VIVUS Reports Third Quarter 2009 Highlights and Financial Results

MOUNTAIN VIEW, Calif., Nov 03, 2009 /PRNewswire-FirstCall 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 third quarter ended September 30, 2009.

Third Quarter Highlights

In the third quarter of 2009, we announced positive results from two final, phase 3 pivotal 56-week studies, EQUIP (OB-302) and CONQUER (OB-303), evaluating the safety and efficacy of our investigational drug candidate Qnexa in more than 3,750 patients across 93 sites. The EQUIP and CONQUER studies met all primary endpoints by demonstrating statistically significant weight loss with all three doses of Qnexa, as compared to placebo. Patients taking Qnexa also achieved significant improvements in cardiovascular and metabolic risk factors including reductions in blood pressure, lipids, and blood sugar.

Highlights from the EQUIP and CONQUER studies include:

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--  Average weight loss of 14.7% (37 lbs) was achieved by patients treated
    with Qnexa for 56 weeks in the EQUIP study;
--  FDA guidance on efficacy benchmarks for weight loss agents exceeded at
    all three doses of Qnexa tested in the clinical program;
--  Completion rates up to 69% were significantly higher than placebo at all
    three doses of Qnexa, indicating favorable tolerability; and

--  Favorable benefit/risk safety profile for Qnexa.
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In the third quarter of 2009, we closed an underwritten public offering of our common stock which provided us with gross proceeds of $108.7 million from the sale of 10,350,000 shares of our common stock at a price per share of $10.50.

"The highlight of the third quarter and the year to date was the announcement of the positive results from the year-long studies of Qnexa for the treatment of obesity. The results demonstrated that patients treated with Qnexa had weight loss up to 14.7% and significant improvement in their co-morbidities. All three doses administered in the studies exceeded the FDA guidance on efficacy endpoints. Progress on the submission of the NDA for Qnexa in obesity remains on schedule and is expected by the end of 2009," stated Leland Wilson, chief executive officer of VIVUS. "Following the announcement of the positive Qnexa results, we were able to raise $108.7 million in gross proceeds from a public offering of our common stock. With the positive results from our phase 3 trials for Qnexa and a cash and investment balance in excess of $226 million at the end of the third quarter, we believe we are well positioned to meet our goals for 2009 and beyond."

Third Quarter Results

Product revenues from the sale of MUSE in the third quarter of 2009 were $4.3 million, as compared to $4.4 million in the third quarter of 2008. License and other revenue was $115,000 and $21 million in the third quarters of 2009 and 2008, respectively. The third quarter 2008 included the recognition of deferred license revenue from Evamist. Recognition of the deferred revenue from the sale of Evamist ended in May 2009. Total revenue for the third quarter of 2009 was $4.4 million, as compared to $25.5 million for the third quarter of 2008.

Operating expenses for the third quarter of 2009 were $24.8 million as compared to $22.6 million for the same period in 2008. The difference in operating expenses for the third quarter was primarily attributable to spending related to our phase 3 clinical trials of avanafil, our orally administered investigational drug candidate for the treatment of erectile dysfunction, partially offset by reduced spending on the obesity trials for Qnexa which were completed in the third quarter of 2009.

Net loss for the third quarter of 2009 was $21.1 million, or $0.30 per share, as compared to net income of $266,000, or $0.00 per share, for the third quarter of 2008.

Nine Month Results

Product revenues from the sale of MUSE for the first nine months of 2009 were $9.7 million, as compared to $10.3 million for the same period of 2008. License and other revenue was $31.7 million for the first nine months as compared to $63.1 million for 2008. The first nine months of 2008 included recognition of deferred license revenue from Evamist. Recognition of the deferred revenue from the sale of Evamist ended in May 2009. Total revenue for the first nine months of 2009 was $41.4 million, as compared to $73.4 million for 2008.

Operating expenses for the first nine months of 2009 were $80.6 million as compared to $75.7 million for the same period in 2008. The difference in operating expenses for 2009 was primarily attributable to spending related to our phase 3 clinical trials of avanafil, partially offset by reduced spending on the Qnexa program for obesity.

