VIVUS Reports Second Quarter 2008 Financial Results and Highlights

MOUNTAIN VIEW, Calif.--(BUSINESS WIRE)--Aug. 4, 2008--VIVUS, Inc. (NASDAQ: VVUS), a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today announced its financial results and highlights for the second quarter of 2008.

Second Quarter 2008 Results

Total revenue for the second quarter of 2008 was $25.3 million, as compared to $4.1 million for the second quarter of 2007. The increase in total revenue over the second quarter last year was primarily due to the recognition of $20.9 million in deferred license revenue earned from the sale in 2007 of Evamist to K-V Pharmaceutical Company ("K-V"). Product revenues from the sale of MUSE in the second quarter of 2008 increased to $4.2 million compared to $4 million in the second quarter of 2007 primarily due to shipments to our European distributor.

License and other revenue will be significant on a quarterly basis until all of the revenue from the sale of Evamist is recognized, currently expected to be May 2009. Since we have received the $150 million in cash from the sale of Evamist and we have no related contingencies, the recognition of license revenue and the corresponding reduction of deferred revenue related to the Evamist sale will have no impact on our cash flows from operations in future periods.

Net income for the second quarter of 2008 was $3.6 million or $0.06 per share, compared to a net loss of $6.7 million or $0.11 per share for the same period last year. The net income in the second quarter of 2008 as compared to the net loss in the second quarter of 2007 is primarily due to the recognition of the K-V deferred license revenue partially offset by an increase in operating expenses in the second quarter. The increase in operating expenses was primarily due to spending related to our phase 3 clinical trials of Qnexa, our investigational product candidate for the treatment of obesity.

Six Month 2008 Results

For the six-month period ending June 30, 2008, total revenues were $48.0 million, compared to $5.8 million for the same period in 2007. The increase in total revenues is primarily due to the recognition of the K-V deferred license revenue. Net loss for the six months ended June 30, 2008 was $3.5 million, or $0.06 per share, compared to a net loss of $14.1 million or $0.24 per share for the same period in 2007. The decrease in the net loss in the six months ended June 30, 2008 as compared to the same period in 2007 is primarily due to the recognition of the K-V deferred license revenue, partially offset by an increase in operating expenses related to our phase 3 clinical trials of Qnexa, our investigational product candidate for the treatment of obesity.

Deerfield Transaction

On April 3, 2008, we entered into several agreements with Deerfield Management Company, L.P., or Deerfield, a healthcare investment fund, and its affiliates that will provide funding for the phase 3 development of avanafil, our investigational product candidate for the treatment of erectile dysfunction ("ED"). Under the agreements Deerfield and its affiliates ("Deerfield Affiliates") agreed to provide $30 million, consisting of $20 million from a Funding and Royalty Agreement ("FARA") entered into with a newly incorporated subsidiary of Deerfield ("Deerfield Sub"), and $10 million from the sale of our common stock. We received the $10 million on April 15, 2008. We have granted Deerfield a royalty interest on sales of MUSE, and on future sales of avanafil, if approved by the FDA. The agreements also provide us with an option to purchase, and the Deerfield Affiliates with an option to compel us to purchase, the Deerfield Sub holding the royalty rights. If we exercise our right to purchase the Deerfield Sub, the net price will be $23 million if exercised within three years, or $26 million if exercised after three years but before four years (the purchase prices are subject to other adjustments as defined in the agreement). After three years from the closing, the Deerfield affiliates may exercise the right to compel us to purchase the Deerfield Sub at a price ranging from $17 million to $26 million based upon various circumstances. The timing on the sale of the shares could be accelerated under certain conditions, as defined in the agreements. Under the FARA, the Deerfield Affiliates made a $3.3 million payment on April 15, 2008 and will make five quarterly payments of approximately $3.3 million, thereafter. The funding provided under the FARA, net of certain costs, represent a financial obligation, which will be recorded as a loan. The principal and interest will be repaid through royalty payments and the exercise of the option rights.

Cash, Cash Equivalents, Available for Sale Securities

VIVUS had cash, cash equivalents and available-for-sale securities of $155.1 million at June 30, 2008, as compared to $179.5 million at December 31, 2007. The decrease in cash, cash equivalents and available-for-sale securities of $24.4 million for the six-month period is the net result of cash used for operating activities of $33.9 million, partially offset by cash provided by investing and financing activities for the first six months of 2008. Included in the financing activities are cash receipts of $10.6 million from Deerfield.

"The highlight of the second quarter was the presentation of the results of the phase 2 study of Qnexa in diabetics at the ADA meeting. In that study, patients treated with Qnexa for six months had significant reductions in blood sugar combined with substantial weight loss and reductions in cardiovascular risk factors," stated Leland Wilson, president and chief executive office of VIVUS. "Additionally, we continued to make steady progress with the phase 3 development program for Qnexa in obesity by completing enrollment in all of the phase 3 trials. Reaching agreement with the FDA on the safety requirements for Luramist, our metered dose testosterone spray for low libido, and completing the Special Protocol Assessment process for the phase 3 design allowed us to initiate discussions with potential corporate partners. Lastly, we believe the financing arrangement with Deerfield provides us with sufficient funding to move avanafil into phase 3 clinical testing. We look forward to continued progress throughout the remainder of 2008."

