VIVUS Reports Third Quarter and First Nine Months 2011 Financial Results

MOUNTAIN VIEW, Calif., Nov. 7, 2011 /PRNewswire/ -- VIVUS, Inc. (NASDAQ: VVUS), a biopharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today reported its financial results for the third quarter and nine months ended September 30, 2011.

Third Quarter Results

For the third quarter ended September 30, 2011, VIVUS reported a net loss of $8.6 million, or $0.10 net loss per share, as compared to a net loss of $18.0 million, or $0.22 net loss per share for the third quarter of 2010. The net loss from continuing operations was $8.8 million, or $0.10 net loss per share, as compared to a net loss from continuing operations of $18.1 million, or $0.22 net loss per share during the third quarter of 2010. The lower net loss in 2011 as compared to 2010 primarily results from reduced research and development spending on Qnexa® and avanafil as these projects progress from the clinical trial stage to the regulatory review stage.

In the third quarter of 2011, we closed on a registered direct offering of our common stock which provided us with gross proceeds of $45.8 million before deduction of fees and expenses related to the offering.

First Nine Months Results

Net loss for the first nine months of 2011 was $34.7 million, or $0.42 net loss per share, as compared to a net loss of $59.6 million, or $0.74 net loss per share for 2010. The decrease in net loss in the first nine months of 2011 as compared to 2010 results primarily from reduced research and development spending on Qnexa and avanafil. In addition, the net loss for the first nine months last year included a $3.2 million loss from discontinued operations of the MUSE business, which was sold in the fourth quarter 2010.

Cash, Cash Equivalents and Available-for-Sale Securities

VIVUS had cash, cash equivalents and available-for-sale securities of $155.3 million at September 30, 2011, as compared to $139.2 million at December 31, 2010. The net increase in cash, cash equivalents and available-for-sale securities of $16.1 million is primarily due to net proceeds of $45.3 million from the registered direct offering of our common stock and $2.0 million from the exercise of common stock options and ESPP purchases offset by cash used in operations of $31.2 million for the first nine months.

Qnexa Update

On October 17, 2011, we resubmitted the Qnexa New Drug Application (NDA). The FDA has accepted the NDA for filing and has designated it as a Class 2 resubmission, which is expected to have a six-month review period from the date of filing. The Prescription Drug User Fee Act (PDUFA) target date is April 17, 2012. The FDA has informed us that an advisory committee of the Division of Metabolism and Endocrinology Products (DMEP) will meet to specifically discuss the Qnexa NDA in the first quarter of 2012.

The Qnexa NDA resubmission seeks approval for the treatment of obesity, including weight loss and maintenance of weight loss 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, dyslipidemia, or central adiposity (abdominal obesity). The proposed labeling includes a contraindication for women of childbearing potential. The resubmission also includes a proposed Risk Evaluation and Mitigation Strategy (REMS).

The Marketing Authorization Application (MAA) for Qnexa was submitted to the European Medicines Agency (EMA) in December 2010. In May of 2011, we received the 120-day list of questions from the Committee for Medicinal Products for Human Use (CHMP) and began preparing our response. The questions and issues raised by the CHMP were consistent with those raised by the FDA. We met with representatives from the CHMP in September 2011 to seek clarification on certain questions. With this clarification, we anticipate submitting our response to the CHMP in the fourth quarter of 2011. We expect the CHMP to issue the 180-day opinion in the first quarter of 2012.

Additional analyses of results from Qnexa studies have been recently presented at various medical meetings including:

- The American Association of Diabetes Educators (AADE) meeting in Las Vegas, NV. Ronette L. Kolotkin, PhD, a clinical psychologist from Obesity and Quality of Life Consulting and Consulting Professor at Duke University Medical Center, and gave an oral presentation of efficacy and safety data that concluded that patients treated with Qnexa during the 56-week EQUIP and CONQUER trials showed statistically significant improvements in quality of life compared to placebo patients. Improvements in quality of life were measured using two validated surveys: the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) and Medical Outcomes Study Short Form-36 (SF-36);

- Multiple abstracts were presented at the 47th European Association for the Study of Diabetes (EASD) Annual Meeting in Lisbon, Portugal. The presentations highlighted the long-term efficacy and safety of Qnexa treatment in metabolically-impaired patients with prediabetes, diabetes, and metabolic syndrome;

- Finally, several abstracts were presented at the 29th Annual Scientific Meeting of The Obesity Society held in Orlando, Florida. The presentations highlighted the long-term efficacy and safety of Qnexa. Specifically, patients treated with Qnexa had significant improvement in liver function and reductions in medications used for diabetes, high blood pressure and high cholesterol. In addition, Qnexa was found effective in treating severely obese patients (BMI>35). Severely obese patients who were treated with Qnexa top dose for two years had weight loss over 12%.

The most commonly reported side effects in the Qnexa clinical studies were dry mouth, paresthesia (tingling), constipation, insomnia, dizziness and dysgeusia (altered taste).

"In the third quarter we made significant progress in advancing Qnexa towards regulatory approval with the resubmission of the Qnexa NDA in October. The Qnexa NDA has been accepted for review and we look forward to the Division of Metabolism and Endocrinology Products Advisory Committee meeting in the first quarter of 2012," stated Leland Wilson, chief executive officer of VIVUS. "With the NDA filing, we are accelerating the commercial planning in anticipation of approval and the launch of Qnexa in the second half of 2012."

Avanafil Update

In August 2011, the FDA accepted our NDA for avanafil, our investigational drug candidate for the treatment of erectile dysfunction (ED). The PDUFA date for the avanafil NDA is April 29, 2012. In previously announced results from the pivotal phase 3 trials, patients treated with avanafil achieved significant improvement in erectile function compared to placebo.

