VIVUS Reports 2009 Fourth Quarter and Full-Year Financial Results

Major Milestone Advancement of Late-Stage Development Programs in Obesity and Erectile Dysfunction

MOUNTAIN VIEW, Calif., March 8, 2010 /PRNewswire via COMTEX News Network/ -- VIVUS, Inc. (Nasdaq: VVUS) today reported its financial results for the fourth quarter and year ended December 31, 2009.

"This past year was transformational for VIVUS given the significant achievements in both the Qnexa and avanafil investigational product programs, which are being developed to address the obesity and erectile dysfunction markets with highly differentiated products that address unmet needs," stated Leland Wilson, chief executive officer of VIVUS. "We look forward to continued clinical and regulatory momentum in 2010 as we continue to work with the FDA during the review of the Qnexa NDA and as we report additional avanafil pivotal data."

Fourth Quarter Results

Product revenues from the sale of MUSE in the fourth quarter of 2009 were $8.5 million as compared to $7.8 million in the fourth quarter of 2008, primarily due to a modest increase in shipments and an increase in domestic prices in 2009. Total revenue for the fourth quarter of 2009 was $8.6 million, as compared to $28.8 million for the fourth quarter of 2008. The decrease in total revenue in the fourth quarter of 2009 compared to the fourth quarter last year was primarily due to the inclusion of deferred license revenue from the sale of Evamist in the fourth quarter of 2008. There was no deferred license revenue recognized in the fourth quarter of 2009 as the monthly Evamist deferred revenue recognition ended in May 2009.

Net loss for the fourth quarter of 2009 was $13.2 million, or $0.16 per share, compared to $6.7 million, or $0.10 per share, for the same period last year. The increase in net loss in the fourth quarter of 2009 as compared to the fourth quarter of 2008 predominantly results from the completion of the monthly 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. In the fourth quarter of 2009, VIVUS also recorded a $2.4 million benefit for income taxes primarily due to a carryback claim of losses generated in 2008 that allowed us to obtain a refund of Federal income taxes paid in 2007.

Year End Results

MUSE revenues of $18.2 million for 2009 were consistent with the $18.1 million recognized in 2008. For 2009, total revenues were $50 million, as compared to $102.2 million for 2008. The decrease in total revenues is mainly due to the last portion of K-V deferred license revenue from the sale of Evamist being recognized in 2009 as compared to 2008, where the company recognized a full year of deferred revenue. Net loss for 2009 was $54.3 million, or $0.75 per share, compared to a net loss of $9.9 million, or $0.16 per share, for 2008. The increase in the net loss is primarily due to a decrease in license and other revenue related to the Evamist transaction. The decrease in operating expenses in 2009 as compared to 2008 was primarily attributable to reduced spending on Qnexa for obesity clinical trials, partially offset by increased spending related to the company's phase 3 clinical trials of avanafil for the treatment of erectile dysfunction, increased selling, general and administrative expense primarily due to Qnexa pre-commercialization expenses and an increase in non-cash share-based compensation expense. In addition, VIVUS had a reduction in other-than-temporary impairment losses in 2009 as compared to 2008.

Cash, Cash Equivalents and Available-for-Sale Securities

VIVUS had cash, cash equivalents and available-for-sale securities of $207 million at December 31, 2009, as compared to $189.2 million at December 31, 2008. The increase in cash, cash equivalents and available-for-sale securities of $17.8 million consists of $102.7 million in net proceeds from the underwritten public offering of our common stock and $10 million in cash from the Deerfield financing offset by cash used in operations and other net cash uses of $94.9 million.

Recent Clinical Development Highlights:

- **Obesity Program:** On December 29, 2009, VIVUS announced that a New Drug Application (NDA) had been submitted to the FDA seeking approval of Qnexa for the treatment of obesity, including weight loss and maintenance of weight loss, in patients who are obese or overweight with co-morbidities such as hypertension, type 2 diabetes, dyslipidemia or central adiposity. Qnexa is the company's proprietary oral investigational drug candidate that incorporates low doses of active

ingredients from two previously FDA-approved products, topiramate and phentermine. VIVUS previously completed a Special Protocol Assessment (SPA) process with the FDA regarding key elements of the pivotal phase 3 protocols (OB-301 and OB-303) of Qnexa for the treatment of obesity and weight-related co-morbidities. On March 1, 2010, VIVUS announced that the FDA had accepted for filing the NDA for Qnexa for the treatment of obesity. Further, the FDA has set October 28, 2010 as the date whereby the company may expect a response to the review of the NDA.