Net loss for the first nine months of 2009 was $41.1 million, or $0.59 per share, as compared to $3.2 million, or $0.05 per share, for 2008.

Cash, Cash Equivalents and Available-for-Sale Securities

VIVUS had cash, cash equivalents and available-for-sale securities of $226.9 million at September 30, 2009, as compared to $189.2 million at December 31, 2008. The increase in cash, cash equivalents and available-for-sale securities of $37.7 million is the net result of cash provided by financing and investing activities, including $102.7 million in net proceeds from the underwritten public offering of our common stock and $10 million in cash from the other financing received in the first nine months of 2009, partially offset by cash used for operating activities.

About VIVUS

VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address unmet needs in obesity, diabetes and sexual health. The company's lead product in clinical development, Qnexa(TM), has recently completed phase 3 clinical trials for the treatment of obesity. Qnexa is also in phase 2 clinical development for the treatment of type 2 diabetes. In the area of sexual health, VIVUS is in phase 3 development with avanafil, a 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 on the market 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 third quarter financial results today, November 3, 2009, beginning at 1:30 p.m. Pacific Time. You can listen to this call by dialing 1-877-857-6173 and outside the U.S. 1-719-325-4932. 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		Nine Months Ended	
September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008
(unaudited)	(unaudited)	(unaudited)	(unaudited)

Revenue:				
US product, net	$3,864	$3,774	$8,125	$7,785
International product	456	657	1,525	2,511
License and other revenue	115	21,046	31,742	63,138
Total revenue	4,435	25,477	41,392	73,434
Operating expenses:				
Cost of goods sold and manufacturing	2,609	2,547	8,089	8,263
Research and development	17,174	15,590	57,501	54,296
Selling, general and administrative	5,008	4,502	14,974	13,099
Total operating expenses	24,791	22,639	80,564	75,658
Income (loss) from operations	(20,356)	2,838	(39,172)	(2,224)
Interest (expense) income, net of other-than-temporary loss on impaired securities	(707)	(2,567)	(1,898)	(1,008)
Income (loss) before provision for income taxes	(21,063)	271	(41,070)	(3,232)
Provision for income taxes	(3)	(5)	(9)	(15)
Net income (loss)	$(21,066)	$266	$(41,079)	$(3,247)
Net income (loss) per share:				
Basic and diluted	$(0.30)	$0.00	$(0.59)	$(0.05)
Shares used in per share computation:				
Basic	70,942	66,122	70,149	61,801
Diluted	70,942	67,784	70,149	61,801

VIVUS, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amount)

	September 30, 2009	December 31, 2008*
	(unaudited)	
Current assets:		
Cash and cash equivalents	$127,819	$66,121
Available-for-sale securities	99,096	121,789
Accounts receivable, net	2,347	4,157
Inventories, net	2,760	3,041
Prepaid expenses and other assets	3,634	3,744
Total current assets	235,656	198,852
Property and equipment, net	6,104	6,726
Restricted cash	700	700
Available-for-sale securities	-	1,344
Total assets	$242,460	$207,622
Current liabilities:		
Accounts payable	$7,208	$17,205
Deferred revenue	462	31,858
Accrued and other liabilities	14,840	14,909
Total current liabilities	22,510	63,972
Notes payable-net of current portion	20,104	11,177
Deferred revenue	914	1,260
Total liabilities	43,528	76,409
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 80,548 at September 30, 2009; 69,667 at December 31, 2008	81	70
Additional paid-in capital	419,547	310,558
Accumulated other comprehensive income	152	354
Accumulated deficit	(220,848)	(179,769)
Total stockholders' equity	198,932	131,213
Total liabilities and stockholders' equity	$242,460	$207,622

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

CONTACT:

VIVUS, Inc. Investor Relations: The Trout Group

Timothy E. Morris
Chief Financial Officer
650-934-5200

Brian Korb
646-378-2923

Media Relations:

Pure Communications, Inc.
Dan Budwick
+1-973-271-6085

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http://www.vivus.com