VIVUS Reports 2010 Fourth Quarter and Full-Year Financial Results

MOUNTAIN VIEW, Calif., Feb. 28, 2011 /PRNewswire/ -- VIVUS, Inc. (Nasdaq: VVUS), a biopharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today reported its highlights and financial results for the fourth quarter and year ended December 31, 2010.

2010 Highlights

- In the QNEXA investigational drug development program, we successfully completed the two-year SEQUEL study, an extension study in 675 patients from the CONQUER study. Results were announced in September and showed sustained weight loss of greater than 10% for both doses of QNEXA over two years.

- In December, we filed the Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, in the European Union for QNEXA as a treatment for obesity. Obesity is a global epidemic, with approximately 150 million European adults affected and the prevalence is rising rapidly.

- In the avanafil investigational drug development program, we completed the two remaining phase 3 studies: in diabetics with erectile dysfunction and the long-term open label safety study. Both studies met all primary efficacy endpoints. The NDA filing for avanafil is scheduled for Q2 2011.

- We divested MUSE and the related assets to Meda AB for $22 million and are eligible to receive a $1.5 million milestone based upon future sales of MUSE. The transaction closed on November 5, 2010. In connection with the sale, all of our loans and long-term notes payable were repaid and our MUSE-related royalty obligations were terminated.

- Lastly, we ended the year with $139.2 million in cash, cash equivalents and available for sale securities.

QNEXA Regulatory Update

On October 28, 2010, we received a Complete Response Letter, or CRL, from the FDA regarding the QNEXA NDA. The FDA issued the CRL to communicate its decision that the NDA could not be approved in its present form. The CRL included the following areas: clinical, labeling, REMS, safety update, and drug scheduling. We held a meeting with the FDA on January 19, 2011, to discuss the items contained in the CRL. At this meeting the FDA requested that we assess the feasibility of performing a retrospective observational study utilizing existing healthcare databases to review fetal outcomes in the offspring of women who received 100mg of topiramate for migraine prophylaxis during pregnancy. In the QNEXA studies, which included 15 births from women exposed to topiramate, there were no reports of any adverse fetal outcomes.

We expect to reach agreement with the FDA, and if deemed feasible, initiate the retrospective observational study on fetal outcomes within the next two months. We will provide more details as soon as an agreement is reached. It is our goal to resubmit the NDA for QNEXA by the end of 2011.

Although no other requests for additional information or studies were made by the FDA at the meeting, there can be no assurances that the FDA will not request or require us to provide additional information or undertake additional studies in connection with the QNEXA NDA.

"In 2010, we also made significant progress with the development of QNEXA as a treatment for obesity by filing for approval in the European Union, and for avanafil we completed the pivotal phase 3 studies," stated Leland Wilson, chief executive officer of VIVUS. "We are working diligently on responding to the FDA's request to assess the feasibility of conducting a retrospective observational study. Our goals for 2011 include the continued advancement towards approval of QNEXA in the US and the EU and filing the NDA for avanafil."

Fourth Quarter Results

In November 2010, we sold MUSE and the related assets. Accordingly, all historical financial results related to the MUSE business have been classified as discontinued operations. In the fourth quarter of 2010, we reported a net loss from continuing operations of $19.1 million, or $0.23 per share, net income from discontinued operations of $12.6 million, or $0.15 per share, and total net loss of $6.5 million, or $0.08 per share. The loss from continuing operations included a $6.0 million loss on the early extinguishment of long term debt repaid in conjunction with the MUSE sale. The net income from discontinued operations in the fourth quarter included a $13.7 million gain from the sale of MUSE.

In the fourth quarter of 2009, we had a net loss from continuing operations of $15.5 million, or $0.19 per share, net income from discontinued operations of $2.3 million, or $0.03 per share, and total net loss of $13.2 million, or $0.16 per share. In the fourth quarter of 2009, research and development expenses included the expenses related to the preparation of the QNEXA NDA, which was filed in December 2009.

Year End Results

For the year ended December 31, 2010, we reported a net loss from continuing operations of $75.4 million, or $0.93 per share, net income from discontinued operations was $9.4 million, or $0.11 per share, and total net loss of $66.1 million, or $0.82 per share. As mentioned above, in the fourth quarter of 2010 we closed the sale of MUSE. We included in the net loss from continuing operations a $6.0 million loss on the early extinguishment of long term debt repaid in conjunction with the MUSE sale and recorded a $13.7 million gain from the sale of MUSE, which is included in the net income from discontinued operations. Also included in the results from continuing operations in 2009 is $31.4 million in revenue, previously deferred, from the sale of Evamist.

