



November 5, 2013

## VIVUS Reports Third Quarter and First Nine Months 2013 Financial Results

MOUNTAIN VIEW, Calif., Nov. 5, 2013 (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 third quarter and nine months ended September 30, 2013.

### Recent Highlights

- On July 1, 2013, we announced the availability of Qsymia in certified retail pharmacies. We continue to add locations and to certify additional chain and independent pharmacies. Qsymia is currently available nationwide in over 31,000 certified retail pharmacies.
- On July 5, 2013, we entered into a License and Commercialization Agreement with Menarini Group, through its subsidiary Berlin-Chemie AG, to commercialize and promote SPEDRA<sup>™</sup> for the treatment of erectile dysfunction in over 40 European countries, plus Australia and New Zealand. Under the agreement, we are eligible to receive up to €79 million based on various approval and sales milestones, €39 million of which may be earned within the first year. In addition, we will receive royalties on SPEDRA sales.
- On September 3, 2013, Seth H. Z. Fischer joined as Chief Executive Officer and a member of the Board of Directors. Mr. Fischer has three decades of healthcare experience in the pharmaceutical and medical device industries, including 29 years with Johnson & Johnson, most recently as Company Group Chairman, Johnson & Johnson and Worldwide Franchise Chairman, Cordis Corporation from 2008 to 2012.
- On September 20, 2013, we submitted to the European Medicines Agency a request for scientific advice regarding use of a pre-specified interim analysis from the AQCLAIM cardiovascular outcomes trial. This scientific advice will provide guidance regarding the resubmission of the marketing authorization application, or MAA, for approval of Qsiva<sup>™</sup> for obesity in Europe under the centralized procedure.
- On October 8, 2013, clinical results were published in *Diabetes Care* showing Qsymia reversed progression to type 2 diabetes among certain medically vulnerable patient populations. High-risk overweight or obese patients with prediabetes and/or metabolic syndrome took Qsymia over a two-year period. In addition to losing weight, these patients experienced reductions of up to 78.7% in the annualized incidence rate of type 2 diabetes.
- On October 11, 2013, we entered into a Licensing and Commercialization Agreement with Auxilium Pharmaceuticals, Inc. for the exclusive rights to market STENDRA<sup>™</sup> in the United States and Canada. Under the Agreement, VIVUS is eligible to receive up to \$300 million based on certain regulatory and sales milestones, including an upfront licensing fee of \$30 million and a \$15 million payment contingent upon a potential label amendment regarding time to erection, in addition to royalties on product sales.
- As part of our ongoing efforts to reduce costs by eliminating expenses that are not essential to expanding the use of Qsymia, we have implemented a cost reduction plan which will reduce our workforce by approximately 20 employees, or 17% of our workforce, excluding the sales force of 150, in the fourth quarter of 2013. We expect to complete the cost reduction plan by the end of 2013, and anticipate incurring pre-tax non-recurring charges related to employee termination costs, operating lease exit costs, and other associated costs in the range of \$6 million to \$8 million in the fourth quarter of 2013, including approximately \$1 million to \$1.5 million in non-cash share-based compensation expense related to the acceleration of the vesting and exercisability of equity awards held by the terminated employees. We expect to realize approximately \$6 million to \$8 million in annual net cost savings beginning in fiscal year 2014.

"Our results for this quarter were disappointing, but we have made changes to improve our performance," stated Seth H. Z. Fischer, chief executive officer. "We strengthened our balance sheet by entering into partnerships with Auxilium and Menarini for commercialization of avanafil (STENDRA/SPEDRA), our erectile dysfunction drug. We have cut costs by reducing our workforce by 17%. We have initiated a process to seek European approval for Qsiva through the centralized procedure. Net product revenue from sales of Qsymia for obesity grew modestly, but we believe that recent growth in certified retail pharmacies, expanding reimbursement coverage and a more focused selling message will allow us to increase sales in 2014."

### Third Quarter Financial Results

For the third quarter of 2013, net product revenue from sales of Qsymia was \$6.4 million. In addition, we recognized \$21.0 million in license revenue from the SPEDRA commercialization agreement with Menarini. 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 three and nine months ended September 30, 2012, net product revenue from sales of Qsymia was \$41,000.

