VIVUS Reports Second Quarter 2009 Financial Results

MOUNTAIN VIEW, Calif., Aug 11, 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 financial results for the second quarter ended June 30, 2009.

Second Quarter Results

Net loss for the second quarter of 2009 was $13.2 million, or $0.19 per share, as compared to net income of $3.6 million, or $0.06 per share, for the second quarter of 2008. The net loss in the second quarter of 2009 as compared to the net income in the second quarter of 2008 is primarily due to a decrease in license and other revenue as a result of the last portion of K-V Pharmaceutical ("K-V") deferred license revenue being recognized in the second quarter of 2009, and increased operating expenses. The increase in operating expenses, as compared to the second quarter of 2008, was primarily attributable to spending related to our phase 3 clinical trials of avanafil, our investigational product candidate for the treatment of erectile dysfunction. Spending on Qnexa, our investigational product for obesity, was consistent quarter over quarter.

Total revenue for the second quarter of 2009 was $14.7 million, as compared to $25.3 million for the second quarter of 2008. Product revenues from the sale of MUSE in the second quarter of 2009 were $4.1 million, as compared to $4.2 million in the second quarter of 2008. License and other revenue of $10.6 million and $21 million in the second quarters of 2009 and 2008, respectively, primarily relates to the sale in 2007 of Evamist to K-V. All of the deferred revenue related to the sale of Evamist has now been recognized. Since we had received the $150 million in cash from the sale of Evamist and we had no related contingencies, the recognition of license revenue and the corresponding reduction of deferred revenue related to the Evamist sale had no impact on our cash flows from operations in 2009 or 2008.

Six Month Results

Net loss for the six months ended June 30, 2009 was $20 million, or $0.29 per share, compared to a net loss of $3.5 million or $0.06 per share for the same period in 2008. The increase in the net loss in the six months ended June 30, 2009 as compared to the same period in 2008 is primarily due to the decrease in K-V deferred license revenue, an increase in operating expenses primarily due to our phase 3 clinical trials of avanafil and increased legal expenses and costs related to the Acrux arbitration and a decrease in interest income. With the completion of the Acrux arbitration, legal expenses are expected to decrease in the second half of 2009. For the six-month period ending June 30, 2009, total revenues were $37 million, compared to $48 million for the same period in 2008. The decrease in total revenues is primarily due to the reduction in K-V deferred license revenue in the six months ended June 30, 2009.

Cash, Cash Equivalents and Available for Sale Securities

VIVUS had cash, cash equivalents and available-for-sale securities of $144.2 million at June 30, 2009, as compared to $189.2 million at December 31, 2008. The decrease in cash, cash equivalents and available-for-sale securities of $45 million is the net result of cash used for operating and investing activities partially offset by cash provided by financing activities, including $6.7 million in cash from the Deerfield financing received in the first six months of 2009.

Qnexa Update

The phase 3 Qnexa development program remains on schedule. In total, over 3,750 patients were enrolled in two 56-week studies. The EQUIP study (OB-302) will determine the impact of Qnexa on patients that are considered morbidly obese (BMI>35). The CONQUER study (OB-303) enrolled patients that are considered overweight (BMI>27) with at least two co-morbidities including high blood pressure, high cholesterol and type 2 diabetics. Top-line results for both of these studies are expected in the third quarter of 2009.

"The highlight of the second quarter was the two podium presentations of Qnexa at this year's American Diabetes Association Scientific Session. The medical and scientific communities have long recognized the link between obesity and type 2 diabetes. Now they are beginning to recognize the importance of weight loss in the treatment of type 2 diabetes. The top-line results from the year-long studies of Qnexa for the treatment of obesity are expected in the third quarter of 2009. Progress on the preparation of the NDA for Qnexa in obesity also remains on schedule for an expected filing by the end of 2009," stated Leland Wilson, president and chief executive officer of VIVUS. "Pivotal studies for avanafil for the treatment of erectile dysfunction are

also in process, with results expected in the fourth quarter of 2009."

About VIVUS

VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address obesity, diabetes and sexual health. The company's lead product in clinical development, Qnexa(TM), is expected to complete phase 3 clinical trials for the treatment of obesity in 2009. 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, and in phase 3 development of Luramist (TM) for the treatment of hypoactive sexual desire disorder (HSDD). For more information about the company, please visit www.vivus.com.

Note to Investors

As previously announced, VIVUS will hold a conference call to discuss the second quarter financial results today, August 11, 2009, beginning at 1:30 p.m. Pacific Time. You can listen to this call by dialing 1-877-548-7907 and outside the U.S. 1-719-325-4848. A 30-day archive of the call 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 or regulatory submissions 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.

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

	Three Months Ended		Six Months Ended	
	June 30, 2009	June 30, 2008	June 30, 2009	June 30, 2008
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue:				
US product, net	$ 3,368	$ 2,923	$ 4,261	$ 4,011
International product	776	1,300	1,069	1,854
License and other revenue	10,581	21,046	31,627	42,092
Total revenue	14,725	25,269	36,957	47,957
Operating expenses:				

Cost of goods sold and manufacturing	2,877	2,929	5,480	5,716
Research and development	20,258	15,335	40,327	38,706
Selling, general and administrative	4,555	4,345	9,966	8,597
Total operating expenses	27,690	22,609	55,773	53,019
Income (loss) from operations	(12,965)	2,660	(18,816)	(5,062)
Interest (expense) income, net of other-than-temporary loss on impaired securities	(239)	924	(1,191)	1,559
Income (loss) before provision for income taxes	(13,204)	3,584	(20,007)	(3,503)
Provision for income taxes	-	(5)	(6)	(10)
Net income (loss)	$ (13,204)	$ 3,579	$ (20,013)	$ (3,513)
Net income (loss) per share:				
Basic and diluted	$ (0.19)	$ 0.06	$ (0.29)	$ (0.06)
Shares used in per share computation:				
Basic	69,805	60,351	69,746	59,616
Diluted	69,805	61,850	69,746	59,616

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

	June 30 2009 (unaudited)	December 31 2008*
Current assets:		
Cash and cash equivalents	$ 27,820	$ 66,121
Available-for-sale securities	116,404	121,789
Accounts receivable, net	3,395	4,157
Inventories, net	2,662	3,041
Prepaid expenses and other assets	3,443	3,744
Total current assets	153,724	198,852
Property and equipment, net	6,287	6,726
Restricted cash	700	700
Available-for-sale securities	-	1,344
Total assets	$ 160,711	$ 207,622
Current liabilities:		
Accounts payable	$ 9,632	$ 17,205
Deferred revenue	462	31,858
Accrued and other liabilities	17,940	14,909
Total current liabilities	28,034	63,972
Notes payable-net of current portion	16,809	11,177
Deferred revenue	1,029	1,260
Total liabilities	45,872	76,409

Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 69,960 at June 30, 2009; 69,667 at December 31, 2008	70	70
Additional paid-in capital	314,282	310,558
Accumulated other comprehensive income	269	354
Accumulated deficit	(199,782)	(179,769)
Total stockholders' equity	114,839	131,213
Total liabilities and stockholders' equity	$160,711	$207,622

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

SOURCE VIVUS, Inc.

http://www.vivus.com