



August 7, 2012

## VIVUS Reports Second Quarter and First Six Months 2012 Financial Results

MOUNTAIN VIEW, Calif., Aug. 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 second quarter and six months ended June 30, 2012.

On July 17, 2012, the U.S. Food and Drug Administration (FDA) approved Qsymia™ as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 or greater (obese), or a BMI of 27 or greater (overweight) in the presence of at least one weight-related comorbidity, such as hypertension, type 2 diabetes mellitus or high cholesterol (dyslipidemia). We anticipate the launch of Qsymia in the United States in the fourth quarter of 2012.

"The approval of Qsymia is the culmination of a decade of committed effort by our employees and consultants, the clinical study site physicians, nurses and coordinators, and approximately 3,700 patients who participated in our clinical program," stated Leland Wilson, chief executive officer of VIVUS. "The second important achievement in the quarter was the FDA approval of STENDRA™ (avanafil) for erectile dysfunction. Strategically, we plan to monetize STENDRA and are currently in discussions with potential partners."

### **Second Quarter Financial Results**

For the second quarter ended June 30, 2012, VIVUS reported a loss of \$24.0 million, or \$0.24 per share, as compared to a loss of \$16.2 million, or \$0.20 per share for the second quarter last year. The increase in net loss is primarily attributable to increased expenses for Qsymia pre-commercialization activities, which are included in general and administrative expenses.

### **First Half Financial Results**

Net loss for the first six months of 2012 is \$42.8 million, or \$0.45 per share, as compared to a loss of \$26.1 million, or \$0.32 per share, for 2011. The increase is primarily due to higher general and administrative expenses incurred in preparation for the Qsymia launch.

### **Cash, Cash Equivalents and Available-for-Sale Securities**

VIVUS had cash, cash equivalents and available-for-sale securities (cash) of \$310.4 million at June 30, 2012, as compared to \$146.8 million at December 31, 2011. The increase in cash of \$163.6 million is primarily the net result of cash provided by financing activities, including the net proceeds of \$192.0 million received from an underwritten public offering of our common stock in March 2012, and cash used for operating activities.

### **Qsymia Update**

Qsymia was approved with a Risk Evaluation and Mitigation Strategy (REMS) with a goal of informing prescribers and female patients of reproductive potential about an increased risk of orofacial clefts in infants exposed to Qsymia during the first trimester of pregnancy, the importance of pregnancy prevention for females of reproductive potential receiving Qsymia and the need to discontinue Qsymia immediately if pregnancy occurs. The Qsymia REMS program includes a Medication Guide, Healthcare Provider training, distribution through certified pharmacies and assessments at specified times.

Qsymia is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m<sup>2</sup> or greater (obese), or 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia. The effect of Qsymia on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of Qsymia in combination with other products intended for weight loss, including prescription and over-the-counter drugs and herbal preparations, have not been established.

Qsymia can cause fetal harm. Data from pregnancy registries and epidemiology studies indicate that a fetus exposed to topiramate, a component of Qsymia, in the first trimester of pregnancy has an increased risk of oral clefts (cleft lip with or without cleft palate). Qsymia must not be used by women who are pregnant; by patients with eye problems (glaucoma); by patients who have been told they have an overactive thyroid; by patients taking a type of anti-depressant called MAOI; or by patients who are allergic to phentermine, topiramate, or any of the ingredients in Qsymia. The most common side effects seen in Qsymia clinical studies were tingling in the hands and feet, dizziness, change in taste, trouble sleeping, constipation, and dry mouth.

For more information about Qsymia, go to [www.Qsymia.com](http://www.Qsymia.com) or for full prescribing information go to <http://www.vivus.com/docs/QsymiaPI.pdf>.

### **STENDRA Update**

Our drug, STENDRA (avanafil), was approved by the FDA on April 27, 2012, for the treatment of erectile dysfunction, or ED. STENDRA is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of ED. In March 2012, we submitted and the European Medicines Agency (EMA) accepted our Marketing Authorization Application (MAA) for avanafil. Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation. VIVUS has development and commercial rights to avanafil for the treatment of sexual dysfunction worldwide with the exception of certain Asian Pacific Rim countries. We intend to market and sell STENDRA in the United States and, if approved, in the EU and other territories outside the United States through collaboration arrangements with third parties.

Administration of STENDRA with any form of organic nitrates, either regularly and/or intermittently, is contraindicated. STENDRA is contraindicated in patients with a known hypersensitivity to any component of the tablet. The most common adverse reactions include headache, flushing, nasal congestion, nasopharyngitis, and back pain.

