



## **VIVUS Reports Second Quarter and First Six Months 2011 Financial Results**

MOUNTAIN VIEW, Calif., Aug. 1, 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 second quarter and six months ended June 30, 2011.

### **Second Quarter Results**

For the second quarter ended June 30, 2011, VIVUS reported a net loss of \$16.2 million, or \$0.20 per share, as compared to a net loss of \$22.8 million, or \$0.28 per share, for the second quarter of 2010. The net loss from continuing operations was \$16.3 million, or \$0.20 net loss per share, as compared to a net loss from continuing operations of \$21.6 million, or \$0.27 net loss per share, during the second quarter of 2010. The lower net loss in 2011 as compared to 2010 primarily results from reduced research and development spending on QNEXA® and avanafil as these projects progress from the clinical trial stage to the regulatory review stage. Included in the net loss for the second quarter of 2011 was a one-time milestone of \$4 million to MTPC due upon the filing of the avanafil NDA. The net loss for the second quarter last year also included a \$1.2 million loss from discontinued operations of the MUSE business that was subsequently sold in the fourth quarter of 2010.

### **First Half Results**

Net loss for the first six months of 2011 was \$26.1 million, or \$0.32 per share, as compared to a net loss of \$41.6 million, or \$0.51 per share, for 2010. The decrease in net loss in the first half of 2011 as compared to 2010 results primarily from reduced research and development spending on QNEXA® and avanafil. In addition, the net loss for the first six months last year included a \$3.4 million loss from discontinued operations of the MUSE business.

### **Cash, Cash Equivalents and Available-for-Sale Securities**

VIVUS had cash, cash equivalents and available-for-sale securities of \$121.6 million at June 30, 2011, as compared to \$139.2 million at December 31, 2010. The decrease in cash, cash equivalents and available-for-sale securities of \$17.6 million is primarily due to cash used in operations offset by proceeds of \$1.9 million from the exercise of common stock options and ESPP purchases.

### **Qnexa Update**

We have commenced the FORTRESS study, a retrospective observational study of fetal outcomes of offspring of women exposed to topiramate. Top-line results of the FORTRESS study are expected in the fourth quarter of 2011.

In July 2011 we announced the top-line results of an additional retrospective study of medical claims data on oral clefts (OC) and major congenital malformations (MCMs) associated with topiramate exposure in utero. This study was conducted using medical claims and pharmacy prescription data from the Wolters Kluwer Pharma Solutions Source® Lx Patient Longitudinal Database. This study identified 778 mother-infant dyads exposed to topiramate within 10 months prior to giving birth. This study compared the incidence rate of OC and MCM in topiramate exposed dyads to two control groups, one comprised of 3,431 dyads exposed to other antiepileptic drugs (AEDs) during pregnancy and a second of 2,307 dyads with a diagnosis of epilepsy, but no exposure to topiramate during pregnancy. The results of the study found there were no statistically significant differences in OC or MCM frequency between the topiramate and control groups. The results of this study will be presented at the International Epilepsy Congress (IEC) in Rome, Italy on August 31, 2011 by Dr. Alison Pack, Associate Professor of Clinical Neurology, Department of Neurology, Columbia University Medical Center. This study was conducted to provide an early assessment of the teratogenic potential of topiramate. The FORTRESS results, expected in the fourth quarter of 2011, along with the results from this study will be used as part of the QNEXA New Drug Application (NDA) resubmission to the U.S. Food and Drug Administration (FDA).

The Marketing Authorization Application (MAA) for QNEXA was submitted to the European Medicines Agency (EMA) in December 2010. In May of 2011 we received the 120-day list of questions from the Committee for Medicinal Products for Human Use (CHMP) and began preparing our response. The questions and issues raised by the CHMP were consistent with those raised by the FDA. We have requested and have been granted a meeting with the rapporteur September 2011 to discuss the 120-day questions. The purpose of this meeting is to provide clarification to certain questions to assist us in preparing our response. Our response to the 120-day questions is expected in the fourth quarter of 2011.