- **Obstructive Sleep Apnea Program:** VIVUS announced positive results from a phase 2 study evaluating the safety and efficacy of Qnexa, our investigational drug candidate, for the treatment of obstructive sleep apnea (OSA). This study demonstrated statistically significant improvement in the apnea/hypopnea index (AHI), which is a measure of the severity of sleep apnea, in patients with OSA treated with Qnexa for 28 weeks. Qnexa-treated patients on average had a 69% reduction in sleep apnea events as compared to patients on placebo. Qnexa-treated patients also experienced significant weight loss, improvements in blood pressure, and overnight blood oxygen levels. OSA is a sleep-related breathing disorder that involves a decrease or complete cessation of airflow into the lungs, despite an ongoing effort to breathe; it is associated with an increased risk of hypertension, diabetes, stroke, sudden cardiac death and all-cause mortality. Approximately 18 million Americans have sleep apnea.

- **Erectile Dysfunction Program:** VIVUS announced positive results from a pivotal phase 3 study evaluating its investigational drug candidate avanafil, a highly specific and selective phosphodiesterase type 5 (PDE5) inhibitor, for the treatment of erectile dysfunction (ED). REVIVE (TA-301) evaluated the safety and efficacy of avanafil in 646 patients; 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 ($p<0.05$). The top-line results of the REVIVE study evaluating the safety and efficacy of avanafil showed that all three doses of avanafil met the FDA-defined primary study endpoints by demonstrating a statistically significant improvement in erectile function as measured by the Sexual Encounter Profile (SEP), improvements in the International Index of Erectile Function (IIEF) score, and a favorable side-effect and safety profile.

"The milestones achieved in 2009 are evidence of VIVUS' commitment to executing on our well-defined business strategy," added Peter Tam, president of VIVUS. "In 2010, we will focus on advancing our pre-commercial and business development initiatives along with executing our clinical and regulatory development plans in both the U.S. and abroad."

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, and in phase 2 development of Luramist(TM) for the treatment of hypoactive sexual desire disorder (HSDD) in women. 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 fourth quarter and year end financial results today, March 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, 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, 2008 and periodic reports filed with the Securities and Exchange Commission.

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

	Three Months Ended		Years Ended	
	December 31, 2009	December 31, 2008	December 31, 2009	December 31, 2008*
	(unaudited)	(unaudited)	(unaudited)	
Revenue:				
US product, net	$7,711	$7,189	$15,836	$14,974
International product	822	565	2,347	3,076
License and other revenue	116	21,045	31,858	84,183
Total revenue	8,649	28,799	50,041	102,233
Operating expenses:				
Cost of goods sold and manufacturing	3,861	3,693	11,950	11,956
Research and development	13,574	22,700	71,075	76,996
Selling, general and administrative	6,059	5,805	21,033	18,904
Total operating expenses	23,494	32,198	104,058	107,856
Loss from operations	(14,845)	(3,399)	(54,017)	(5,623)
Interest (expense) income, net of other-than-temporary loss on impaired securities	(816)	(3,306)	(2,714)	(4,314)
Loss before benefit (provision) for income taxes	(15,661)	(6,705)	(56,731)	(9,937)
Benefit (provision) for income taxes	2,449	12	2,440	(3)
Net loss	$(13,212)	$(6,693)	$(54,291)	$(9,940)
Net loss per share:				
Basic and diluted	$(0.16)	$(0.10)	$(0.75)	$(0.16)

Shares used in per share computation:				
Basic and diluted	80,581	69,454	72,779	63,724

*The Condensed Consolidated Statement of Operations at December 31, 2008 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 2009 (unaudited)	December 31 2008*
Current assets:		
Cash and cash equivalents	$40,750	$66,121
Available-for-sale securities	166,241	121,789
Accounts receivable, net	7,259	4,157
Inventories, net	2,702	3,041
Prepaid expenses and other assets	6,410	3,744
Total current assets	223,362	198,852
Property and equipment, net	5,970	6,726
Restricted cash	700	700
Available-for-sale securities	-	1,344
Total assets	$230,032	$207,622
Current liabilities:		
Accounts payable	$8,485	$17,205
Deferred revenue	463	31,858
Accrued and other liabilities	13,562	14,909
Total current liabilities	22,510	63,972
Notes payable-net of current portion	19,998	11,177
Deferred revenue	798	1,260
Total liabilities	43,306	76,409
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 80,607 at December 31, 2009; 69,667 at December 31, 2008;	81	70

Additional paid-in capital	420,708	310,558
Accumulated other comprehensive income (loss)	(3)	354
Accumulated deficit	(234,060)	(179,769)
Total stockholders' equity	186,726	131,213
Total liabilities and stockholders' equity	$230,032	$207,622

*The Condensed Consolidated Balance Sheet at December 31, 2008 has been derived from the Company's audited financial statements at that date.

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