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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**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)  
**September 26, 2011**

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**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)

**(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 7.01. Regulation FD Disclosure**

On September 26, 2011, the Company announced that at the American Neurological Association, or ANA, meeting in San Diego, CA, a poster titled "Retrospective Analysis of Major Congenital Malformations and Oral Clefts Associated With *In Utero* Topiramate Exposure," authored by Dr. Mark W. Green, Director of the Center for Headache and Pain Medicine and Professor of Neurology and Anesthesiology at the Mount Sinai School of Medicine, will be presented on Tuesday, September 27, 2011. The study concluded that topiramate did not significantly increase the rates of Major Congenital Malformation or Oral Cleft.

The study was conducted using retrospective data from Wolters Kluwer Pharma Solutions Source® Lx Patient Longitudinal Database that followed patients' pharmacy and medical claims to identify infants exposed to topiramate during pregnancy and identified 778 mother-infant dyads exposed to topiramate within 10 months prior to giving birth.

The incident rate of Oral Clefts, or OCs, and Major Congenital Malformations, or MCMs, in the topiramate exposed group was compared to OC and MCM incident rates in three non-topiramate exposed control groups: a migraine without epilepsy group, a group of patients exposed to acute-preventive migraine drugs, or APMD, during pregnancy, and a diabetes group. The study found that the risk for MCMs in infants born to diabetic mothers was significantly higher than seen in infants exposed to TPM *in utero*. The MCM and OC rates seen in the diabetes control group are comparable to those reported in the literature. Consistency of these data compared to published references for the diabetes control group and the Random Sample provide assurance that this data would likely be representative of other clinical settings. The elevated rate of MCMs in the Random Sample compared with the general population estimates may be due to selection bias that could exist in the claims database.

Results of the study are summarized as follows:

Groups	Dyads	# OC	% OC	Relative Risk (95% CI)	# MCM	% MCM	Relative Risk (95% CI)
<b>Topiramate</b>	<b>778</b>	<b>2</b>	<b>0.26</b>		<b>32</b>	<b>4.11</b>	
Migraine	26,920	46	0.17	1.50 (0.37, 6.19)	1,081	4.02	1.02 (0.73, 1.45)
Migraine APMD	2,964	11	0.37	0.69 (0.15, 3.12)	123	4.15	0.99 (0.68, 1.45)
Diabetes	13,083	36	0.28	0.93 (0.23, 3.87)	878	6.71	0.61 (0.43, 0.87)
Random Sample	100,001	166	0.17	1.55 (0.38, 6.23)	3,961	3.96	1.04 (0.74, 1.46)

The study, funded by VIVUS, was conducted utilizing Wolters Kluwer datasets from the United States and followed patients' Pharmacy and Medical Claims (January 2003 - December 2010) and covered an estimated 177 million lives. Probable exposure during pregnancy was refined using data on script fill date, days of medication supplied, infant birth date, and ICD-9 codes for birth term. Copies of the poster are available at [www.vivus.com](http://www.vivus.com). The results of this study will be included in the resubmission of the QNEXA New Drug Application for the initial indication for overweight or obese men and women of non-childbearing potential. The top-line results of the FORTRESS study are expected in December 2011, with validation of FORTRESS results expected in the third quarter of 2012.

By filing this information, the Company makes no admission as to the materiality of any information in this report. The information contained in this report 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 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 Securities and Exchange Commission, through press releases or through other public disclosure.

The information in this 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 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.**

By: /s/ John L. Slebir

**John L. Slebir**

**Vice President and General Counsel**

Date: September 26, 2011