Recently, the positive safety and efficacy results from the avanafil phase 3 study in diabetics were presented by Dr. Irwin Goldstein, Director of Sexual Medicine at Alvarado Hospital, San Diego, CA, during the poster session at the 47th European Association for the Study of Diabetes (EASD) Annual Meeting in Lisbon, Portugal. This was the first public European presentation of avanafil safety and efficacy data in diabetic patients.

The most commonly reported side effects in the avanafil clinical studies included headache, flushing, nasopharyngitis and nasal congestion.

The MAA for avanafil is being prepared and we plan to file it with the EMA in the first quarter of 2012.

"We've made significant progress with the development of Qnexa and avanafil over the past 12 months, and now both NDAs have been accepted for regulatory review," stated Peter Tam, president of VIVUS. "With the PDUFA dates for both Qnexa and avanafil in April, next year will be a very exciting time for our company."

About VIVUS

VIVUS is a biopharmaceutical company developing therapies to address obesity, sleep apnea, diabetes and male sexual health. The company's lead investigational product in clinical development, Qnexa, has completed phase 3 clinical trials for the treatment of obesity and is currently being considered for approval by US and EU regulators. VIVUS received a Complete Response Letter, or CRL, to the initial Qnexa NDA on October 28, 2010. We resubmitted the Qnexa NDA in October 2011, with an FDA action date of April 17, 2012. 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 has submitted an NDA for avanafil, a PDE5 inhibitor being studied for the treatment of erectile dysfunction, with an FDA action date of April 29, 2012. 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 7, 2011, 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/.

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, dyslipidemia, or central adiposity (abdominal obesity), with a contraindication that excludes the use of Qnexa by women of child-bearing potential; the timing and results of the retrospective observational study of fetal outcomes in infants born to mothers exposed to topiramate during pregnancy; the reliability of the electronic medical claims healthcare databases used in the FORTRESS study; the FDA's interpretation of and agreement with the information VIVUS submitted relating to teratogenicity and cardiovascular safety; the FDA's interpretation of the data from our SEQUEL study (OB-305) and Sleep Apnea study (OB-204); that we may be required to conduct additional prospective studies or retrospective observational studies or 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 results of external studies to assess the teratogenic risk of topiramate; results of the REMS or cardiovascular outcomes for obesity advisory meetings; the outcome of the second advisory committee meeting for Qnexa; the impact, if any, of the agreement by one of our competitors with an obesity compound to conduct or complete a cardiovascular outcomes study pre-approval; impact on future sales based on specific indication and contraindications contained in the label and extent of the REMS, distribution and patient access program; the FDA's response to the NDA filed for avanafil; our ability to successfully commercialize or establish a marketing partnership for avanafil or our partner's ability to obtain 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 efforts and our reliance on third parties; 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 regulations; our ability to demonstrate through clinical testing the safety and effectiveness of our investigational drug candidates; our dependence on the performance of our collaborative partners; 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; 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 120-day questions, the FDA's requests stemming from the end-of-review meeting or the results of the retrospective observational study of fetal outcomes in infants born to mothers exposed to topiramate during pregnancy 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, 2010, and periodic reports filed with the Securities and Exchange Commission.

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

	Three Months Ended		Nine Months Ended	
	September 30 2011	September 30 2010	September 30 2011	September 30 2010
Operating expenses:				
Research and development	$ 3,738	$ 10,091	$ 19,253	$ 33,878
General and administrative	5,203	6,724	15,934	18,638
Total operating expenses	8,941	16,815	35,187	52,516
Loss from operations	(8,941)	(16,815)	(35,187)	(52,516)
Interest and other income (expense), net	132	(1,321)	210	(3,799)
Loss from continuing operations before income taxes	(8,809)	(18,136)	(34,977)	(56,315)

Provision for income taxes	(3)	-	(6)	(1)
Net loss from continuing operations	(8,812)	(18,136)	(34,983)	(56,316)
Net income (loss) from discontinued operations	185	157	306	(3,238)
Net loss	$ (8,627)	$ (17,979)	$ (34,677)	$ (59,554)
Basic and diluted net income (loss) per share:				
Continuing operations	$ (0.10)	$ (0.22)	$ (0.42)	$ (0.70)
Discontinued operations	0.00	0.00	0.00	(0.04)
Net loss per share	$ (0.10)	$ (0.22)	$ (0.42)	$ (0.74)
Shares used in per share computation:				
Basic	84,818	81,172	82,866	80,926
Diluted	90,302	82,966	88,240	80,926

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

	September 30 2011	December 31 2010*
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 71,479	$ 37,216
Available-for-sale securities	83,776	101,970
Inventories	3,107	3,225
Prepaid expenses and other assets	1,045	1,648
Current assets of discontinued operations	-	6
Total current assets	159,407	144,065
Property and equipment, net	321	221
Total assets	$ 159,728	$ 144,286
Current liabilities:		
Accounts payable	$ 1,835	$ 2,395
Accrued and other liabilities	5,074	6,377
Current liabilities of discontinued operations	2,344	3,512
Total current liabilities	9,253	12,284
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 88,882 at September 30, 2011; 81,568 at December 31, 2010, respectively	89	82
Additional paid-in capital	485,169	432,041
Accumulated other comprehensive income	19	4
Accumulated deficit	(334,802)	(300,125)
Total stockholders' equity	150,475	132,002
Total liabilities and stockholders' equity	$ 159,728	$ 144,286

*The Condensed Consolidated Balance Sheet at December 31, 2010 has been derived from the Company's audited financial statements at that date.

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