VIVUS Reports Third Quarter and First Nine Months 2010 Financial Results

MOUNTAIN VIEW, Calif., Nov. 8, 2010 /PRNewswire-FirstCall/ -- VIVUS, Inc. (Nasdaq: VVUS), a biopharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today reported its financial results for the third quarter and nine months ended September 30, 2010.

Third Quarter Highlights

On September 21, 2010, we announced top-line results from a two-year study of Qnexa which showed significant and sustained weight loss of greater than 10% over two years. Patients taking top- and mid-dose Qnexa achieved and maintained weight loss over two years of 11.4% and 10.4% of their initial body weight, respectively, as compared to placebo-treated patients with 2.5% weight loss (ITT-LOCF, p<0.0001). The findings come from the SEQUEL study (OB-305), a 52-week extension study for a subset of patients who completed the previously reported 56-week CONQUER study. The total study period was 108 weeks. SEQUEL included 675 obese or overweight patients, all of whom had two or more weight related co-morbidities, and an average baseline BMI of 36.1. Consistent with the first year experience, QNEXA therapy was well tolerated, with no new or unexpected adverse events. The most common side effects seen were constipation, tingling, dry mouth, altered taste and insomnia.

On October 1, 2010, we entered into a definitive asset purchase agreement with Meda to transfer our rights and assets related to MUSE, transurethral alprostadil, for the treatment of erectile dysfunction (ED).The acquisition price was $23.5 million, which includes an upfront cash payment of $22 million. The Company is eligible to receive a one-time milestone payment of $1.5 million based on future sales of MUSE. Meda has been our European distributor of MUSE since 2002. The assets sold include the United States and foreign MUSE patents, existing inventory and the manufacturing facility located in Lakewood, New Jersey. The sale will allow VIVUS to focus on the approval and commercialization of QNEXA and the development of avanafil. This transaction closed on November 5, 2010. Prior to the closing, VIVUS regained all the rights to MUSE and avanafil held by Deerfield Management Company, L.P. and affiliates and by Crown Bank, N. A. The financial results for MUSE are accounted for as discontinued operations.

Third Quarter Results

For the three months ended September 30, 2010, we reported a net loss of $18 million, or $0.22 net loss per share, as compared to a net loss of $21.1 million, or $0.30 net loss per share, during the same period in 2009. The decrease in net loss in the second quarter of 2010 as compared to the second quarter of 2009 primarily results from the decrease in research and development spending due to the completion of the Phase 3 clinical trials for Qnexa for the treatment of obesity, partially offset by increased general and administrative expenses, primarily due to Qnexa pre-commercialization activities in the third quarter 2010.

Nine Months Results

For the nine months ended September 30, 2010, we reported a net loss of $59.6 million, or $0.74 net loss per share, as compared to a net loss of $41.1 million, or $0.59 net loss per share, during the same period in 2009. The increase in net loss in the nine months ended September 30, 2010 as compared to the nine months ended September 30, 2009 results from the completion of the recognition of the Evamist deferred revenue in 2009 and increased general and administrative expenses, primarily due to Qnexa pre-commercialization activities, partially offset by decreased research and development spending due to the completion of the pivotal phase 3 clinical trials for Qnexa for the treatment of obesity.

Cash, Cash Equivalents and Available-for-Sale Securities

VIVUS had cash, cash equivalents and available-for-sale securities of $158.2 million at September 30, 2010, as compared to $206.8 million at December 31, 2009. The decrease in cash, cash equivalents and available-for-sale securities of $48.6 million is primarily due to cash used in operations and other net cash uses offset by proceeds of $2.4 million from the exercise of common stock options and ESPP purchases.

Qnexa Regulatory Update

On October 28, 2010, we received a Complete Response Letter (CRL) from the FDA regarding the Qnexa NDA. The FDA

issued the CRL to communicate its decision that the NDA cannot be approved in its present form. At the present time, we are preparing a written response to the FDA's requests for information in the CRL.

