VIVUS Reports First Quarter 2011 Financial Results

MOUNTAIN VIEW, Calif., May 2, 2011 /PRNewswire/ -- VIVUS, Inc. (Nasdaq: VVUS), a biopharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today reported its financial results for the first quarter ended March 31, 2011.

First Quarter Results

For the quarter ended March 31, 2011, VIVUS reported a net loss of $9.9 million or $0.12 per share as compared to a net loss of $18.8 million or $0.23 per share for the first quarter of 2010. The net loss from continuing operations was $9.9 million, or $0.12 net loss per share, as compared to a net loss from continuing operations of $16.6 million, or $0.21 net loss per share, during the first quarter of 2010. The lower net loss in 2011 as compared to 2010 results from reduced research and development spending on QNEXA® and avanafil as these projects progress from the clinical trial stage to the approval stage. The net loss for the first quarter last year also included a $2.2 million loss from discontinued operations of the MUSE business that was subsequently sold in the fourth quarter of 2010.

Cash, Cash Equivalents and Available-for-Sale Securities

VIVUS had cash, cash equivalents and available-for-sale securities of $130.4 million at March 31, 2011, as compared to $139.2 million at December 31, 2010. The decrease in cash, cash equivalents and available-for-sale securities of $8.8 million is primarily due to cash used in operations and other net cash uses offset by proceeds of $1.5 million from the exercise of common stock options.

QNEXA Regulatory Update

VIVUS met with the Food and Drug Administration, or FDA, on April 14, 2011 to discuss the feasibility of performing a retrospective observational study utilizing existing electronic healthcare databases to assess fetal outcomes, which include major congenital malformations and oral cleft, in the offspring of women who were exposed to topiramate during pregnancy. We have reached agreement, subject to the finalization of the written protocol, with the FDA on the retrospective observational study objectives and design, primary endpoints, and eligibility criteria. The co-primary endpoints will be the relative risk of major congenital malformations and oral cleft in the offspring of women exposed to topiramate during pregnancy as compared to a control group that was not exposed to topiramate. The retrospective observational study, will be called FORTRESS, for Fetal Outcome Retrospective TopiRamate ExpoSure Study. In addition, we discussed with the FDA a potential resubmission of the QNEXA NDA for a limited indication, which would include only men and women of non-child bearing potential. Agreement on the content of such a submission has also been reached, should we choose to pursue a limited indication. The final indication and timing of the resubmission will be dependent upon the results of the retrospective observational study. Our goal is to resubmit the QNEXA NDA in the fourth quarter of 2011. We have confirmed with the FDA that any resubmission will be considered a Class 2 resubmission with a 6-month review goal. The FDA has also indicated that a resubmission would likely be discussed at a second advisory committee meeting.

About VIVUS

VIVUS is a biopharmaceutical company developing therapies to address obesity, sleep apnea, diabetes and male sexual health. The company's lead investigational product in clinical development, QNEXA, has completed phase 3 clinical trials for the treatment of obesity and is currently being considered for approval by US and EU regulators. VIVUS received a Complete Response Letter, or CRL, to the initial QNEXA NDA on October 28, 2010. QNEXA is also in phase 2 clinical development for the treatment of type 2 diabetes and obstructive sleep apnea. In the area of sexual health, VIVUS is in phase 3 development with avanafil, a PDE5 inhibitor being studied for the treatment of erectile dysfunction. For more information about the company, please visit www.vivus.com.

Note to Investors

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the first quarter financial results today, May 2, 2011, beginning at 1:30 p.m. Pacific Time. Investors can listen to this call by dialing 1-877-359-2916 and outside the U.S. 1-224-357-2386. A webcast replay will be available for 30 days and can be accessed at http://ir.vivus.com/.

Certain statements in this press release are forward-looking 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," "estimate" and "intend," among others. 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 our response to the FDA's requests from the End of Review meeting; our response to, and continued dialogue with, the FDA relating to matters raised in the FDA's CRL; the timing and results of the retrospective observational study of fetal outcomes in infants born to mothers exposed to topiramate during pregnancy; the FDA's interpretation of and agreement with the information VIVUS submitted and may submit relating to teratogenicity and cardiovascular safety; the FDA's interpretation of the data from our SEQUEL study, or OB-305; the FDA's requests, if any, to conduct additional prospective studies or retrospective observational studies or to provide further analysis of clinical trial data; the review and questions from the EMA and CHMP on the MAA; substantial competition; the impact on future sales based on specific indication and contraindications contained in the label and the extent of the Risk Evaluation and Mitigation Strategies program; uncertainties of litigation and intellectual property and patent protection; reliance on sole-source suppliers; limited sales and marketing resources and dependence upon third parties; risks related to the development of innovative products; risks related to the failure to obtain FDA or foreign authority clearances or approval; noncompliance with FDA or foreign regulations; and our dependence on the performance of our collaborative partners. As with any pharmaceutical in development, there are significant risks in the development, the regulatory approval, and commercialization of new products. There are no guarantees that our response to the FDA's CRL or the results of the retrospective observational study of fetal outcomes in infants born to mothers exposed to topiramate during pregnancy and subsequent meetings and communications will be sufficient to satisfy the FDA's safety concerns, that the FDA will not require us to conduct any additional prospective studies or retrospective observational studies, or that any product will receive regulatory approval for any indication or prove to be commercially successful. VIVUS does not undertake an obligation to update or revise any forward-looking statements. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ending December 31, 2010, and periodic reports filed with the Securities and Exchange Commission.

VIVUS, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(unaudited)

	Three Months Ended	
	March 31 2011	**March 31 2010**
Operating expenses:		
Research and development	$ 4,480	$ 10,211
General and administrative	5,428	5,164
Total operating expenses	9,908	15,375
Loss from operations	(9,908)	(15,375)
Interest and other income (expense), net	42	(1,233)
Loss from continuing operations before income taxes	(9,866)	(16,608)
Provision for income taxes	(1)	(1)
Net loss from continuing operations	(9,867)	(16,609)
Net income (loss) from discontinued operations	14	(2,209)
Net loss	$ (9,853)	$ (18,818)
Basic and diluted net income (loss) per share:		
Continuing operations	$ (0.12)	$ (0.21)
Discontinued operations	0.00	(0.02)

Net loss per share	$ (0.12)	$ (0.23)
Shares used in per share computation:		
Basic	81,819	80,698
Diluted	84,111	80,698

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CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amount)

	March 31 2011	December 31 2010*
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 31,334	$ 37,216
Available-for-sale securities	99,101	101,970
Inventories	3,225	3,225
Prepaid expenses and other assets	1,686	1,648
Current assets of discontinued operations	-	6
Total current assets	135,346	144,065
Property and equipment, net	188	221
Total assets	$ 135,534	$ 144,286
Current liabilities:		
Accounts payable	$ 1,587	$ 2,395
Accrued and other liabilities	4,988	6,377
Current liabilities of discontinued operations	3,125	3,512
Total current liabilities	9,700	12,284
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 81,888 at March 31, 2011; 81,568 at December 31, 2010, respectively	82	82
Additional paid-in capital	435,701	432,041
Accumulated other comprehensive income	29	4
Accumulated deficit	(309,978)	(300,125)
Total stockholders' equity	125,834	132,002
Total liabilities and stockholders' equity	$ 135,534	$ 144,286

*The Condensed Consolidated Balance Sheet at December 31, 2010 has been derived from the Company's audited financial statements at that date.

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