

VIVUS INC
Form 8-K
January 07, 2013

**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)

January 7, 2013

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.)

**1172 CASTRO STREET
MOUNTAIN VIEW, CA 94040**

(Address of principal executive offices, including zip code)

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(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))
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Item 2.02. Results of Operations and Financial Condition

VIVUS, Inc., or the Company, is providing the following information regarding its business. The operating metrics discussed below relate to the Company's product, Qsymia (phentermine and topiramate extended-release) and are based on the most recent data available to the Company at the time of this filing.

Qsymia Prescriptions Shipped*

	Four weeks ending 10/26/12	Four weeks ending 11/23/12	Four weeks ending 12/21/12
Qsymia prescriptions shipped	5,394**	7,749	12,978

*The data in the above table represents Qsymia prescriptions shipped to patients. In addition, the data in the above table is derived from data made available to the Company from third parties; due to this and other factors, the data reported above may be subject to adjustment should the Company receive adjusted information from these third parties.

**The total prescriptions shipped for the four weeks ending October 26, 2012 was previously reported as 4,904. This amount has been adjusted based on additional information provided from one of the certified pharmacies.

On November 19, 2012, the Company initiated the Qsymia Get Started! Free Trial Offer Program in two of the certified pharmacies. A third certified pharmacy began participating in this program in late December 2012. According to this program, the Company is, for a limited time, offering to eligible patients a 14-capsule starting dose of Qsymia, 3.75 mg/23 mg (phentermine and topiramate extended-release), at no charge to the patient. After initiation of the program a significant portion of the prescriptions at the 3.75 mg/23 mg dose level were shipped at no charge from the participating certified pharmacies to the patient under this program.

Qsymia was approved by the U.S. Food and Drug Administration, or FDA, in July 2012. The Company sells Qsymia product in the U.S. through certified pharmacies in its Qsymia Home Delivery Network. Given the Company's limited history of selling Qsymia and the lengthy product return period, the Company has not been able to reliably estimate expected returns of Qsymia at the time of shipment to the pharmacies. Therefore, the Company recognizes revenue when units are shipped by the pharmacies to patients through prescriptions, at which point, the product is not subject to return. The Company obtains the prescription fulfillment data directly from the pharmacies or their designated third party service providers to determine the amount of revenue to recognize.

As the Company has disclosed in its previous filings with the Securities and Exchange Commission, its ability to effectively and profitably commercialize Qsymia will depend in part on its ability to create market demand for Qsymia through education, marketing and sales activities; achieve market acceptance of Qsymia and generate product revenue; receive adequate levels of reimbursement from third-party payers, such as private insurance programs and pharmacy benefit managers; and comply with the post-marketing requirements established by the FDA, including the Risk Evaluation and Mitigation Strategy, or REMS, and any other requirements established by the FDA in the future.

Important Information Regarding Prescriptions Shipped and Net Revenue

The relationship between the number of prescriptions shipped and net revenue may vary based on a number of factors. In particular, product revenue is recognized net of reductions that may vary from period to period. These reductions include cash consideration paid to the certified pharmacies for services rendered by the pharmacies in accordance with certified pharmacy services network agreements, and include a fixed rate per prescription shipped and monthly program management and data fees. Other reductions include certain prompt pay cash discounts and allowances offered to the certified pharmacies which are recognized as a reduction of revenue at the later of the date at which the related revenue is recognized or the date at which the allowance is offered.

Calculating certain of these items involves estimates and judgments based on revenue or invoice data and historical experience. Amounts accrued for revenue deductions are adjusted when trends, significant events, or actual results indicate that adjustment is appropriate. Revisions of estimates for revenue deductions are recorded as a reduction of revenue in the period in which the information that gives rise to the revision becomes known.

In addition, the prescriptions shipped from participating certified pharmacies under the Qsymia Get Started! Free Trial Offer Program at no charge will result in no revenue.

The Company relies on third parties to provide prescription data generated by the certified pharmacies on a weekly basis. Accordingly, due to this and other factors, the data reported in the above table may be subject to adjustment should the Company receive adjusted information from these third parties.

The Company launched the sales of Qsymia on September 17, 2012. Accordingly, there is a limited amount of information regarding the number of prescriptions shipped and net revenue related to Qsymia. The Company believes that investors should view the data provided in this Current Report on Form 8-K with caution, as data for a single period or limited period, as in this case, may not be representative of a trend or otherwise predictive of future results. The Company believes that investors should consider the Company's results over several quarters or longer when analyzing the Company's performance.

Item 7.01. Regulation FD Disclosure

The information contained in Item 2.02 of this Current Report on Form 8-K is incorporated herein by reference.

By filing this information, the Company makes no admission as to the materiality of any information in this Current Report on Form 8-K. The information contained in this Current Report on Form 8-K is intended to be considered in the context of the Company's filings with the Securities and Exchange Commission and other public announcements that the Company makes, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission, through press releases or through other public disclosure.

The information in Item 2.02 and Item 7.01 of this Current Report on Form 8-K shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, (the Exchange Act), or otherwise subject to the liabilities of that Section, or incorporated by reference into any of the Registrant'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.

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/ Lee B. Perry
Lee B. Perry
Vice President and Chief Accounting Officer

Date: January 7, 2013