



February 25, 2013

VIVUS Reports 2012 Fourth Quarter and Full-Year Financial Results

MOUNTAIN VIEW, Calif., Feb. 25, 2013 (GLOBE NEWSWIRE) -- VIVUS, Inc. (Nasdaq:VVUS), a biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs in obesity, sleep apnea, diabetes and sexual health, today provided a business update and reported its financial results for the fourth quarter and year ended December 31, 2012.

"We believe in the long-term value of our franchise, and are focused on retaining and enhancing that value for our stockholders," stated Leland Wilson, chief executive officer of VIVUS. "In 2012, we obtained FDA approval for Qsymia™ and STENDRA™ and launched Qsymia in the U.S. Since approval, we have dedicated resources and been actively engaged in the process of educating physicians and creating awareness for Qsymia. In order to expand access to Qsymia, we submitted to FDA in mid-October 2012 a modification of the REMS that, pending approval, would allow patients to access Qsymia through select certified retail pharmacies. We continue to make substantial progress in obtaining reimbursement coverage. Our goals for 2013 include expanding both access and reimbursement for Qsymia as well as securing partnerships for STENDRA."

Recent Highlights

- In February 2013, VIVUS announced the publication of a study concluding that weight loss resulting from treatment with Qsymia led to significant improvements in cholesterol, blood pressure and triglycerides in obese and overweight patients experiencing one or more of these associated conditions.
- In December 2012, VIVUS announced an agreement with Express Scripts, which manages the pharmacy benefit for approximately 26.3 million lives in the U.S., adding Qsymia as a standard benefit option to the Express Scripts National Formulary.
- In September 2012, VIVUS launched Qsymia in the U.S., the first FDA-approved, once-daily combination therapy and the first new medication available in 13 years for the treatment of obesity.

Fourth Quarter 2012 Results

For the three months ended December 31, 2012, the company reported a net loss of \$56.7 million, or \$0.56 per share, compared to a net loss of \$11.5 million, or \$0.13 per share, for the same period the prior year. The increase in net loss was primarily attributable to higher selling, general and administrative expenses related to commercialization activities for Qsymia. In the fourth quarter of 2012, the company recognized net product revenues of \$2.0 million from sales of Qsymia.

Year End 2012 Results

For the year ended December 31, 2012, the company reported a net loss of \$139.9 million, or \$1.42 per share, compared to a loss of \$46.1 million, or \$0.55 per share, for the year ended December 31, 2011. The increase was primarily due to higher selling, general and administrative expenses incurred for the commercialization of Qsymia.

Mr. Wilson continued, "We are executing a commercialization strategy focused on driving awareness of Qsymia and the important role it can play in the medical obesity treatment paradigm. There is an addressable patient population in the U.S. of approximately 100 million people, and less than 2% are currently being treated with pharmacotherapy for obesity. We believe that Qsymia can change this dynamic. Qsymia is the first-ever and only FDA-approved oral medication shown to achieve more than 10% average weight loss, and we believe there is a significant opportunity to improve patient care and drive value for our shareholders. Throughout 2013, our strategy is focused on enhancing the infrastructure necessary to support Qsymia's broad distribution and expand reimbursement access."

Note to Investors

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the fourth quarter and full-year financial results today, February 25, 2013, beginning at 4:30 pm Eastern Time. Investors can listen to this call by dialing 1-877-359-2916 and outside the U.S. (++) 224-357-2386. A webcast replay will be available for 30 days and can be accessed at

<http://ir.vivus.com/>.

About Qsymia

Qsymia was approved with a REMS with the goal of informing prescribers and 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 home delivery pharmacies, implementation system and a time table for assessments.

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, or BMI, of 30 kg/m² or greater (obese), or 27 kg/m² 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, visit www.Qsymia.com or for full prescribing information see <http://www.vivus.com/docs/QsymiaPI.pdf>.

About STENDRA

STENDRA (avanafil), was approved by FDA on April 27, 2012 for the treatment of erectile dysfunction, or ED. STENDRA is a phosphodiesterase 5, or PDE5, inhibitor indicated for the treatment of ED.

In March 2012, we submitted and the EMA accepted our MAA for avanafil. The approved trade name for STENDRA in the EU is SPEDRA™. In July 2012, we received the Day 120 List of Questions from the EMA. The Day 120 List of Questions covers broad range of topics including, without limitation, questions relating to clinical relevance in certain populations as well as questions regarding drug-drug interaction and pharmacokinetics. We are in the process of preparing our response to the CHMP.

Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation, or 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. Through collaboration arrangements with third parties, we intend to commercialize STENDRA in the United States and, if approved, in the EU and other territories outside the United States.

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, visit www.STENDRA.com, or for full prescribing information see <http://www.stendra.com/assets/pdf/STENDRA-avanafil-tablets-full-PI.pdf>.

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.

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 limited 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 United States Food and Drug Administration, or 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 Risk Evaluation and Mitigation Strategy, or REMS, requirements; the impact of distribution of Qsymia through a certified home delivery pharmacy network; whether or not the FDA approves our amendment to the REMS for Qsymia, which, if approved, would allow dispensing through select certified retail pharmacies to increase access while meeting all requirements of the REMS; that we may be required to provide further analysis of previously submitted clinical trial data; the negative opinion of the European Medicines Agency's, or EMA, Committee for Medicinal Products for Human Use, or CHMP, for the Marketing Authorization Application, or MAA, for Qsymia; our ability to successfully commercialize or establish a marketing partnership for avanafil, which will be marketed in the U.S. under the name STENDRA™; the ability of our partners to obtain and maintain regulatory approvals to manufacture and adequately supply our products to meet demand; 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 results of post-marketing studies are not favorable; compliance with post-marketing regulatory standards is not maintained; 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 the commercialization of new products. There are no guarantees that the product will receive regulatory approval outside the United States 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's 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		Years Ended	
	December 31 2012	December 31 2011	December 31 2012	December 31 2011*
	(unaudited)	(unaudited)	(unaudited)	
Revenue:				
Net product revenue	\$ 1,971	\$ --	\$ 2,012	\$ --
Operating expenses:				
Cost of goods sold	183	--	187	--
Research and development	7,758	5,351	32,065	24,604
Selling, general and administrative	50,314	6,538	109,665	22,472
Total operating expenses	58,255	11,889	141,917	47,076
Loss from operations	(56,284)	(11,889)	(139,905)	(47,076)
Interest and other income, net	69	30	199	240
Loss from continuing operations before income taxes	(56,215)	(11,859)	(139,706)	(46,836)
Provision for income taxes	(14)	(184)	(27)	(190)

Loss from continuing operations	(56,229)	(12,043)	(139,733)	(47,026)
(Loss) income from discontinued operations	<u>(430)</u>	<u>580</u>	<u>(148)</u>	<u>886</u>
Net loss	<u><u>\$ (56,659)</u></u>	<u><u>\$ (11,463)</u></u>	<u><u>\$ (139,881)</u></u>	<u><u>\$ (46,140)</u></u>
Basic and diluted net income (loss) per share:				
Continuing operations	\$ (0.56)	\$ (0.14)	\$ (1.42)	\$ (0.56)
Discontinued operations	<u>(0.00)</u>	<u>0.01</u>	<u>(0.00)</u>	<u>0.01</u>
Net loss per share	<u><u>\$ (0.56)</u></u>	<u><u>\$ (0.13)</u></u>	<u><u>\$ (1.42)</u></u>	<u><u>\$ (0.55)</u></u>
Shares used in per share computation:				
Basic and diluted	100,626	88,921	98,289	84,392

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

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

	December 31	December 31
	2012	2011*
	(unaudited)	
Current assets:		
Cash and cash equivalents	\$ 58,605	\$ 39,554
Available-for-sale securities	155,981	107,282
Accounts receivable, net	2,778	--
Inventories	25,353	3,107
Prepaid expenses and other assets	<u>19,446</u>	<u>1,793</u>
Total current assets	262,163	151,736
Property and equipment, net	<u>1,951</u>	<u>320</u>
Total assets	<u><u>\$ 264,114</u></u>	<u><u>\$ 152,056</u></u>
Current liabilities:		
Accounts payable	\$ 25,375	\$ 2,940
Accrued and other liabilities	13,777	6,392
Deferred revenue	1,150	--
Current liabilities of discontinued operations	<u>903</u>	<u>1,640</u>
Total current liabilities	41,205	10,972
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	709,022	487,324
Accumulated other comprehensive income	33	25
Accumulated deficit	<u>(486,146)</u>	<u>(346,265)</u>
Total stockholders' equity	<u><u>222,909</u></u>	<u><u>141,084</u></u>

Total liabilities and stockholders' equity

\$ 264,114

\$ 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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