VIVUS Reports First Quarter 2010 Financial Results

MOUNTAIN VIEW, Calif., May 3, 2010 /PRNewswire via COMTEX News Network/ -- 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 first quarter ended March 31, 2010.

First Quarter 2010 Highlights

- On January 7, 2010, we announced positive results from a Phase 2 study evaluating the safety and efficacy of Qnexa, our investigational product candidate, for the treatment of obstructive sleep apnea, or OSA. This study demonstrated statistically significant improvement in the apnea/hypopnea index, or AHI, which is a measure of the severity of sleep apnea, in patients with OSA treated with Qnexa for 28 weeks. Qnexatreated patients on average had a 69% reduction in sleep apnea and hypopnea events as compared to patients on placebo (ITT-LOCF p <0.001 active vs. placebo).

- On January 11, 2010, we announced new data from an analysis of the recently completed Phase 3 study, REVIVE TA-301, of avanafil, an investigational product candidate for the treatment of erectile dysfunction, or ED. Patients who attempted intercourse within 15 minutes of dosing were successful 67%, 69% and 72% of the time on 50, 100 and 200 mg of avanafil, respectively, as compared to 29% of the patients on placebo (p<0.05).

- On March 1, 2010, we announced that the FDA had accepted for filing the New Drug Application, or NDA, for Qnexa for the treatment of obesity. The Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. FDA is tentatively scheduled to review the NDA for Qnexa for the treatment of obesity on July 15, 2010. Further, the FDA has set October 28, 2010 as the Prescription Drug User Fee Act, or PDUFA, date whereby we may expect a response to the review of the NDA.

"The highlight of the quarter was the acceptance of the Qnexa NDA and the notification of the tentative Advisory Committee meeting on July 15, 2010. We look forward to discussing the results of the phase 3 studies with Advisory Committee," stated Leland Wilson, chief executive officer of VIVUS. "Early in the quarter we reported positive results from the phase 2 study of Qnexa in obstructive sleep apnea, a serious unmet medical need. Obstructive Sleep Apnea is now the third potential indication for Qnexa and we are working with the FDA to design a phase 3 program. In addition we also reported new data from the first phase 3 avanafil study that showed efficacy in 15 minutes, further distinguishing the product from the existing oral ED therapies."

First Quarter Results

Product revenues from the sale of MUSE in the first quarter of 2010 were $1.6 million as compared to $1.2 million in the first quarter of 2009 due to the increase in number of units sold in 2010 as compared to last year. Total revenue for the first quarter of 2010 was $1.7 million as compared to $22.2 million for the first quarter of 2009. The decrease in total revenue in the first quarter of 2010 compared to the first quarter last year was primarily due to the inclusion of deferred license revenue from the sale of Evamist in the first quarter of 2009. There was no deferred license revenue recognized in the first quarter of 2010 as the monthly Evamist deferred revenue recognition ended in May 2009.

Net loss for the first quarter of 2010 was $18.8 million, or $0.23 per share, compared to $6.8 million, or $0.10 per share, for the same period last year. The increase in net loss in the first quarter of 2010 as compared to the first quarter of 2009 predominantly results from the completion of the recognition of the Evamist deferred revenue in 2009 and to a lesser extent, decreased research and development spending due to the completion of the 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 $194.9 million at March 31, 2010, as compared to $207 million at December 31, 2009. The decrease in cash, cash equivalents and available-for-sale securities of $12.1 million is primarily due to cash used in operations and other net cash uses offset by proceeds of $1 million from the exercise of common stock options.

About VIVUS

VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health. The company's lead investigational product in clinical development, Qnexa(R), has completed phase 3 clinical trials for the treatment of obesity and an NDA has been filed and accepted by the FDA, with an action date of 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 potentially best-in-class PDE5 inhibitor for the treatment of erectile dysfunction. MUSE(R) (alprostadil), a first generation therapy for the treatment of ED, is already commercially available and generating revenue for VIVUS. 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 3, 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, 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 future clinical studies discussed in this press release will be completed or successful 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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VIVUS, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended	
	March 31 2010 (unaudited)	March 31 2009 (unaudited)
Revenue:		
US product, net	$1,102	$893
International product	514	293
License and other revenue	116	21,046
Total revenue	1,732	22,232

Operating expenses:		
Cost of goods sold and manufacturing	2,411	2,603
Research and development	10,223	20,069
Selling, general and administrative	6,585	5,411
Total operating expenses	19,219	28,083
Loss from operations	(17,487)	(5,851)
Interest (expense) income, net of other-than-temporary loss on impaired securities	(1,323)	(952)
Loss before provision for income taxes	(18,810)	(6,803)
Provision for income taxes	(8)	(6)
Net loss	$(18,818)	$(6,809)
Net loss per share:		
Basic and diluted	$(0.23)	$(0.10)
Shares used in per share computation:		
Basic and diluted	80,698	69,687

VIVUS, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except par value amount)

	March 31 2010 (unaudited)	December 31 2009*
Current assets:		
Cash and cash equivalents	$14,906	$40,750
Available-for-sale securities	179,966	166,241
Accounts receivable, net	883	7,259
Inventories, net	3,212	2,702
Prepaid expenses and other assets	4,351	6,410
Total current assets	203,318	223,362
Property and equipment, net	5,724	5,970
Restricted cash	700	700
Total assets	$209,742	$230,032
Current liabilities:		
Accounts payable	$6,010	$8,485
Accrued and other liabilities	12,524	14,025

Total current liabilities	18,534	22,510
Notes payable-net of current portion	19,955	19,998
Deferred revenue	682	798
Total liabilities	39,171	43,306
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 80,855 at March 31, 2010; 80,607 at December 31, 2009	81	81
Additional paid-in capital	423,360	420,708
Accumulated other comprehensive income (loss)	8	(3)
Accumulated deficit	(252,878)	(234,060)
Total stockholders' equity	170,571	186,726
Total liabilities and stockholders' equity	$209,742	$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.