



February 24, 2014

## VIVUS Reports Fourth Quarter and Year-End 2013 Financial Results

MOUNTAIN VIEW, Calif., Feb. 24, 2014 (GLOBE NEWSWIRE) -- VIVUS, Inc. (Nasdaq:VVUS), a biopharmaceutical company commercializing Qsymia<sup>®</sup> (phentermine and topiramate extended-release) capsules CIV for the treatment of obesity, today provided a business update and reported its financial results for the fourth quarter and year ended December 31, 2013.

### Recent Highlights

- On November 13, 2013, we announced that the United States Patent and Trademark Office had issued U.S. Patent Nos. 8,580,298, covering compositions of Qsymia, and 8,580,299, covering methods for effecting weight loss using Qsymia. The newly issued patents are assigned to VIVUS and are expected to extend patent exclusivity for Qsymia in the U.S. to 2029.
- On November 21, 2013, we announced our support for new clinical practice guidelines developed by the American Heart Association, American College of Cardiology and The Obesity Society, in conjunction with the National Heart, Lung and Blood Institute, urging healthcare providers to take an active role in helping overweight or obese patients achieve and maintain a healthy body weight. The guidelines also state that obesity medication can be considered as an adjunct to lifestyle intervention to help appropriate patients (individuals with BMI  $\geq 30$  or BMI  $\geq 27$  with at least one obesity-associated comorbid condition) achieve their weight loss goals. A concurrent publication in the *Journal of the American Medical Association* by researchers from the National Institutes of Health found that medications approved for long-term obesity treatment, when used as an adjunct to lifestyle intervention, lead to an increased likelihood of achieving clinically meaningful weight loss.
- On December 12, 2013, we announced a License and Commercialization Agreement with Sanofi to commercialize avanafil on an exclusive basis in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia. Sanofi will be responsible for obtaining regulatory approval in its territories. Under the terms of the agreement, VIVUS is eligible to receive up to \$61 million in upfront payments, regulatory and sales milestones. VIVUS will also receive escalating royalties based on net sales over the life of the agreement.
- On January 2, 2014, we disclosed that we had entered into a Rebate Agreement with CaremarkPCS Health, LLC, a pharmacy benefit manager, under which Qsymia will be available as either a preferred brand (tier-2) or non-preferred brand (tier-3) with copayments ranging from \$15.00 to \$75.00 for those members of Caremark whose benefit design includes obesity drug coverage. This agreement helped to increase to 43% the percentage of U.S. commercial lives with access to Qsymia at tier-3 or better.
- On January 14, 2014, we announced a collaboration with Aetna, one of the nation's leading diversified health care benefits companies, to integrate Qsymia into a pilot program designed to evaluate the benefits of prescription medication combined with lifestyle support for weight loss. The pilot program is currently being offered to self-insured plan sponsors, and includes outreach to appropriate members and health care providers regarding covered options. It is expected to provide insight regarding impact on health outcomes, workplace productivity and the potential for reductions in medical costs. The program is projected to run through year-end 2014.
- On January 21, 2014, we announced that the U.S. Food and Drug Administration had accepted a supplemental application that proposes to revise the STENDRA<sup>™</sup> (avanafil) prescribing information with efficacy and safety information from Study TA-501, entitled "A Randomized, Double-Blind, Placebo-Controlled Evaluation of Avanafil for On-Demand Treatment of Men with Erectile Dysfunction." VIVUS had previously announced positive results from this multicenter, placebo-controlled study designed to assess the efficacy of two dosage strengths of STENDRA approximately 15 minutes after dosing. The PDUFA date for the supplemental filing is September 20, 2014.

"The market for obesity pharmacotherapeutics is developing, and we are making progress in key areas such as physician education, reimbursement coverage and guidelines for treatment," stated Seth H. Z. Fischer, chief executive officer. "While our financial results for this most recent quarter and for 2013 overall were disappointing, we believe in the long-term prospects for this market as we continue our efforts to make Qsymia the drug of choice for patients that are obese or overweight with weight-related medical conditions."

