May 7, 2012

VIVUS Reports First Quarter 2012 Financial Results

MOUNTAIN VIEW, Calif., May 7, 2012 (GLOBE NEWSWIRE) -- VIVUS,Inc. (Nasdaq:VVUS), a biopharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today reported its financial results for the first quarter ended March 31, 2012.

First Quarter Financial Results

For the quarter ended March 31, 2012, VIVUS had a net loss of $18.8 million, or $0.20 per share, as compared to a loss of $9.9 million, or $0.12 per share for the first quarter last year. The increase in net loss was primarily attributable to increased general and administrative expenses from spending on Qnexa pre-commercialization activities.

Cash, Cash Equivalents and Available-for-Sale Securities

VIVUS had cash, cash equivalents and available-for-sale securities (cash) of $333.4 million at March 31, 2012, as compared to $146.8 million at December 31, 2011. The increase in cash of $186.6 million is primarily the net result of the proceeds of $192.0 million received from an underwritten public offering of our common stock in March 2012, offset by cash used in operations for the quarter.

"The positive Advisory Committee vote of 20-2 to recommend approval of Qnexa was the highlight of the first quarter. With the positive vote, we accelerated the pre-commercialization efforts and resultant spending in the first quarter. The Qnexa PDUFA was extended to July 17, 2012 and we continue to work with the FDA as they finalize their review of the Qnexa REMS program," stated Leland Wilson, chief executive officer of VIVUS. "In April 2012, the Stendra™ (avanafil) NDA was approved. The approval of Stendra on April 27, 2012 is a tremendous accomplishment. I wish to thank all the members of the Stendra development team including our partner, Mitsubishi Tanabe Pharma Corporation (MTPC). With the approval of the NDA we look to progress our business development discussions towards commercialization of Stendra in the US and our territories outside of the U.S."

Qnexa Regulatory Update

On February 22, 2012, at the meeting of the U.S. Food and Drug Administration Endocrinologic and Metabolic Drugs Advisory Committee, the Advisory Committee voted 20-2 to recommend that Qnexa be granted marketing approval by the FDA for the treatment of obesity in adults. The FDA is not bound by the recommendations of the Advisory Committee, but will consider the guidance during the review of the Qnexa NDA.

On April 4, 2012, at the FDA's request, we submitted a comprehensive Risk Evaluation and Mitigation Strategy, or REMS, for Qnexa. The Prescription Drug User Fee Act, or PDUFA, target date for Qnexa was April 17, 2012. As the submission of the comprehensive REMS was within three months of the PDUFA target date it was considered a major amendment to the Qnexa NDA, and in order to provide time for a full review of the submission, the FDA extended the PDUFA target date by three months, to July 17, 2012.

In April 2012, we submitted our 180-day response to the Committee for Medicinal Products for Human Use (CHMP) to the List of Outstanding Issues for the Qnexa Marketing Authorization Application (MAA) for the European Union (EU). We anticipate a response from the CHMP in the second quarter of 2012.

Stendra Regulatory Update

On April 27, 2012, we announced that the FDA had approved Stendra (avanafil) tablets for the treatment of erectile dysfunction (ED), marking the first new prescription agent approved in nearly a decade for the condition that afflicts as many as 30 million men in the U.S. More than 1,200 men with ED participated in clinical studies evaluating the safety and efficacy of Stendra. Stendra at all doses tested (50mg, 100mg, 200mg) met all primary efficacy endpoints. Significant improvement in erectile function was observed for all doses in Stendra-treated patients compared to placebo. Stendra can be taken approximately 30 minutes before sexual activity. Stendra should not be taken more than once per day. For more information about Stendra, please visit www.Stendra.com.

VIVUS is currently in discussion with potential partners to commercialize avanafil in the United States and in its territories outside of the U.S. Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation (MTPC). VIVUS has development and commercial rights to avanafil for the treatment of sexual dysfunction worldwide with the exception of certain Asian Pacific Rim countries. In South Korea, avanafil is approved and is marketed by JW Pharma under the brand name Zepeed under its agreement with MTPC. In March 2012, we submitted and the European Medicines Agency accepted our MAA for avanafil.

Note to Investors

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the first quarter financial results today, May 7, 2012, beginning at 1:30 p.m. Pacific Time. Investors 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/.