Net loss for the third quarter of 2013 was \$48.2 million, or \$0.48 net loss per share, as compared to a net loss of \$40.4 million, or \$0.40 net loss per share, during the third quarter of 2012. The increased net loss for the third quarter of 2013, as compared to the third quarter of 2012, is primarily attributable to higher selling, general and administrative expenses of \$6.9 million, increased interest expense of \$7.7 million, and \$20.7 million of non-recurring charges related to the proxy contest in connection with our 2013 Annual Meeting of Stockholders, which was resolved in July 2013 and resulted in a change in the majority of the members of our Board of Directors. As a result of the proxy contest, we incurred \$2.9 million of severance charges in connection with the resignations of our former chief executive officer and president, \$5.1 million of fees and related expenses (including approximately \$3.0 million of out-of-pocket expenses to be reimbursed to First Manhattan Company), and \$12.7 million of non-cash share-based compensation expense related to the automatic acceleration of vesting of unvested stock options held by certain employees, which resulted from the change in the majority of the members of our Board. These increases were partially offset by license revenue of \$21.0 million.

The table below presents - on a non-GAAP basis - the net loss for the quarter ended September 30, 2013, making adjustments for one-time expenses related to the proxy contest and one-time revenue related to our agreement with Menarini (in thousands):

	<u>Three Months Ended September 30, 2013</u>
GAAP <sup>1</sup> net loss	\$ (48,204)
Adjustment - Non-recurring charges related to proxy contest	(20,742)
Adjustment - License revenue related to Menarini license agreement	<u>21,000</u>
Non-GAAP net loss	<u>\$ (47,946)</u>

<sup>1</sup>U.S. generally accepted accounting principles

For the third quarter of 2013, there were approximately 109,000 Qsymia prescriptions dispensed, an increase of 35% compared to second quarter 2013. Approximately 28,000 of these prescriptions were dispensed under the Free Trial Offer. The majority of these prescriptions were dispensed through the Qsymia certified retail pharmacy network.

### **First Nine Months Financial Results**

Net product revenue from sales of Qsymia for the first nine months of 2013 was \$16.0 million, and the license revenue was \$21.0 million. For the nine months ended September 30, 2013, we reported a net loss of \$157.3 million or \$1.56 net loss per share, as compared to a net loss of \$83.2 million, or \$0.85 net loss per share, during the first nine months of 2012. The increased net loss for the first nine months of 2013 is primarily attributable to increased selling and marketing expenses related to commercialization activities for Qsymia. Included in the net loss for the nine months ended September 30, 2013 was \$24.7 million in non-recurring charges in connection with our 2013 Annual Meeting of Stockholders and related severance charges, including \$12.7 million of non-cash share-based compensation expense, and a total charge of \$10.2 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee for Qsymia, and \$11.9 million of higher interest expense related to the long-term debt incurred in April and May of 2013, as described below. These increases were partially offset by license revenue of \$21.0 million.

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

Cash, cash equivalents and available-for-sale securities (cash) totaled \$346.4 million at September 30, 2013, as compared to \$214.6 million at December 31, 2012. The increase of \$131.8 million is primarily due to net cash provided by financing activities, including the 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, and less net cash used in operating activities of \$121.2 million, including \$26.6 million in net upfront payments received from Menarini in connection with the SPEDRA agreement. In October 2013, we received \$30 million in an upfront payment from the STENDRA license and commercialization agreement with Auxilium.

### **Reconciliation of Non-GAAP Financial Measure**

This press release contains disclosure related to VIVUS's non-GAAP net loss for the three months ended September 30, 2013, which constitutes a non-GAAP financial measure within the meaning of Regulation G as promulgated by the Securities and Exchange Commission. Regarding non-GAAP net loss, VIVUS believes that excluding the one-time proxy contest expenses and the upfront Menarini license revenue provides to management and investors additional insight into current operations. In particular, management finds it useful to exclude these items in order to more readily correlate the company's operating activities with the company's ability to generate cash from operations. VIVUS management believes that the non-GAAP financial measure presented in its press release, when considered together with GAAP financial measures, provides information that is useful to investors in understanding period-over-period operating results. An analysis of any non-GAAP financial measure should be used in conjunction with results presented in accordance with GAAP.

### **Note to Investors**

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the third quarter and first nine months of 2013 financial results today, November 5, 2013, 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.