"The FORTRESS protocol has been reviewed and approved by the FDA. The results of the retrospective study announced in July 2011 and Danish study published in the May 2011 issue of the *Journal of the American Medical Association* both concluded that topiramate was not a major teratogen. We look forward to the FORTRESS results and resubmission of the QNEXA NDA in the fourth quarter of 2011," stated Peter Tam, president of VIVUS.

### **Avanafil Update**

In June 2011, we submitted an NDA to the FDA seeking approval of avanafil, our investigational drug for the treatment of erectile dysfunction (ED). The NDA submission follows the successful completion of an extensive phase 3 program for avanafil, which included over 1,350 patients, where avanafil was shown to be well tolerated and effective in treating men with ED.

"The highlight of the second quarter was the filing of the NDA for avanafil. Congratulations to all of the members of the avanafil development team who worked diligently to achieve this significant corporate milestone. In a large and growing market, avanafil, if approved, should be well positioned to assist ED patients looking for a fast treatment alternative," stated Leland Wilson, chief executive officer of VIVUS.

### **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 has submitted an NDA for avanafil, a PDE5 inhibitor being studied for the treatment of erectile dysfunction. For more information about the company, please visit [www.vivus.com](http://www.vivus.com).

### **Note to Investors**

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the second quarter financial results today, August 1, 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 or FORTRESS; 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		Six Months Ended	
	June 30	June 30	June 30	June 30
	2011	2010	2011	2010
Operating expenses:				
Research and development	\$ 11,035	\$ 13,576	15,515	23,787
General and administrative	5,303	6,750	10,731	11,914
Total operating expenses	16,338	20,326	26,246	35,701
Loss from operations	(16,338)	(20,326)	(26,246)	(35,701)
Interest and other income (expense), net	36	(1,245)	78	(2,478)
Loss from continuing operations before income taxes	(16,302)	(21,571)	(26,168)	(38,179)
Provision for income taxes	(2)	-	(3)	(1)
Net loss from continuing operations	(16,304)	(21,571)	(26,171)	(38,180)
Net income (loss) from discontinued operations	107	(1,186)	121	(3,395)
Net loss	\$ (16,197)	\$ (22,757)	\$ (26,050)	\$ (41,575)
Basic and diluted net income (loss) per share:				
Continuing operations	\$ (0.20)	\$ (0.27)	\$ (0.32)	\$ (0.47)
Discontinued operations	0.00	(0.01)	0.00	(0.04)
Net loss per share	\$ (0.20)	\$ (0.28)	\$ (0.32)	\$ (0.51)
Shares used in per share computation:				
Basic	81,928	80,903	81,874	80,801
Diluted	84,133	80,903	84,120	80,801

**VIVUS, Inc.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except par value amount)

	June 30	December 31
	2011	2010*
	(unaudited)	
Current assets:		
Cash and cash equivalents	\$ 28,312	\$ 37,216
Available-for-sale securities	93,304	101,970
Inventories	3,107	3,225
Prepaid expenses and other assets	1,198	1,648
Current assets of discontinued operations	-	6
Total current assets	125,921	144,065
Property and equipment, net	280	221
Total assets	\$ 126,201	\$ 144,286
Current liabilities:		
Accounts payable	\$ 6,224	\$ 2,395

Accrued and other liabilities	5,282	6,377
Current liabilities of discontinued operations	2,662	3,512
Total current liabilities	<u>14,168</u>	<u>12,284</u>

Commitments and contingencies

Stockholders' equity:

Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - 81,971 at June 30, 2011; 81,568 at December 31, 2010, respectively	82	82
Additional paid-in capital	438,077	432,041
Accumulated other comprehensive income	49	4
Accumulated deficit	(326,175)	(300,125)
Total stockholders' equity	<u>112,033</u>	<u>132,002</u>
Total liabilities and stockholders' equity	<u>\$ 126,201</u>	<u>\$ 144,286</u>

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

**CONTACT:**

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