Second Quarter 2008 Highlights

The highlights of the second quarter of 2008 included:

Qnexa for Diabetes

-- Completion of Phase 2 Study of Qnexa for Diabetes - In June 2008, we announced the positive results of OB-202, a 28-week, phase 2 clinical trial in type 2 diabetics. Subjects treated with Qnexa had a reduction in HbA1c, a common measure of glycemic control, of 1.2%, from 8.7% to 7.5%, as compared with a reduction of 0.6%, from 8.6% to 8.0%, in subjects in the placebo group (p less than 0.001). Subjects treated with Qnexa also lost 8.0% of their baseline body weight, or 7.7 kg, as compared to 1.2% weight loss, or 1.3 kg, observed in the placebo group (p less than 0.001). Fasting plasma glucose levels were reduced in the Qnexa arm from 174.7 mg/dL to 141.9 mg/dL, and decreased from 174 mg/dL to 166.6 mg/dL in the placebo group (p less than 0.001). Qnexa patients also had significant improvement in cardiovascular risk factors including blood pressure, triglycerides levels and waist circumference. The trial randomized 206 subjects at 10 sites. The Qnexa treatment group had a study completion rate of 85%, as compared to 72% in the placebo arm. Qnexa subjects reported an overall improvement when evaluated for quality of life, including physical function, self-esteem and distress. Qnexa was well-tolerated, with no treatment-related serious adverse events ("SAEs"). The most common treatment-related adverse events were nausea, paresthesias, constipation, dry mouth and dizziness.

Avanafil

-- Entered into Funding Collaboration for the Phase 3 Studies of Avanafil for Erectile Dysfunction - In April 2008, we entered into agreements with Deerfield. Under the terms of the agreements, Deerfield will provide $30 million for the phase 3 program for avanafil. VIVUS previously announced positive results from a phase 2 study to evaluate the effects of avanafil, its next-generation, fast-acting, highly selective, investigational oral phosphodiesterase type 5 ("PDE5") inhibitor, in men with erectile dysfunction ("ED"). The study was a multicenter, double-blind, randomized, parallel-design study in 284 men conducted to assess the safety and efficacy of different doses of avanafil for the treatment of ED.

Patients were instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. Results showed that up to 84% of avanafil doses resulted in erections sufficient for vaginal penetration, as compared to placebo (p less than 0.001). The most commonly recorded adverse event was headache and there were no reports of visual disturbances. Avanafil was well-tolerated at all doses and no serious adverse events were reported.

About the Qnexa Diabetes OB-202 Study

In the OB-202 study, subjects underwent a four-week dose escalation period followed by 24 weeks of treatment. The study was a randomized, double-blind, placebo-controlled prospective trial, with subjects randomized to receive Qnexa (15 mg phentermine/100 mg topiramate) or placebo. The study included 206 subjects (141 females, 65 males) with an average age of 49 years. Baseline BMIs were greater than 35 in both groups, and baseline body weight was 94.7 kg in the Qnexa group and 98.1 kg in the placebo group. At baseline, subjects had glycosylated hemoglobin (HbA1c) of 8.7%. Most of the subjects had been diagnosed with diabetes for more than five years (59 %). Sixty percent of subjects were on two or more oral diabetic medications. Patients on antidepressant medications such as SSRIs and SNRIs were allowed to participate in the study. Subjects were instructed to follow a simple diet and lifestyle modification program throughout the study. The primary endpoint was change in glycemic control as reflected by measurements of HbA1c. After enrollment, subjects were stratified at randomization for either low HbA1c (7-8%) or high HbA1c (greater than8-12%). Secondary endpoints included weight loss and various cardiovascular risk factors. Investigators were allowed to intervene and add/adjust anti-diabetic and anti-hypertensive medications during the study based on predetermined rescue criteria and nationally recognized standards of care. Qnexa was well-tolerated, with no treatment-related SAEs. The most common treatment-related adverse events were nausea, paresthesias, constipation, dry mouth and dizziness. Subjects completing the study were allowed to enroll in an extension study, DM-230. The extension study will continue to monitor HbA1c levels, body weight, other metabolic endpoints, and patient safety over an additional six months.

About the Qnexa Phase 3 Obesity Program

Qnexa is our investigational product candidate currently under development for obesity. A phase 2 study in obese, non-diabetic patients with controlled co-morbidities previously reported weight loss of 10.7% over 24 weeks on an intent-to-treat basis. The phase 3 Qnexa program includes two pivotal, double-blind, placebo-controlled, multi-center studies that will compare the efficacy and safety of Qnexa to placebo during a 56-week treatment period. The first study, known as EQUIP (OB-302), has enrolled approximately 1,250 morbidly obese adult subjects with a Body Mass Index (BMI) of 35 or greater with or without controlled co-morbidities. The second trial, known as CONQUER (OB-303), has enrolled overweight and obese adult subjects with BMIs from 27 to 45 and at least two co-morbid conditions, such as hypertension, dyslipidemia and type 2 diabetes. The co-primary endpoints for these studies are the mean percent weight loss and the percentage of subjects achieving a weight loss of 5% or more.