For more information about STENDRA, go to [www.STENDRA.com](http://www.STENDRA.com) or for full prescribing information go to <http://www.stendra.com/assets/pdf/STENDRA-avanafil-tablets-full-PI.pdf>.

### **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 7, 2012, beginning at 1:15 p.m. Pacific Time. Investors can listen to this call by dialing 1-877-359-2916 and outside the U.S. 224-357-2386. Slides will be available for viewing at <http://ir.vivus.com>. 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 commercializing and developing innovative, next-generation therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health for U.S., Europe and other world markets. Qsymia 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](http://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, our lack of commercial experience with Qsymia in the U.S.; the timing of initiation and completion of the clinical studies required as part of the approval of Qsymia by the FDA; the response from the FDA to the data that VIVUS will submit relating to post-approval clinical studies; the impact of the indicated uses and contraindications contained in the Qsymia label and the REMS requirements; the impact of distribution of Qsymia through a certified pharmacy network; that we may be required to provide further analysis of previously submitted clinical trial data; our response to questions and requests for additional information including additional pre-clinical or clinical studies from the EMA, and the Committee for Medicinal Products for Human Use, or CHMP, of the MAA, for Qsymia (referred to as Qsiva in the EU); 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 experience; our reliance on third parties and our collaborative partners; our 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 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 CHMP's 180-day list of outstanding issues and subsequent meetings and communications will be sufficient to satisfy the CHMP's safety concerns, that the foreign authorities will not require us to conduct any additional prospective studies or retrospective observational studies, or that any product will receive foreign 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)

(unaudited)

	Three Months Ended		Six Months Ended	
	June 30 2012	June 30 2011	June 30 2012	June 30 2011
Operating expenses:				
Research and development	\$ 8,873	\$ 11,035	\$ 15,007	\$ 15,515
General and administrative	15,444	5,303	28,082	10,731
Total operating expenses	24,317	16,338	43,089	26,246
Loss from operations	(24,317)	(16,338)	(43,089)	(26,246)
Interest and other income (expense), net	54	36	71	78
Loss from continuing operations before income taxes	(24,263)	(16,302)	(43,018)	(26,168)
Provision for income taxes	(3)	(2)	(10)	(3)
Loss from continuing operations	(24,266)	(16,304)	(43,028)	(26,171)
Income from discontinued operations	218	107	202	121
Net loss	<u>\$ (24,048)</u>	<u>\$ (16,197)</u>	<u>\$ (42,826)</u>	<u>\$ (26,050)</u>
Basic and diluted net loss per share:				
Continuing operations	\$ (0.24)	\$ (0.20)	\$ (0.45)	\$ (0.32)
Discontinued operations	0.00	0.00	0.00	0.00
Net loss per share	<u>\$ (0.24)</u>	<u>\$ (0.20)</u>	<u>\$ (0.45)</u>	<u>\$ (0.32)</u>
Shares used in per share computation:				
Basic and diluted	99,777	81,928	96,022	81,874

VIVUS, Inc.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amount)

	June 30 2012	December 31 2011*
(unaudited)		
Current assets:		
Cash and cash equivalents	\$ 80,940	\$ 39,554
Available-for-sale securities	229,451	107,282
Inventories	3,430	3,107
Prepaid expenses and other assets	7,845	1,793

Total current assets	321,666	151,736
Property and equipment, net	<u>412</u>	<u>320</u>
Total assets	<u>\$ 322,078</u>	<u>\$ 152,056</u>
Current liabilities:		
Accounts payable	\$ 6,246	\$ 2,940
Accrued and other liabilities	7,678	6,392
Current liabilities of discontinued operations	<u>899</u>	<u>1,640</u>
Total current liabilities	14,823	10,972
Commitments and contingencies		
Stockholders' equity:		
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - 100,141 at June 30, 2012; 88,975 at December 31, 2011, respectively	100	89
Additional paid-in capital	696,259	487,235
Accumulated other comprehensive (loss) income	(13)	25
Accumulated deficit	<u>(389,091)</u>	<u>(346,265)</u>
Total stockholders' equity	<u>307,255</u>	<u>141,084</u>
Total liabilities and stockholders' equity	<u>\$ 322,078</u>	<u>\$ 152,056</u>

\*The Condensed Consolidated Balance Sheet at December 31, 2011 has been derived from the audited financial statements as of that date.

CONTACT: VIVUS, Inc.

Timothy E. Morris  
Chief Financial Officer  
morris@vivus.com

Investor Relations:  
The Trout Group  
Brian Korb  
bkorb@troutgroup.com  
646-378-2923