### Fourth Quarter Financial Results

For the fourth quarter of 2013, total net product revenue was \$9.2 million, of which \$7.7 million was from sales of Qsymia and the remaining amount was from STENDRA and SPEDRA. In addition, we recognized \$34.8 million in license revenue under our commercialization agreements with Auxilium and Sanofi related to STENDRA or SPEDRA. In September 2012, we began distributing Qsymia to the certified home delivery pharmacies in our network, and Qsymia became available in retail pharmacies in July 2013. For the fourth quarter of 2012, net product revenue from sales of Qsymia was approximately \$2.0 million.

For the fourth quarter of 2013, net loss was \$17.2 million, or \$0.17 net loss per share, as compared to a net loss of \$56.7 million, or \$0.56 net loss per share, during the fourth quarter of 2012. The decreased net loss for the fourth quarter of 2013, as compared to the fourth quarter of 2012, was primarily attributable to license revenue from the commercialization agreements with Auxilium and Sanofi related to STENDRA and SPEDRA, higher net product revenue, and a decrease of \$13.7 million in selling, general and administrative expenses during the quarter, offset by increased net interest and other expense of \$8.4 million and \$8.0 million of non-recurring charges during the fourth quarter of 2013 related to the previously announced cost reduction plan.

For the fourth quarter of 2013, there were approximately 124,000 Qsymia prescriptions dispensed, an increase of approximately 14% compared to the third quarter of 2013. Prescription volume for the fourth quarter was impacted by the holidays in November and December.

### **Year End 2013 Financial Results**

For the year ended December 31, 2013, total net product revenue was \$25.2 million, of which \$23.7 million was from sales of Qsymia and the remaining amount was from STENDRA. Total license revenue was \$55.8 million from the license and commercialization agreements for STENDRA and SPEDRA.

For the year ended December 31, 2013, net loss was \$174.5 million, or \$1.72 net loss per share, as compared to a net loss of \$139.9 million, or \$1.42 net loss per share, for the year ended December 31, 2012. The increase in net loss was primarily attributable to higher selling, general and administrative expenses related to commercialization activities for Qsymia. Included in the net loss for the year ended December 31, 2013 was \$32.7 million in non-recurring charges related to the proxy contest in connection with our 2013 Annual Meeting of Stockholders and associated severance charges, including \$14.1 million of non-cash share-based compensation expense, a total charge of \$10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee for Qsymia, and \$20.2 million of net interest and other expense primarily related to the long-term debt incurred in April and May of 2013.

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

Cash, cash equivalents and available-for-sale securities (cash) totaled \$343.3 million at December 31, 2013, as compared to \$214.6 million at December 31, 2012. The increase of \$128.7 million includes cash provided by financing activities, including net proceeds of \$48.4 million from the Senior Secured Notes with BioPharma and \$241.8 million from the Convertible Notes, less cash used to purchase capped calls of \$34.7 million, in addition to \$61.6 million in net upfront payments received from the three license and commercialization agreements for STENDRA and SPEDRA, partially offset by cash used in operating and investing activities.

### **Note to Investors**

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the fourth quarter and year ended December 31, 2013 financial results today, February 24, 2014, beginning at 1:30PM Pacific Time. Investors may listen to this call by dialing 1-877-359-2916 in the U.S. and ++224-357-2386 outside the U.S. A webcast replay will be available for 30 days and may be accessed at <http://ir.vivus.com/>.

### **About Qsymia**

Qsymia is approved in the U.S. and is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults 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 medical condition such as high blood pressure, type 2 diabetes, or high cholesterol.

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.

### **Important Safety Information**

Qsymia<sup>®</sup> (phentermine and topiramate extended-release) capsules CIV is contraindicated in pregnancy; in patients with glaucoma; in hyperthyroidism; in patients receiving treatment or within 14 days following treatment with monoamine oxidase inhibitors (MAOIs); or in patients with hypersensitivity to sympathomimetic amines, topiramate, or any of the inactive ingredients in Qsymia.

Qsymia can cause fetal harm. Females of reproductive potential should have a negative pregnancy test before treatment and monthly thereafter and use effective contraception consistently during Qsymia therapy. If a patient becomes pregnant while taking Qsymia, treatment should be discontinued immediately, and the patient should be informed of the potential hazard to the fetus.

