
**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 7, 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 August 7, 2018, VIVUS, Inc., or the Company, issued a press release regarding its financial results for the second quarter ended June 30, 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 August 7, 2018.
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EXHIBIT INDEX

<u>Number</u>	<u>Description</u>
99.1	Press Release issued by VIVUS, Inc. dated August 7, 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: August 7, 2018

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VIVUS Reports Second Quarter 2018 Financial Results

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

CAMPBELL, CA., August 7, 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 June 30, 2018 and provided a business update.

“The successful completion of the PANCREAZE acquisition and the transaction with Athyrium Capital Management to restructure a portion of our debt and access additional capital are transformative events for VIVUS,” said John Amos, Chief Executive Officer at VIVUS. “We are now strongly positioned to build a robust portfolio of cash flow-positive assets that have clinical and commercial value. Additionally, the positive pharmacokinetic data reported for VI-0106 support continued evaluation of this novel formulation of tacrolimus in the treatment of pulmonary arterial hypertension, a serious disease with no curative therapy. We are exploring options for advancing this promising program in a manner consistent with our focus on reducing our debt. I am excited that we are making tangible progress toward our goal of becoming a profit-generating specialty pharmaceutical company.”

Recent Business Highlights

- **VIVUS closes PANCREAZE® acquisition and debt restructuring**

In June 2018, VIVUS announced that it had met the closing conditions, including Hart-Scott-Rodino review, related to the Company’s acquisition of U.S. and Canadian rights to PANCREAZE (pancrelipase) Delayed-Release Capsules for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other conditions from Janssen Pharmaceuticals, Inc. for \$135 million in cash. Concurrently, VIVUS completed a financing agreement with affiliates of Athyrium Capital Management, L.P., to restructure a portion of the Company’s debt.

- **VIVUS announces positive preliminary Phase 1 VI-0106 results for PAH**

In July 2018, VIVUS announced positive preliminary results from a Phase 1 clinical study evaluating VI-0106, a proprietary soft capsule formulation of tacrolimus for the treatment of pulmonary arterial hypertension (PAH). The key findings from the pharmacokinetic (PK) study involving healthy volunteers showed that prototype formulations had PK profiles consistent with earlier in-vitro evaluations, and an increased Area Under the Curve compared to available immediate release tacrolimus.

- **VIVUS Appoints Kenneth Suh as President**

VIVUS recently announced the appointment of Ken Suh to the position of President. Previously, Mr. Suh was President and CEO of Willow Biopharma Inc., a wholly-owned subsidiary of VIVUS, Inc.

Financial Results

Revenue consisted of the following:

	(In thousands) Three Months Ended June 30,	
	2018	2017
Qsymia net product revenue	\$ 11,134	\$ 8,518
PANCREAZE net product revenue	2,116	—
Supply revenue	1,042	2,119
Royalty revenue	668	590
Total revenue	\$ 14,960	\$ 11,227

Qsymia net product revenue increased to \$11.1 million in the first quarter of 2018 as compared to \$8.5 million in the second quarter of 2017. The increase was primarily driven by the increase in shipments to 94,000 units in the second quarter of 2018 as compared to 83,000 units in the same period in 2017. Approximately 96,000 and 105,000 Qsymia prescriptions were dispensed in the second quarters of 2018 and 2017, respectively.

PANCREAZE net product revenue was \$2.1 million in the second quarter and consists of shipments made from the date of our acquisition of PANCREAZE on June 8, 2018 through June 30, 2018. During this period, we shipped 7,000 units of PANCREAZE.

Total cost of goods sold excluding amortization was \$3.3 million and \$3.4 million in the second quarters of 2018 and 2017, respectively. The decrease was primarily a result of lower shipments of STENDRA/SPEDRA partially offset by higher shipments of Qsymia and the addition of PANCREAZE product revenue during the quarter.

Amortization of intangible assets was \$1.3 million and \$181,000 in the second quarters of 2018 and 2017, respectively. In 2018, the increase was due to the amortization of costs capitalized associated with the acquisition of PANCREAZE.

