VIVUS Reports Second Quarter and First Six Months 2010 Financial Results

MOUNTAIN VIEW, Calif., Aug 02, 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 financial results for the second quarter and six months ended June 30, 2010.

Second Quarter Results

Product revenues from the sale of MUSE in the second quarter of 2010 were $3.8 million as compared to $4.1 million in the second quarter of 2009 due to a small decrease in U.S. shipments. Total revenue for the second quarter of 2010 was $3.9 million as compared to $14.7 million for the second quarter of 2009. The decrease in total revenue in the second quarter of 2010 compared to the second quarter last year was primarily due to the inclusion of deferred license revenue from the sale of Evamist in the second quarter of 2009. There was no deferred license revenue recognized in 2010 as the monthly Evamist deferred revenue recognition ended in May 2009.

Net loss for the second quarter of 2010 was $22.8 million, or $0.28 per share, as compared to net loss of $13.2 million, or $0.19 per share, for the second quarter of 2009. The increase in net loss in the second quarter of 2010 as compared to the second quarter of 2009 results from the completion of the recognition of the Evamist deferred revenue in 2009 and increased selling, general and administrative expenses, primarily due to Qnexa pre-commercialization expenses 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.

First Half Results

Product revenues from the sale of MUSE in the first half of 2010 were $5.4 million as compared to $5.3 million for 2009. Total revenue for the first half of 2010 was $5.6 million as compared to $37.0 million for 2009. The decrease in total revenue in the second quarter of 2010 compared to the second quarter last year was primarily due to the inclusion of deferred license revenue from the sale of Evamist in the first half of 2009.

Net loss for the first six months of 2010 was $41.6 million, or $0.51 per share, as compared to net loss of $20.0 million, or $0.29 per share, for 2009. The increase in net loss in the first half of 2010 as compared to 2009 results from the completion of the recognition of the Evamist deferred revenue in 2009 and increased selling, general and administrative expenses, primarily due to Qnexa pre-commercialization expenses 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 $174.8 million at June 30, 2010, as compared to $207.0 million at December 31, 2009. The decrease in cash, cash equivalents and available-for-sale securities of $32.2 million is primarily due to cash used in operations and other net cash uses offset by proceeds of $1.3 million from the exercise of common stock options and ESPP purchases.

Qnexa Update

On July 15, 2010 the Endocrinologic and Metabolic Drugs Advisory Committee of the U.S. Food and Drug Administration (FDA) voted against the following question: "Based on the current available data, do you believe the overall benefit-risk assessment of PHEN/TPM (QNEXA) is favorable to support its approval for the treatment of obesity in individuals with a BMI > 30 kg/m2 or > 27 kg/m2 with weight-related co-morbidities?" The three co-morbidities included hypertension, diabetes and dyslipidemia.

The vote from the Endocrinologic and Metabolic Drugs Advisory Committee is a recommendation. The FDA will take the Committee's recommendation into consideration during its review of the NDA and will make a determination. The FDA may or may not follow the Committee's recommendation. We intend to work closely with the FDA leading up to our October 28, 2010 PDUFA date to address the labeling and safety questions raised during the proceedings. The impact of the negative vote of the Committee may delay or decrease the approvability of Qnexa.

We have conducted a one-year extension study of a subset of patients who have completed the 56-week CONQUER study.

The SEQUEL study is a double-blind, placebo-controlled, 3-arm, prospective study across 36 centers comparing Qnexa to placebo over an additional 52-week treatment period. Patients in SEQUEL continued receiving the same treatment they had been receiving, in a blinded fashion, from the CONQUER study. The co-primary endpoints for this study are the differences between treatments in weight loss and percent weight loss from the beginning of the CONQUER trial to the end of the treatment period. Patients were asked to continue a hypocaloric diet representing a 500-calorie/day deficit and were advised to follow a simple lifestyle modification program.

SEQUEL enrolled approximately 650 obese or overweight patients with a BMI that equaled or exceeded 22 kg/m2 with controlled co-morbidities. Patients were followed for 52 weeks of treatment with patients continuing in their respective CONQUER treatment group receiving either once-a-day treatment with mid-dose Qnexa, full-dose Qnexa or placebo. This extension study was not required by the FDA nor did it need to be completed in support of the NDA for Qnexa for the treatment of obesity. The purpose of this study is to support the Marketing Authorization Application, or MAA, filing in Europe. The results of the SEQUEL study are expected before the end of the third quarter of 2010.