The most commonly observed side effects in controlled clinical studies, 5% or greater and at least 1.5 times placebo, include paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth.

### **About Avanafil**

STENDRA (avanafil) is approved in the U.S. by the FDA for the treatment of erectile dysfunction. Auxilium Pharmaceuticals, Inc. has exclusive marketing rights to STENDRA in the U.S. and Canada.

STENDRA will be available through retail and mail order pharmacies. Auxilium plans to offer programs that will help patients with out-of-pocket costs.

SPEDRA, the trade name for avanafil in the EU, is approved by the EMA for the treatment of erectile dysfunction in the EU. VIVUS has granted an exclusive license to the Menarini Group through its subsidiary Berlin-Chemie AG to commercialize and promote SPEDRA for the treatment of erectile dysfunction in over 40 European countries plus Australia and New Zealand.

VIVUS has granted an exclusive license to Sanofi to commercialize avanafil in Africa, the Middle East, Turkey, and the Commonwealth of Independent States (CIS) including Russia.

Avanafil is licensed from Mitsubishi Tanabe Pharma Corporation (MTPC). VIVUS owns worldwide development and commercial rights to avanafil for the treatment of sexual dysfunction, with the exception of certain Asian-Pacific Rim countries. VIVUS is in discussions with other parties for the commercialization rights to its remaining territories.

For more information about STENDRA, please visit [www.Stendra.com](http://www.Stendra.com).

### **Important Safety Information**

STENDRA<sup>™</sup> (avanafil) is prescribed to treat erectile dysfunction (ED).

Do not take STENDRA if you take nitrates, often prescribed for chest pain, as this may cause a sudden, unsafe drop in blood pressure.

Discuss your general health status with your healthcare provider to ensure that you are healthy enough to engage in sexual activity. If you experience chest pain, nausea, or any other discomforts during sex, seek immediate medical help.

STENDRA may affect the way other medicines work. Tell your healthcare provider if you take any of the following; medicines called HIV protease inhibitors, such as ritonavir (Norvir<sup>®</sup>), indinavir (Crixivan<sup>®</sup>), saquinavir (Fortavase<sup>®</sup> or Invirase<sup>®</sup>) or atazanavir (Reyataz<sup>®</sup>); some types of oral antifungal medicines, such as ketoconazole (Nizoral<sup>®</sup>), and itraconazole (Sporanox<sup>®</sup>); or some types of antibiotics, such as clarithromycin (Biaxin<sup>®</sup>), telithromycin (Ketek<sup>®</sup>), or erythromycin.

In the rare event of an erection lasting more than 4 hours, seek immediate medical help to avoid long-term injury.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medicines, including STENDRA) reported a sudden decrease or loss of vision. It is not possible to determine whether these events are related directly to these medicines or to other factors. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including STENDRA, and call a doctor right away.

Sudden decrease or loss of hearing has been rarely reported in people taking PDE5 inhibitors, including STENDRA. It is not possible to determine whether these events are related directly to the PDE5 inhibitors or to other factors. If you experience sudden decrease or loss of hearing, stop taking STENDRA and contact a doctor right away. If you have prostate problems or high blood pressure for which you take medicines called alpha blockers or other anti-hypertensives, your doctor may start you on a lower dose of STENDRA.

Drinking too much alcohol when taking STENDRA may lead to headache, dizziness, and lower blood pressure.

STENDRA in combination with other treatments for ED is not recommended.

STENDRA does not protect against sexually transmitted diseases, including HIV.

The most common side effects of STENDRA are headache, flushing, runny nose and congestion.

Please see full patient prescribing information for STENDRA (50 mg, 100 mg, 200 mg) tablets.