Research and development expense was \$2.0 million and \$1.0 million in the second quarters of 2018 and 2017, respectively. Research and development expenses were impacted by increased development efforts of tacrolimus for the treatment of pulmonary arterial hypertension, specifically the Phase 1

pharmacokinetic study and continued formulation efforts

General and administrative expense was \$8.2 million and \$6.2 million for the second quarters of 2018 and 2017, respectively. The increase in general and administrative was primarily due to one-time expenses of approximately \$2.0 million related to advisory services and expenses related to the acquisition of PANCREAZE and the restructuring of our debt, in addition to the additional expense of adding three new members of our senior leadership team.

Selling and marketing expense for the commercialization of Qsymia totaled \$3.5 million and \$5.4 million in the second quarters of 2018 and 2017, respectively. The decrease was due to the continued cost control initiatives, including the realignment of our sales force, and the refinement of our marketing and promotional programs.

Total interest expense for the second quarter of 2018 was \$8.7 million, as compared to \$8.5 million in the second quarter of 2017.

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Net loss for the second quarter of 2018 was \$12.6 million, as compared to \$13.4 million in the second quarter of 2017. Cash, cash equivalents and available-for-sale securities were \$123.5 million at June 30, 2018.

Non-GAAP EBITDA for the second quarter of 2018 was (\$1.0) million, as compared to (\$4.0) in the second quarter of 2017. Excluding the one-time expenses discussed above, VIVUS generated EBITDA of approximately \$1.0 million during the second quarter of 2018.

Conference Call Details

VIVUS will hold a conference call and an audio webcast to provide a business update and to discuss the 2018 second quarter financial results today, August 7, 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 7977356. 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.

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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 PANCREAZE

PANCREAZE is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis or other conditions. PANCREAZE may help your body use fats, proteins, and sugars from food. PANCREAZE contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas. PANCREAZE is safe and effective in children when taken as prescribed by your doctor.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about PANCREAZE?

- PANCREAZE may increase your chance of having a serious, rare bowel disorder called fibrosing colonopathy that may require surgery.
- The risk of having this condition may be reduced by following the dosing instructions that your healthcare provider gave you.

Call your doctor right away if you have any unusual or severe stomach area (abdominal) pain, bloating, trouble passing stool (having bowel movements), nausea, vomiting, or diarrhea.

Take PANCREAZE exactly as prescribed by your doctor. Do not take more or less PANCREAZE than directed by your doctor.

What are the possible side effects of PANCREAZE?

PANCREAZE may cause serious side effects, including:

- **A rare bowel disorder** called fibrosing colonopathy.
- **Irritation of the inside of your mouth.** This can happen if PANCREAZE is not swallowed completely.
- **Increase in blood uric acid levels.** This may cause worsening of swollen, painful joints (gout) caused by an increase in your blood uric acid levels.
- **Allergic reactions** including trouble with breathing, skin rashes, or swollen lips.

Call your doctor right away if you have any of these symptoms.

The most common side effects include pain in your stomach (abdominal pain) and gas.

Other possible side effects: PANCREAZE and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs people eat as pork. These pigs may carry viruses. Although it

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has never been reported, it may be possible for a person to get a viral infection from taking pancreatic enzyme products that come from pigs.

These are not all the side effects of PANCREAZE. Talk to your doctor about any side effect that bothers you or does not go away.

You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What should I tell my doctor before taking PANCREAZE?

Tell your doctor if you:

- are allergic to pork (pig) products.
- have a history of blockage of your intestines, or scarring or thickening of your bowel wall (fibrosing colonopathy).
- have gout, kidney disease, or high blood uric acid (hyperuricemia).
- have trouble swallowing capsules.
- have any other medical condition.
- are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

The Product Information and Medication Guide for PANCREAZE is available at www.pancreaze.com.

About STENDRA/SPEDRA (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.

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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.

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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 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 the timing, strategy, tactics and success of the marketing and sales of PANCREAZE; 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 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.