"As demonstrated by the results of the two-year SEQUEL study, Qnexa patients continue to see weight loss greater than 10%. We received the Qnexa CRL on October 28, 2010. In response to the FDA's requests, we are working to submit the final study report from SEQUEL and address their requests in a written response to the CRL," stated Leland Wilson, chief executive officer of VIVUS. "In addition to the release of the SEQUEL data, in the third quarter of 2010 we announced the sale of MUSE to Meda. This transaction closed on November 5, 2010. The MUSE transaction marks the end of an era and I wish to thank the hundreds of employees that have been involved in the MUSE business since its inception and approval in 1996. The balance sheet remains strong and through the remainder of 2010 we are focused on the written response to the CRL for Qnexa, the filing for approval of Qnexa in the European Union and additional phase 3 trial results from avanafil."

About VIVUS

VIVUS is a biopharmaceutical company developing therapies to address obesity, sleep apnea, diabetes and male sexual health. The company's lead product in clinical development, Qnexa(R), completed phase 3 clinical trials for the treatment of obesity and an NDA was filed and accepted by the FDA. VIVUS received a Complete Response Letter (CRL) from the FDA and is preparing a written response to address the FDA's requests for information included in the CRL. Qnexa is also in phase 2 clinical development for the treatment of type 2 diabetes and obstructive sleep apnea. In the area of male 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 third quarter financial results today, November 8, 2010, 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. These forward-looking statements are based on VIVUS' 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 VIVUS' written response to the FDA's complete response letter; the FDA's interpretation of the data VIVUS submits relating to the teratogenicity and cardiovascular safety; the FDA's interpretation of the data from our SEQUEL study (OB-305) and our sleep apnea study (OB-204); that we may be required to conduct additional clinical trials; our history of losses and variable quarterly results; substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; 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 our response to the FDA's complete response letter will be sufficient to satisfy the FDA's safety concerns, that the FDA will not require us to conduct additional clinical 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 statement. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2009 and periodic reports filed with the Securities and Exchange Commission.

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CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Three Months Ended		Nine Months Ended	
	September 30	**September 30**	**September 30**	**September 30**

	2010	2009	2010	2009
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue:				
License and other revenue	$ -	$ -	$ -	$ 31,395
Operating expenses:				
Research and development	10,091	17,149	33,878	57,398
General and administrative	6,747	3,447	18,661	10,398
Total operating expenses	16,838	20,596	52,539	67,796
Loss from operations	(16,838)	(20,596)	(52,539)	(36,401)
Interest (expense) income, net of other-than-temporary loss on impaired securities	(1,323)	(617)	(3,802)	(1,629)
Loss before provision for income taxes	(18,161)	(21,213)	(56,341)	(38,030)
Provision for income taxes	(1)	(1)	(1)	(1)
Loss from continuing operations	(18,162)	(21,214)	(56,342)	(38,031)
Income (loss) from discontinued operations	183	148	(3,212)	(3,048)
Net loss	$ (17,979)	$ (21,066)	$ (59,554)	$ (41,079)
Basic and diluted net loss per share:				
Continuing operations	$ (0.22)	$ (0.30)	$ (0.70)	$ (0.55)
Discontinued operations	0.00	0.00	(0.04)	(0.04)
Net loss per share	$ (0.22)	$ (0.30)	$ (0.74)	$ (0.59)
Shares used in per share computation:				
Basic	81,172	70,942	80,926	70,149
Diluted	82,966	73,324	80,926	70,149

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CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amount)

	September 30 2010	December 31 2009*
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 29,036	$ 40,533
Available-for-sale securities	129,162	166,241
Inventories, net	1,803	-
Prepaid expenses and other assets	2,306	3,968
Current assets of discontinued operations	7,786	12,620
Total current assets	170,093	223,362
Property and equipment, net	240	290
Non-current assets of discontinued operations	5,595	6,380
Total assets	$ 175,928	$ 230,032
Current liabilities:		

Accounts payable	$ 4,677	$ 8,082
Accrued and other liabilities	10,405	6,891
Current liabilities of discontinued operations	5,330	7,537
Total current liabilities	20,412	22,510
Notes payable-net of current portion	15,255	15,255
Non-current liabilities of discontinued operations	5,068	5,541
Total liabilities	40,735	43,306
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 81,206 at September 30, 2010; 80,607 at December 31, 2009, respectively	81	81
Additional paid-in capital	428,703	420,708
Accumulated other comprehensive income (loss)	23	(3)
Accumulated deficit	(293,614)	(234,060)
Total stockholders' equity	135,193	186,726
Total liabilities and stockholders' equity	$ 175,928	$ 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.

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