"Several presentations on Qnexa at various medical conferences continued our commitment to share our results with healthcare professionals. On the regulatory front, we continue to work with the FDA to address the items discussed at the recent Advisory Committee meeting. The two-year data from the SEQUEL study will provide information on the long-term efficacy and safety of Qnexa. We look forward to working with the FDA as we approach the PDUFA date on October 28, 2010," stated Leland Wilson, chief executive officer of VIVUS. "In the second quarter of 2010 we continued the advancement of avanafil. The results of the REVIVE-Diabetes study showed avanafil treatment was successful in improving erectile function in men with diabetes. The results were consistent with those observed in the first phase 3 study in men with ED from a general population."

About Qnexa

Qnexa (Q-NEX-uh) is an investigational drug candidate being developed to address weight loss. Qnexa is a once-a-day, proprietary, oral, controlled-release formulation of low dose phentermine and topiramate, which is believed to address both appetite and satiety - the two main mechanisms that impact eating behavior - in one capsule. In phase 2 and 3 clinical data to date, Qnexa has demonstrated significant weight loss, glycemic control, reduction in sleep apnea events and improvement in cardiovascular risk factors.

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), 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 PDE5 inhibitor being studied for the treatment of erectile dysfunction. 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 second quarter financial results today, August 2, 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	
	June 30 2010	June 30 2009
	(unaudited)	(unaudited)
Revenue:		
US product, net	$3,036	$3,368
International product	749	776
License and other revenue	115	10,581
Total revenue	3,900	14,725
Operating expenses:		
Cost of goods sold and manufacturing	2,904	2,877
Research and development	14,175	20,258
Selling, general and administrative	8,234	4,555
Total operating expenses	25,313	27,690
Loss from operations	(21,413)	(12,965)
Interest (expense) income, net of other-than-temporary loss on impaired securities	(1,336)	(239)

Loss before provision for income taxes	(22,749)	(13,204)
Provision for income taxes	(8)	-
Net loss	$(22,757)	$(13,204)
Net loss per share: Basic and diluted	$(0.28)	$(0.19)
Shares used in per share computation: Basic and diluted	80,903	69,805

	Six Months Ended	
	June 30 2010	June 30 2009
	(unaudited)	(unaudited)
Revenue:		
US product, net	$4,138	$4,261
International product	1,263	1,069
License and other revenue	231	31,627
Total revenue	5,632	36,957
Operating expenses:		
Cost of goods sold and manufacturing	5,315	5,480
Research and development	24,398	40,327
Selling, general and administrative	14,819	9,966
Total operating expenses	44,532	55,773
Loss from operations	(38,900)	(18,816)
Interest (expense) income, net of other-than-		

temporary loss on impaired securities	(2,659)	(1,191)
Loss before provision for income taxes	(41,559)	(20,007)
Provision for income taxes	(16)	(6)
Net loss	$(41,575)	$(20,013)
Net loss per share: Basic and diluted	$(0.51)	$(0.29)
Shares used in per share computation: Basic and diluted	80,801	69,746

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

	June 30 2010 (unaudited)	December 31 2009*
Current assets:		
Cash and cash equivalents	$11,545	$40,750
Available-for-sale securities	163,257	166,241
Accounts receivable, net	2,072	7,259
Inventories, net	3,407	2,702
Prepaid expenses and other assets	5,163	6,410
Total current assets	185,444	223,362
Property and equipment, net	5,443	5,970
Restricted cash	700	700
Total assets	$191,587	$230,032
Current liabilities:		
Accounts payable	$4,735	$8,485
Accrued and other liabilities	16,224	14,025
Total current liabilities	20,959	22,510
Notes payable-net of current portion	19,914	19,998
Deferred revenue	567	798
Total liabilities	41,440	43,306

Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 80,964 at June 30, 2010; 80,607 at December 31, 2009	81	81
Additional paid-in capital	425,679	420,708
Accumulated other comprehensive income (loss)	22	(3)
Accumulated deficit	(275,635)	(234,060)
Total stockholders' equity	150,147	186,726
Total liabilities and stockholders' equity	$191,587	$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.