VIVUS, Inc.
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VIVUS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)

	June 30, 2018 Unaudited	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 57,181	\$ 66,392
Available-for-sale securities	66,361	159,943
Accounts receivable, net	11,071	12,187
Inventories	22,259	17,712
Prepaid expenses and other current assets	6,399	7,178
Total current assets	163,271	263,412
Property and equipment, net	445	542
Intangible and other non-current assets	141,545	1,014
Total assets	<u>\$ 305,261</u>	<u>\$ 264,968</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 4,345	\$ 10,072
Accrued and other liabilities	26,879	21,475
Deferred revenue	1,897	2,075
Current portion of long-term debt	—	5,147
Total current liabilities	33,121	38,769
Long-term debt, net of current portion	295,498	230,536
Deferred revenue, net of current portion	4,243	4,674
Non-current accrued and other liabilities	283	327
Total liabilities	333,145	274,306
Commitments and contingencies		
Stockholders' deficit:		
Preferred stock; \$1.00 par value; 5,000 shares authorized; no shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock; \$.001 par value; 200,000 shares authorized; 106,187 and 105,977 shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	106	105
Additional paid-in capital	839,310	834,730
Accumulated other comprehensive loss	(508)	(608)
Accumulated deficit	(866,792)	(843,565)
Total stockholders' deficit	(27,884)	(9,338)
Total liabilities and stockholders' deficit	<u>\$ 305,261</u>	<u>\$ 264,968</u>

VIVUS, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Revenue:				
Net product revenue	\$ 13,250	\$ 8,518	\$ 22,882	\$ 26,138
License and milestone revenue	—	—	—	5,000
Supply revenue	1,042	2,119	2,725	5,931
Royalty revenue	668	590	1,253	1,170
Total revenue	14,960	11,227	26,860	38,239
Operating expenses:				
Cost of goods sold (excluding amortization)	3,286	3,389	5,916	9,375
Amortization of intangible assets	1,273	181	1,364	362
Selling, general and administrative	11,711	11,630	21,779	23,061
Research and development	2,042	1,014	3,445	3,194
Total operating expenses	18,312	16,214	32,504	35,992
(Loss) income from operations	(3,352)	(4,987)	(5,644)	2,247
Interest expense and other expense, net	9,218	8,398	17,567	16,700
Loss before income taxes	(12,570)	(13,385)	(23,211)	(14,453)
Provision for (benefit from) income taxes	4	1	16	(11)
Net loss	<u>\$ (12,574)</u>	<u>\$ (13,386)</u>	<u>\$ (23,227)</u>	<u>\$ (14,442)</u>
Basic and diluted net loss per share:	<u>\$ (0.12)</u>	<u>\$ (0.13)</u>	<u>\$ (0.22)</u>	<u>\$ (0.14)</u>
Shares used in per share computation:				
Basic and diluted	<u>106,116</u>	<u>105,712</u>	<u>106,065</u>	<u>105,596</u>

VIVUS, INC.

GAAP to NON-GAAP RECONCILIATION
NET LOSS to EBITDA
(In thousands)
(Unaudited)

A reconciliation between net loss on a GAAP basis and non-GAAP EBITDA is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Net loss	\$ (12,574)	\$ (13,386)	\$ (23,227)	\$ (14,442)
Adjustments:				
Interest expense and other expense, net	9,218	8,398	17,567	16,700
Depreciation of fixed assets	65	68	131	139
Amortization of intangible assets	1,273	181	1,364	362
Share-based compensation expense	1,049	741	1,974	1,468
Provision for (benefit from) income taxes	4	1	16	(11)
Non-GAAP EBITDA	<u>\$ (965)</u>	<u>\$ (3,997)</u>	<u>\$ (2,175)</u>	<u>\$ 4,216</u>

Use of Non-GAAP Financial Measures

We supplement our condensed consolidated financial statements presented on a GAAP basis by providing an additional measure which is considered non-GAAP under applicable SEC rules. We believe that the disclosure of this non-GAAP measure provides investors with additional information that reflects the basis upon which our management assesses and operates our business. This non-GAAP financial measure is not in accordance with GAAP and should not be viewed in isolation or as a substitute for GAAP net loss and is not a substitute for, or superior to, measures of financial performance performed in conformity with GAAP.

We define non-GAAP EBITDA as net loss before interest and other expense, depreciation of fixed assets, amortization of intangible assets, share-based compensation expense and provision for or benefit from income taxes. Management believes that non-GAAP EBITDA is a meaningful indicator of our performance and provides useful information to investors regarding our results of operations and financial condition.