The phase 3 program also includes a six-month confirmatory factorial study, known as EQUATE (OB-301), in obese subjects with BMIs from 30 to 45. This trial is designed to evaluate two dose levels of Qnexa compared to placebo and to the individual components in Qnexa. The primary endpoints will be similar to those evaluated in the pivotal studies. Safety and tolerability of Qnexa will be determined by reports of adverse events, physical exam, clinical laboratory data, electrocardiogram, cognitive function tests, psychological assessments, and clinical assessment of clinical laboratory variables. The phase 3 program has enrolled a total of approximately 4,500 subjects.

About VIVUS

VIVUS, Inc. is a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products. The current portfolio includes investigational product candidates addressing obesity and sexual health. The investigational pipeline includes: Qnexa™, which is in phase 3, for the treatment of obesity and has completed phase 2 for the treatment of type 2 diabetes; Luramist™ (Testosterone MDTS®), for which a phase 2 study has been completed for the treatment of Hypoactive Sexual Desire Disorder ("HSDD"); and avanafil, for which a phase 2 study has been completed for the treatment of erectile dysfunction ("ED"). MUSE® is approved and currently on the market for the treatment of ED. For more information on clinical trials and products, please visit the company's web site at http://www.vivus.com/.

Note to Investors

As previously announced, VIVUS will hold a conference call to discuss the second quarter financial results today, August 4, 2008, beginning at 1:30 p.m. Pacific Time. You can listen to this call by dialing 1-800-299-7098 and outside the U.S. 1-617-

801-9715, and entering passcode 77408177. A 30-day archive of the call can be accessed at http://ir.vivus.com/.

A replay of the conference call will be available beginning at 6:30 p.m. PT on August 4, 2008 for two weeks. Access numbers for this replay are: 1-888-286-8010 (U.S./Canada) and 1-617-801-6888 (international). The access code for the replay is 46871050.

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, 2007 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		Six Months Ended	
	June 30, 2008	June 30, 2007	June 30, 2008	June 30, 2007
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Revenue:				
US product, net	$ 2,923	$ 3,037	$ 4,011	$ 3,497
International product	1,300	946	1,854	2,059
License and other revenue	21,046	115	42,092	231
Total revenue	25,269	4,098	47,957	5,787
Operating expenses:				
Cost of goods sold and manufacturing	2,929	3,191	5,716	5,762
Research and development	15,335	3,955	38,706	6,966
Selling, general and administrative	4,345	4,192	8,597	8,297
Total operating expenses	22,609	11,338	53,019	21,025
Income (loss) from operations	2,660	(7,240)	(5,062)	(15,238)
Interest and other income, net	924	568	1,559	1,181
Income (loss) before provision for income				

taxes	3,584	(6,672)	(3,503)	(14,057)
Provision for income taxes	(5)	(6)	(10)	(12)
Net income (loss)	$ 3,579	$(6,678)	$(3,513)	$(14,069)
Net income (loss) per share:				
Basic and diluted	$ 0.06	$ (0.11)	$ (0.06)	$ (0.24)
Shares used in per share computation:				
Basic	60,351	58,475	59,616	58,359
Diluted	61,850	58,475	59,616	58,359

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

	June 30 2008	December 31 2007*
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 66,641	$ 37,838
Available-for-sale securities	85,647	141,672
Accounts receivable, net	3,686	4,202
Inventories, net	2,817	2,567
Prepaid expenses and other assets	3,012	5,313
Total current assets	161,803	191,592
Property and equipment, net	7,028	7,417
Restricted cash	700	700
Available-for-sale securities, non-current	2,808	-
Total assets	$ 172,339	$ 199,709
Current liabilities:		
Accounts payable	$ 11,216	$ 7,768
Deferred revenue-short term	73,718	84,183
Accrued and other liabilities	10,480	9,411
Total current liabilities	95,414	101,362
Notes payable	5,862	5,062
Deferred revenue-long term	1,492	33,118
Total liabilities	102,768	139,542
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 60,673 at June 30, 2008; 58,873 at December 31, 2007	61	59
Additional paid-in capital	242,966	230,005

Accumulated other comprehensive loss	(114)	(68)
Accumulated deficit	(173,342)	(169,829)
Total stockholders' equity	69,571	60,167
Total liabilities and stockholders' equity	$ 172,339	$ 199,709

* The Condensed Consolidated Balance Sheet at December 31, 2007 has been derived from the Company's audited financial statements at that date.

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SOURCE: VIVUS, Inc.