisted of the following:

	Three Months Ended March 31,	
	2018	2017
Qsymia product revenue, net	\$ 9,632	\$ 17,620 ⁽¹⁾
License and milestone revenue	—	5,000
STENDRA/SPEDRA supply revenue	1,683	3,812
STENDRA/SPEDRA royalty revenue	585	580
Total revenue	<u>\$ 11,900</u>	<u>\$ 27,012</u>

⁽¹⁾ Includes one-time accounting adjustment of \$7.3 million

Net Qsymia product revenue decreased to \$9.6 million in the first quarter of 2018 as compared to \$10.3 million in the first quarter of 2017, excluding the one-time change in accounting adjustment of \$7.3 million in the first quarter of 2017 for the change to the “sell-in” revenue recognition methodology. In the first quarters of 2018 and 2017, VIVUS shipped approximately 83,000 and 89,000 units of Qsymia to the wholesalers, respectively. Approximately 92,000 and 102,000 Qsymia prescriptions were dispensed in the first quarters of 2018 and 2017, respectively.

Total cost of goods sold was \$2.7 million and \$6.2 million in the first quarters of 2018 and 2017, respectively. The decrease was primarily a result of lower Qsymia product revenue and the lower STENDRA/SPEDRA supply revenue as described above.

Research and development expense was \$1.4 million and \$2.2 million in the first quarters of 2018 and 2017, respectively. In 2017, research and development expenses were impacted by the payment of license fees to Selten for the acquisition of tacrolimus. Excluding these license fees, development costs increased due to the ongoing development of tacrolimus.

General and administrative expense was \$5.8 million and \$6.0 million for the first quarters of 2018 and 2017, respectively. Selling and marketing expense for the commercialization of Qsymia totaled \$4.3 million and \$5.5 million in the first quarters of 2018 and 2017, respectively. Sales and marketing expense in 2017 included a \$0.7 million one-time adjustment related to the one-time accounting adjustment.



Conference Call Details

As previously announced, VIVUS will hold a conference call and an audio webcast to provide a business update and to discuss the 2018 first quarter financial results today, May 8, 2018, beginning at 4:30PM Eastern Time. Investors may listen to this call by dialing toll-free 1-877-359-2916 in the U.S. and 1-224-357-2386 from outside the U.S. The audience passcode is 1366646. A webcast replay will be available for 30 days and may be accessed at <http://ir.vivus.com/events-and-presentations>.

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.

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

Important Safety Information for Qsymia

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 for STENDRA

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 specialty pharmaceutical 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.

Forward-Looking Statements

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 the integration and continued operations of Willow and our ability to achieve expected synergies; risks and uncertainties related to diversion of our resources and difficulty in retaining critical employees of the acquired business; risks and uncertainties related to our ability to address or potentially reduce our outstanding balance of the convertible notes due in 2020; risks and uncertainties related to our expected future revenues, operations and expenditures; risks and uncertainties related to our ability to identify and acquire development and cash flow generating assets; risks and uncertainties related to our agreement with Janssen Pharmaceuticals, Inc. for the acquisition of all product rights for PANCREAZE in the U.S. and Canada, including that the closing of the agreement is subject to governmental reviews and other closing conditions; risks and uncertainties related to our commercialization of PANCREAZE as a new product and our recently changed management team initiating the commercialization of PANCREAZE; 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 Board of Directors and senior management team. These risks and uncertainties could cause actual results to differ materially from those referred to in these

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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 14, 2018, and as amended by the Form 10-K/A filed on April 26, 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.

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

	Three Months Ended March 31,	
	2018	2017
Revenue:		
Net product revenue	\$ 9,632	\$ 17,620
License and milestone revenue	—	5,000
Supply revenue	1,683	3,812
Royalty revenue	585	580
Total revenue	11,900	27,012

Operating expenses:		
Cost of goods sold	2,721	6,167
Research and development	1,403	2,180
Selling, general and administrative	10,068	11,431
Total operating expenses	<u>14,192</u>	<u>19,778</u>
(Loss) income from operations	(2,292)	7,237
Interest expense and other expense, net	8,349	8,302
(Loss) income before income taxes	(10,641)	(1,068)
Provision (benefit) for income taxes	12	(12)
Net (loss) income	<u>\$ (10,653)</u>	<u>\$ (1,056)</u>
Basic net (loss) income per share	<u>\$ (0.10)</u>	<u>\$ (0.01)</u>
Diluted net (loss) income per share	<u>\$ (0.10)</u>	<u>\$ (0.01)</u>
Shares used in per share computation:		
Basic	<u>106,014</u>	<u>105,479</u>
Diluted	<u>106,014</u>	<u>105,479</u>

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

	March 31, 2018 (Unaudited)	December 31, 2017*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 76,805	\$ 66,392
Available-for-sale securities	132,320	159,943
Accounts receivable, net	11,291	12,187
Inventories	21,006	17,712
Prepaid expenses and other assets	6,447	7,178
Total current assets	<u>247,869</u>	<u>263,412</u>
Property and equipment, net	510	542
Non-current assets	924	1,014
Total assets	<u>\$ 249,303</u>	<u>\$ 264,968</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 4,786	\$ 10,072
Accrued and other liabilities	20,788	21,475
Deferred revenue	2,179	2,075
Current portion of long-term debt	836	5,147
Total current liabilities	<u>28,589</u>	<u>38,769</u>
Long-term debt, net of current portion	235,671	230,536
Deferred revenue, net of current portion	4,279	4,674
Non-current accrued and other liabilities	307	327
Total liabilities	<u>268,846</u>	<u>274,306</u>
Commitments and contingencies		
Stockholders' deficit:		
Common stock and additional paid-in capital	835,760	834,835
Accumulated other comprehensive loss	(1,085)	(608)
Accumulated deficit	(854,218)	(843,565)
Total stockholders' deficit	<u>(19,543)</u>	<u>(9,338)</u>
Total liabilities and stockholders' deficit	<u>\$ 249,303</u>	<u>\$ 264,968</u>

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