

August 6, 2013

# VIVUS Reports Second Quarter and First Six Months 2013 Financial Results

MOUNTAIN VIEW, Calif., Aug. 6, 2013 (GLOBE NEWSWIRE) -- VIVUS,Inc. (Nasdaq:VVUS) ("VIVUS"), which sells the obesity drug Qsymia<sup>®</sup> (phentermine and topiramate extended-release) capsules CIV in the United States, today provided a business update and reported its financial results for the second quarter and six months ended June 30, 2013.

## **Recent Highlights**

On July 22, 2013, we announced that our Board of Directors had appointed Michael Astrue to serve as its non-executive chairman of the Board of Directors and Anthony (Tony) Zook to serve as our chief executive officer. Mr. Zook was also appointed to our Board of Directors on July 25, 2013. Mr. Astrue formerly served as chief executive officer of Transkaryotic Therapies, chairman of the Massachusetts Biotechnology Council, and Commissioner of Social Security. Mr. Zook formerly served as executive vice president for Global Commercial Operations for AstraZeneca and president of MedImmune.

"It is a pleasure to join VIVUS as CEO and I look forward to working with the VIVUS team, including the Board of Directors," stated Tony Zook, chief executive officer of VIVUS. "We intend to move quickly on four main goals: 1) expand use of Qsymia through targeted patient and physician education; 2) find the right partner for Qsymia to expand PCP reach; 3) create a pathway for centralized approval in Europe; and 4) eliminate expenses that are not essential to expanding use of Qsymia. We are already making progress on these four goals."

- On July 18, 2013, we entered into a settlement agreement with First Manhattan Co., or the Settlement Agreement, terminating the pending proxy contest with respect to the election of our Board of Directors at our 2013 annual meeting of stockholders, or the Annual Meeting. The Settlement Agreement provides that the Annual Meeting be adjourned to August 14, 2013.
- On July 1, 2013, we announced initial availability of Qsymia through approximately 8,000 Walgreens, Costco and Duane Reade retail pharmacies nationwide. As of today, the number of retail pharmacies through which Qsymia is available is approaching 10,000 nationwide. We intend to continue certifying and adding to the Qsymia retail pharmacy network, including well-known national and regional chains as well as independent pharmacies, in the coming weeks and months.
- On June 26, 2013, the European Commission, or EC, adopted the implementing decision granting marketing authorization for SPEDRA™ (the approved trade name for avanafil in the European Union, or EU) for the treatment of erectile dysfunction (ED) in the EU.
- On July 5, 2013, we entered into a License and Commercialization Agreement, or the SPEDRA Agreement, and a Commercial Supply Agreement with Menarini to commercialize and promote SPEDRA for the treatment of ED in over 40 European countries, plus Australia and New Zealand. Under the SPEDRA Agreement, we will receive an upfront payment and various approval and sales milestones plus royalties on SPEDRA sales. Within the first year, we expect to receive approximately €39 million, including upfront payments totaling €16 million. Menarini will also reimburse us for payments made to cover various obligations to MTPC during the term of the SPEDRA Agreement. We are eligible to receive up to €79 million in milestones and other payments over the life of the SPEDRA Agreement in addition to royalties.
- On June 19, 2013, we announced study results showing avanafil is effective for sexual activity within 15 minutes in men with ED. In the study, avanafil patients achieved statistically significant improvement over placebo, in the mean proportion of attempts that resulted in erections sufficient for successful intercourse, as early as 10 minutes for the 200 mg dose and 12 minutes for the 100 mg dose after being taken. We intend to file an amendment to the current STENDRA and SPEDRA labels to include these results.
- On May 21, 2013, we closed an offering of \$220.0 million in 4.5% Convertible Senior Notes due May 1, 2020, or the Convertible Notes. In addition, on May 29, 2013, the Initial Purchasers exercised in full their option to purchase an additional \$30.0 million aggregate principal amount of the Convertible Notes. Total net proceeds from the Convertible Notes were approximately \$241.8 million. The Convertible Notes are senior unsecured obligations of the Company and bear interest at a fixed rate of 4.50% per annum, payable semiannually in arrears on May 1 and November 1 of each year, beginning on November 1, 2013, unless earlier purchased or converted.

## Second Quarter Financial Results

In the second quarter of 2013, net product revenue from sales of Qsymia was \$5.5 million. For the quarter ended June 30, 2013, we reported a net loss of \$55.5 million, or \$0.55 net loss per share, as compared to a net loss of \$24.0 million, or \$0.24 net loss per share during the second quarter of 2012. The increased net loss in the second quarter of 2013, as compared to the second quarter of 2012, is primarily attributable to increased selling, general and administrative expenses related to commercialization activities for Qsymia. Included in the net loss for the quarter ended June 30, 2013 were \$2.8 million related to the proxy contest and a total charge of \$4.4 million for Qsymia inventories on hand in excess of demand, plus a purchase commitment fee due to the manufacturer of Qsymia.