About VIVUS

VIVUS is a biopharmaceutical company developing therapies to address obesity, sleep apnea, diabetes and male sexual health. The company's lead investigational drug candidate in clinical development, Qnexa, has completed phase 3 clinical trials for the treatment of obesity and is currently being considered for approval by U.S. and EU regulators. VIVUS received a Complete Response Letter, or CRL, to the initial Qnexa NDA on October 28, 2010. VIVUS resubmitted the Qnexa NDA in October 2011, which has a FDA action date of July 17, 2012. On February 22, 2012, in a 20-to-2 vote, the U.S. Food and Drug Administration Endocrinologic and Metabolic Drugs Advisory Committee recommended that Qnexa be granted marketing approval by the FDA for the treatment of obesity in adults. Qnexa is also in phase 2 clinical development for the treatment of type 2 diabetes and obstructive sleep apnea. For more information about the company, please visit www.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," "estimate," "expect," "intend," "likely," "may," "plan," "potential," "predict," "opportunity" and "should," among others. 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, the response from the United States Food and Drug Administration, or FDA, to our resubmission of the New Drug Application, or NDA, for Qnexa for the treatment of obesity, including weight loss and maintenance of weight loss, recommended for obese patients (BMI ≥30 kg/m2), or overweight patients (BMI ≥27 kg/m2) with weight-related co-morbidities such as hypertension, type 2 diabetes or dyslipidemia, with a contraindication that excludes the use of Qnexa by women who are pregnant; the timing and final results of the retrospective observational study of fetal outcomes in infants born to mothers exposed to topiramate during pregnancy, or FORTRESS; the reliability of the electronic medical claims healthcare databases used in FORTRESS; the FDA's interpretation of and agreement with the information VIVUS submitted relating to teratogenicity and cardiovascular safety; that we may be required to provide further analysis of clinical trial data; our response to questions and requests for additional information including additional pre-clinical or clinical studies from the European Medicines Agency, or EMA, and the Committee for Medicinal Products for Human Use, or CHMP, of the Marketing Authorization Application, or MAA, for Qnexa; the FDA's interpretation of the results of external studies to assess the teratogenic risk of topiramate; the impact of the results of the REMS or cardiovascular outcomes for obesity advisory committee meetings; whether or not the FDA chooses to follow the recommendation of the second advisory committee in its vote in favor of approval of Qnexa; the impact, if any, of the agreement and initiation by one of our competitors with an obesity compound to conduct or complete a cardiovascular outcomes study pre-approval; the impact on future sales based on specific indication and contraindications contained in the label and extent of the REMS and distribution system and patient access program for Qnexa, if approved; our ability to successfully commercialize or establish a marketing partnership for avanafil, which will be marketed in the U.S. under the name Stendra, or our partner's ability to obtain and maintain regulatory approval to manufacture and adequately supply avanafil for commercial use; our history of losses and variable quarterly results; substantial competition; risks related to the failure to protect our intellectual property and litigation in which we may become involved; uncertainties of government or third party payer reimbursement; our reliance on sole source suppliers; our limited sales and marketing and manufacturing capabilities; our reliance on third parties and our collaborative partners; failure to continue to develop innovative investigational drug candidates and drugs; risks related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; the timing of initiation and completion of clinical trials and submissions to the FDA or foreign authorities; the volatility and liquidity of the financial markets; our liquidity and capital resources; our ability to successfully create a commercial infrastructure in the U.S. to launch Qnexa; and our expected future revenues, operations and expenditures. As with any pharmaceutical in development, there are significant risks in the development, the regulatory approval, and commercialization of new products. There are no guarantees that our response to the FDA's CRL or CHMP's 180-day list of outstanding issues, the FDA's requests stemming from the end-of-review meeting or the results of the FORTRESS study and subsequent meetings and communications will be sufficient to satisfy the FDA or CHMP's safety concerns, that the FDA or foreign authorities will not require us to conduct any additional prospective studies or retrospective observational studies, 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 statements. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ending December 31, 2011, 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	
	March 31 2012	**March 31 2011**
	(unaudited)	(unaudited)
Operating expenses:		
Research and development	$ 6,134	$ 4,480
General and administrative	12,638	5,428
Total operating expenses	18,772	9,908
Loss from operations	(18,772)	(9,908)
Interest and other income (expense), net	17	42
Loss from continuing operations before income taxes	(18,755)	(9,866)
Provision for income taxes	(7)	(1)
Net loss from continuing operations	(18,762)	(9,867)
Net income (loss) from discontinued operations	(16)	14
Net loss	$ (18,778)	$ (9,853)
Basic and diluted net loss per share:		
Continuing operations	$ (0.20)	$ (0.12)
Discontinued operations	0.00	0.00
Net loss per share	$ (0.20)	$ (0.12)
Shares used in per share computation:		
Basic and diluted	92,267	81,819

VIVUS, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amount)

	March 31 2012	**December 31 2011***
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 200,682	$ 39,554
Available-for-sale securities	132,715	107,282
Inventories	2,897	3,107
Prepaid expenses and other assets	2,124	1,793
Total current assets	338,418	151,736

Property and equipment, net	298	320
Total assets	$ 338,716	$ 152,056
Current liabilities:		
Accounts payable	$ 4,805	$ 2,940
Accrued and other liabilities	6,910	6,392
Current liabilities of discontinued operations	1,339	1,640
Total current liabilities	13,054	10,972
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 99,701 at March 31, 2012; 88,975 at December 31, 2011, respectively	100	89
Additional paid-in capital	690,612	487,235
Accumulated other comprehensive income (loss)	(7)	25
Accumulated deficit	(365,043)	(346,265)
Total stockholders' equity	325,662	141,084
Total liabilities and stockholders' equity	$ 338,716	$ 152,056

*The Condensed Consolidated Balance Sheet at December 31, 2011 has been derived from the Company's audited financial statements at that date.

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