Cash, Cash Equivalents and Available-for-Sale Securities

VIVUS had cash, cash equivalents and available-for-sale securities (U.S. Treasuries) of $139.2 million at December 31, 2010, as compared to $206.8 million at December 31, 2009. The change in cash, cash equivalents and available-for-sale securities of $67.6 million for the year is the net result of cash used for operating and financing activities, including the proceeds from the MUSE sale and the payoff of long term debt.

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 regulators. 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. 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 fourth quarter and year-end financial results today, February 28, 2011, beginning at 1:30 p.m. Pacific Time. You 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," "estimated" 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 the FDA's complete response letter, or CRL; the feasibility assessment of performing a retrospective observational study of infants born to mothers exposed to 100 mg of topiramate for migraine prophylaxis during pregnancy and the results, if any, from the retrospective observational study, the FDA's interpretation of and agreement with the information VIVUS submitted relating to teratogenicity and cardiovascular safety; the FDA's meeting minutes; the FDA's interpretation of the data from our SEQUEL study, or OB-305; the FDA's requests, if any, to conduct additional clinical trials, provide further analysis of clinical trial data or to conduct retrospective observational studies; substantial competition; the impact on future sales under a limited label and restrictions on distribution; 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 their request stemming from the End of Review meeting will be sufficient to satisfy the FDA's safety concerns, and that the FDA will not require us to conduct any additional clinical or non-clinical 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, 2009, and periodic reports filed with the Securities and Exchange Commission.

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VIVUS, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended		Years Ended	
	December 31 2010	December 31 2009	December 31 2010	December 31 2009*
	(unaudited)	(unaudited)	(unaudited)	
Revenue:				
License and other revenue	$ -	$ -	$ -	$ 31,395
Operating expenses:				
Research and development	6,093	13,521	39,971	70,940
General and administrative	7,018	3,685	25,656	13,870
Total operating expenses	13,111	17,206	65,627	84,810
Loss from operations	(13,111)	(17,206)	(65,627)	(53,415)
Interest and other income (expense), net of loss on early extinguishment of debt and other-than-temporary loss on impaired securities	(6,000)	(725)	(9,798)	(2,349)
Loss from continuing operations before income taxes	(19,111)	(17,931)	(75,425)	(55,764)
Benefit (provision) for income taxes	(8)	2,388	(9)	2,379
Net loss from continuing operations	(19,119)	(15,543)	(75,434)	(53,385)
Net income (loss) from discontinued operations	12,608	2,331	9,369	(906)
Net loss	$ (6,511)	$ (13,212)	$ (66,065)	$ (54,291)
Basic and diluted net income (loss) per share:				
Continuing operations	$ (0.23)	$ (0.19)	$ (0.93)	$ (0.74)
Discontinued operations	0.15	0.03	0.11	(0.01)
Net loss per share	$ (0.08)	$ (0.16)	$ (0.82)	$ (0.75)
Shares used in per share computation:				
Basic	81,288	80,581	81,017	72,779
Diluted	83,541	83,672	83,821	72,779

*The Condensed Consolidated Statement of Operations at December 31, 2009 has been derived from the Company's audited financial statements at that date.

VIVUS, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amount)

	December 31 2010	December 31 2009*
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 37,216	$ 40,533
Available-for-sale securities	101,970	166,241
Inventories	3,225	-
Prepaid expenses and other assets	1,648	4,106
Current assets of discontinued operations	6	12,482
Total current assets	144,065	223,362
Property and equipment, net	221	259
Non-current assets of discontinued operations	-	6,411
Total assets	$ 144,286	$ 230,032
Current liabilities:		
Accounts payable	$ 2,395	$ 8,082
Accrued and other liabilities	6,377	6,769
Current liabilities of discontinued operations	3,512	7,659
Total current liabilities	12,284	22,510
Notes payable-net of current portion	-	15,255
Non-current liabilities of discontinued operations	-	5,541
Total liabilities	12,284	43,306
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 81,568 at December 31, 2010; 80,607 at December 31, 2009, respectively	82	81
Additional paid-in capital	432,041	420,708
Accumulated other comprehensive income (loss)	4	(3)
Accumulated deficit	(300,125)	(234,060)
Total stockholders' equity	132,002	186,726
Total liabilities and stockholders' equity	$ 144,286	$ 230,032

*The Condensed Consolidated Balance Sheet at December 31, 2009 has been derived from the Company's audited financial statements at that date.

SOURCE VIVUS, Inc.