For the second quarter of 2013, there were approximately 81,000 Qsymia prescriptions dispensed, of which approximately 24,000 were dispensed under the Free Trial Offer. All of these prescriptions were dispensed through the certified mail order home delivery system. As patients switch to retail, we anticipate that the future number of prescriptions dispensed through the mail order system will decline and prescriptions dispensed through certified retail pharmacies will grow and eventually surpass the number of prescriptions currently dispensed through mail order.

### **First Half Financial Results**

Net product revenue from sales of Qsymia in the first half of 2013 was \$9.6 million. For the six months ended June 30, 2013, we reported a net loss of \$109.1 million, or \$1.08 net loss per share, as compared to a net loss of \$42.8 million, or \$0.45 net loss per share during the first half of 2012. The increased net loss in the first half of 2013 is again primarily attributable to increased selling, general and administrative expenses related to commercialization activities for Qsymia. Included in the net loss for the six months ended June 30, 2013 were \$3.5 million related to the proxy contest and a total charge of \$10.2 million for Qsymia inventories, including a purchase commitment fee, as explained above.

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

Cash, cash equivalents and available-for-sale securities (cash) totaled \$358.3 million at June 30, 2013, as compared to \$214.6 million at December 31, 2012. The increase of \$143.7 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 cash used in operating activities of \$110.3 million.

### Note to Investors

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the second quarter and first six months of 2013 financial results today, August 6, 2013, beginning at 1:30PM Pacific 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 <a href="http://ir.vivus.com/">http://ir.vivus.com/</a>.

### 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/m2 or greater (obese) or 27 kg/m2 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

SPEDRA<sup>™</sup>, the trade name for avanafil in the EU, has been approved by the EMA for the treatment of erectile dysfunction in the EU.

STENDRA is approved by the FDA for the treatment of erectile dysfunction in the U.S. VIVUS, through collaboration arrangements with third parties, intends to market and sell STENDRA in the U.S. and under the trade name SPEDRA in the EU and other territories outside the U.S. 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 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 is currently in discussions with potential partners to commercialize STENDRA in the U.S. and its other territories throughout the world.

For more information about STENDRA, please visit <u>www.Stendra.com</u>.

### **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®), 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 <u>www.vivus.com</u>.

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 continue to certify and add to the Qsymia retail pharmacy network and sell Qsymia through this network; risks and uncertainties related to the milestones, payments and royalties under the SPEDRA Agreement; 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 prescriptions dispensed through the mail order system and through certified retail pharmacies; risks and uncertainties related to the completion of our STENDRA partnering discussions on acceptable terms and on a timely basis; and risks and uncertainties related to the launch and commercialization of SPEDRA in the EU. 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		Six Months Ended	
	June 30	June 30	June 30	June 30
	2013	2012	2013	2012
Revenue:				
Net product revenue	\$ 5,534	\$	\$ 9,646	\$
Operating expenses:				
Cost of goods sold	572		962	
Inventory impairment and commitment fee	4,448		10,225	
Research and development	9,232	8,873	16,278	15,007
Selling, general and administrative	42,727	15,444	87,423	28,082
Total operating expenses	56,979	24,317	114,888	43,089
Loss from operations	(51,445)	(24,317)	(105,242)	(43,089)
Interest and other income (expense), net	(4,183)	54	(4,148)	71
interest and other income (expense), net	(4,103)		(4,140)	
Loss from continuing operations before income taxes	(55,628)	(24,263)	(109,390)	(43,018)
Provision for income taxes	(7)	(3)	(13)	(10)
Loss from continuing operations	(55,635)	(24,266)	(109,403)	(43,028)
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Income from discontinued operations	123	218	315	202
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Net loss	φ (၁၁,၁12)	⊅ (∠4,∪48)	\$ (109,088)	⊅ (4∠,8∠0)
Basic and diluted net income (loss) per share:				
Continuing operations	\$ (0.55)	\$ (0.24)	\$ (1.08)	\$ (0.45)
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Discontinued operations			<u> </u>	
Net loss per share	\$ (0.55)	\$ (0.24)	\$ (1.08)	\$ (0.45)
Shares used in per share computation:				
Basic and diluted	100,739	99,777	100,700	96,022

# VIVUS, Inc. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30	December 31
	2013	2012*
	(unaudited)	
Current assets:		
Cash and cash equivalents	\$ 124,713	\$ 58,605
Available-for-sale securities	233,542	155,981
Accounts receivable, net	5,085	2,778
Inventories	34,217	25,353
Prepaid expenses and other assets	18,338	19,159
Total current assets	415,895	261,876
Property and equipment, net	3,329	1,951
Non-current assets	7,788	287
Total assets	\$ 427,012	\$ 264,114
Current liabilities:		
Accounts payable	\$ 16,777	\$ 25,375
Accrued and other liabilities	16,047	14,680
Deferred revenue	2,846	1,150
Total current liabilities	35,670	41,205
Long term debt	206,220	
Total liabilities	241,890	41,205
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	780,382	709,022
Accumulated other comprehensive income	(26)	33
Accumulated deficit	(595,234)	(486,146)
Total stockholders' equity	185,122	222,909
Total liabilities and stockholders' equity	\$ 427,012	\$ 264,114

\*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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