### **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 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 and are subject to risks, uncertainties and other factors, including risks and uncertainties related to the extension of patent exclusivity for Qsymia in the U.S.; risks and uncertainties related to upfront payments, regulatory and sales milestones, as well as royalties, under the License and Commercialization Agreement with Sanofi; risks and uncertainties related to the insight provided by the Aetna pilot program on the impact on health outcomes, workplace productivity and the potential for reductions in medical costs, including the timing of the program; risks and uncertainties related to the FDA acceptance of a supplemental application that proposes to revise the STENDRA prescribing information to include recent study results; and risk and uncertainties related to the long-term prospects for the obesity market, as well as our continuing efforts to make Qsymia the drug of choice in this market. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. Investors should read the risk factors set forth in VIVUS's Form 10-K for the year ending December 31, 2012, as amended by the Form 10-K/A filed on April 30, 2013 and by the Form 10-K/A filed on June 12, 2013, and periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

### **VIVUS, Inc.**

#### **CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share amounts)

	<b>Three Months Ended</b>		<b>Years Ended</b>	
	<b>December 31 2013</b>	<b>December 31 2012</b>	<b>December 31 2013</b>	<b>December 31 2012*</b>
	(unaudited)	(unaudited)	(unaudited)	
Revenue:				
Net product revenue	\$ 9,219	\$ 1,971	\$ 25,244	\$ 2,012
License and other revenue	34,838	--	55,838	--
<b>Total revenue</b>	<b>44,057</b>	<b>1,971</b>	<b>81,082</b>	<b>2,012</b>
Operating expenses:				
Cost of goods sold	3,165	183	4,868	187
Inventory impairment and commitment fee	--	--	10,225	0
Research and development	4,994	7,758	29,677	32,065
Selling, general and administrative	36,569	50,314	158,235	109,665
Non-recurring charges	8,024	--	32,691	--
<b>Total operating expenses</b>	<b>52,752</b>	<b>58,255</b>	<b>235,696</b>	<b>141,917</b>
<b>Loss from operations</b>	<b>(8,695)</b>	<b>(56,284)</b>	<b>(154,614)</b>	<b>(139,905)</b>

Interest and other expense (income), net	8,418	(69)	20,235	(199)
Loss from continuing operations before income taxes	(17,113)	(56,215)	(174,849)	(139,706)
Provision for income taxes	51	14	97	27
Loss from continuing operations	(17,164)	(56,229)	(174,946)	(139,733)
(Loss) income from discontinued operations	--	(430)	490	(148)
Net loss	<u>\$ (17,164)</u>	<u>\$ (56,659)</u>	<u>\$ (174,456)</u>	<u>\$ (139,881)</u>
Basic and diluted net income (loss) per share:				
Continuing operations	\$ (0.17)	\$ (0.56)	\$ (1.72)	\$ (1.42)
Discontinued operations	--	--	--	--
Net loss per share	<u>\$ (0.17)</u>	<u>\$ (0.56)</u>	<u>\$ (1.72)</u>	<u>\$ (1.42)</u>
Shares used in per share computation:				
Basic and diluted	102,379	100,626	101,174	98,289

\*The Condensed Consolidated Statement of Operations at December 31, 2012 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)

	<b>December 31</b>	<b>December 31</b>
	<b>2013</b>	<b>2012*</b>
	(unaudited)	
Current assets:		
Cash and cash equivalents	\$ 103,262	\$ 58,605
Available-for-sale securities	240,024	155,981
Accounts receivable, net	12,214	2,778
Inventories	48,503	25,353
Prepaid expenses and other assets	19,938	19,159
Total current assets	<u>423,941</u>	<u>261,876</u>
Property and equipment, net	1,954	1,951
Non-current assets	5,901	287
Total assets	<u>\$ 431,796</u>	<u>\$ 264,114</u>
Current liabilities:		
Accounts payable	\$ 10,759	\$ 25,375
Accrued and other liabilities	23,993	14,680
Deferred revenue	17,255	1,150
Total current liabilities	<u>52,007</u>	<u>41,205</u>
Long term debt	213,106	--
Deferred revenue-net of current portion	10,360	--

Non-current accrued and other liabilities	2,954	--
Total liabilities	<u>278,427</u>	<u>41,205</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	813,905	709,022
Accumulated other comprehensive income	66	33
Accumulated deficit	<u>(660,602)</u>	<u>(486,146)</u>
Total stockholders' equity	<u>153,369</u>	<u>222,909</u>
Total liabilities and stockholders' equity	<u>\$ 431,796</u>	<u>\$ 264,114</u>

\*The Condensed Consolidated Balance Sheet at December 31, 2012 has been derived from the Company's audited financial statements at that date.

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