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™ (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®), indinavir (Crixivan®), saquinavir (Fortavase® or Invirase®) or atazanavir (Reyataz®); some types of oral antifungal medicines, such as ketoconazole (Nizoral®), and itraconazole (Sporanox®); or some types of antibiotics, such as clarithromycin (Biaxin®), telithromycin (Ketek®), 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 our ability to eliminate expenses that are not essential to expanding the use of Qsymia and fully realize the anticipated benefits from our cost reduction plan, including the timing thereof; risks and uncertainties related to the impact of greater restructuring costs than currently anticipated and lower annual net cost savings than currently expected; risks and uncertainties related to the impact of the cost reduction plan on our business and unanticipated charges not currently contemplated that may occur as a result of the cost reduction plan; risks and uncertainties related to our ability to continue to certify and add to the Qsymia retail pharmacy network and sell Qsymia through this network; risks and uncertainties related to our ability to increase Qsymia sales in 2014 through growth in certified retail pharmacies, expansion of reimbursement coverage and the use of a more focused selling message; risks and uncertainties related to the milestones, payments and royalties under the STENDRA and SPEDRA agreements; risks and uncertainties related to filing an amendment to the current STENDRA and SPEDRA labels to include recent study results; risks and uncertainties related to the number of Qsymia prescriptions dispensed through the mail order system and through certified retail pharmacies; risks and uncertainties related to the launch and commercialization of SPEDRA in the EU; risks and uncertainties related to the resubmission of the MAA for approval of Qsiva for obesity in Europe under the centralized procedure; and risks and uncertainties related to the timing, strategy, tactics and success of avanafil commercialization by Auxilium in the U.S. or Canada. 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)  
(Unaudited)

	Three Months Ended		Nine Months Ended	
	September 30 2013	September 30 2012	September 30 2013	September 30 2012
Revenue:				
Net product revenue	\$ 6,379	\$ 41	\$ 16,025	\$ 41
License revenue	<u>21,000</u>	<u>--</u>	<u>21,000</u>	<u>--</u>
Total revenue	<u>27,379</u>	<u>41</u>	<u>37,025</u>	<u>41</u>
Operating expenses:				
Cost of goods sold	741	4	1,703	4
Inventory impairment and commitment fee	--	--	10,225	--
Research and development	8,405	9,300	24,683	24,307
Selling, general and administrative	38,167	31,269	121,666	59,351
Non-recurring charges	<u>20,743</u>	<u>--</u>	<u>24,667</u>	<u>--</u>
Total operating expenses	<u>68,056</u>	<u>40,573</u>	<u>182,944</u>	<u>83,662</u>
Loss from operations	(40,677)	(40,532)	(145,919)	(83,621)
Interest and other expense (income), net	<u>7,669</u>	<u>(59)</u>	<u>11,817</u>	<u>(130)</u>
Loss from continuing operations before income taxes	(48,346)	(40,473)	(157,736)	(83,491)
Provision for income taxes	<u>33</u>	<u>3</u>	<u>46</u>	<u>13</u>
Loss from continuing operations	(48,379)	(40,476)	(157,782)	(83,504)
Income from discontinued operations	<u>175</u>	<u>80</u>	<u>490</u>	<u>282</u>
Net loss	<u>\$ (48,204)</u>	<u>\$ (40,396)</u>	<u>\$ (157,292)</u>	<u>\$ (83,222)</u>
Basic and diluted net income (loss) per share:				
Continuing operations	\$ (0.48)	\$ (0.40)	\$ (1.56)	\$ (0.85)
Discontinued operations	<u>--</u>	<u>--</u>	<u>--</u>	<u>--</u>
Net loss per share	<u>\$ (0.48)</u>	<u>\$ (0.40)</u>	<u>\$ (1.56)</u>	<u>\$ (0.85)</u>
Shares used in per share computation:				
Basic and diluted	100,904	100,438	100,769	97,505

**VIVUS, Inc.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	<b>September 30</b>	<b>December 31</b>
	<b>2013</b>	<b>2012*</b>
	(unaudited)	
<b>Current assets:</b>		
Cash and cash equivalents	\$ 143,121	\$ 58,605
Available-for-sale securities	203,328	155,981
Accounts receivable, net	6,589	2,778
Inventories	37,918	25,353
Prepaid expenses and other assets	20,680	19,159
<b>Total current assets</b>	<b>411,636</b>	<b>261,876</b>
Property and equipment, net	2,968	1,951
<b>Non-current assets</b>	<b>7,874</b>	<b>287</b>
<b>Total assets</b>	<b>\$ 422,478</b>	<b>\$ 264,114</b>
<b>Current liabilities:</b>		
Accounts payable	\$ 17,730	\$ 25,375
Accrued and other liabilities	21,112	14,680
Deferred revenue	20,147	1,150
<b>Total current liabilities</b>	<b>58,989</b>	<b>41,205</b>
Long term debt	209,642	--
<b>Total liabilities</b>	<b>268,631</b>	<b>41,205</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity:</b>		
Common stock and additional paid-in capital	797,193	709,022
Accumulated other comprehensive income	92	33
Accumulated deficit	(643,438)	(486,146)
<b>Total stockholders' equity</b>	<b>153,847</b>	<b>222,909</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 422,478</b>	<b>\$ 264,114</b>

\*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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