VIVUS INC
Form 8-K
November 02, 2010

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)

October 29, 2010

VIVUS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33389**	**94-3136179**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1172 CASTRO STREET

MOUNTAIN VIEW, CA 94040

(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events

On October 29, 2010, VIVUS, Inc., or the Company, conducted a conference call and webcast discussion of the Complete Response Letter from the U.S. Food and Drug Administration, or the FDA, regarding the Company s New Drug Application for the investigational new drug QNEXA® (phentermine/topiramate) Controlled-Release Capsules. A copy of the transcript of the conference call is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K and the exhibits 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 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.

* * *

By filing this Current Report on Form 8-K and furnishing this information, the Company makes no admission as to the materiality of any information in this report. 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, or the SEC, 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 report, 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 SEC, through press releases or through other public disclosure.

The Company cautions you that certain statements included in this report and the attached exhibit that are not a description of historical facts are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as anticipate, believe, forecast, estimated and intend, among others. These forward-looking statemen are based on the Company s current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the timing and substance of the Company s response to the FDA s Complete Response Letter; the FDA s interpretation of the data the Company submits relating to teratogenicity and cardiovascular safety; the FDA s interpretation of the data from the Company s clinical studies, including the Company s SEQUEL study (OB-305); that the Company may be required to conduct additional clinical trials; substantial competition; uncertainties of patent protection and litigation; reliance on sole source suppliers; limited sales and marketing efforts and dependence upon third parties; risks related to the development of innovative products; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that the Company s response to the FDA s Complete Response Letter will be sufficient to satisfy the FDA s safety concerns, that the FDA will not require the Company to conduct additional clinical studies or that any product will receive regulatory approval for any indication or prove to be commercially successful. The Company does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Company s Form 10-K for the year ended December 31, 2009 and periodic reports filed with the SEC.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
99.1	Transcript of the Conference Call on October 29, 2010, 7:30 a.m. CT

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.

By: /s/ Lee B. Perry
Lee B. Perry
Vice President and Chief Accounting Officer

Date: November 2, 2010

EXHIBIT INDEX

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