

May 8, 2013

# **VIVUS Reports First Quarter 2013 Financial Results**

MOUNTAIN VIEW, Calif., May 8, 2013 (GLOBE NEWSWIRE) -- VIVUS, Inc. (Nasdaq:VVUS), a biopharmaceutical company commercializing and developing innovative, next-generation therapies to address unmet needs in obesity and sexual health, today provided a business update and reported its financial results for the first quarter ended March 31, 2013.

"The FDA's approval of the REMS modification allowing distribution of Qsymia through certified retail pharmacy locations was a significant achievement in our ongoing efforts to expand access to Qsymia," stated Leland Wilson, chief executive officer of VIVUS. "We have begun to lay the foundation and our team is working diligently to ensure availability of Qsymia in certified retail pharmacies."

## **Recent Highlights**

- On April 16, 2013, the FDA approved an amendment to the REMS that allows for distribution of Qsymia<sup>®</sup> (phentermine and topiramate extended-release) capsules CIV through certified retail pharmacy locations. We intend to certify pharmacies and announce retail availability in the third quarter of 2013.
- In April 2013, the CHMP adopted a positive opinion recommending the granting of a marketing authorization for avanafil (SPEDRA<sup>™</sup>) for the treatment of erectile dysfunction in the EU. The CHMP recommendation has been referred to the European Commission and a final decision is expected within approximately two months.
- On March 25, 2013, we entered into a Purchase and Sale Agreement with BioPharma Secured Investments III Holdings Cayman LP ("BioPharma"), providing for the purchase of a debt-like instrument. At the initial closing on April 9, 2013, we received \$50 million, less \$1.1 million in funding and facility payments. Subject to the terms and conditions of the agreement and at our sole discretion, we may also elect prior to December 31, 2013 to receive an additional \$60 million, less \$600,000 in a funding payment, at the secondary closing, which is subject to customary closing conditions and which closing shall occur, if at all, no later than January 15, 2014.

## First Quarter 2013 Results

In the first quarter of 2013, net product revenues from sales of Qsymia were \$4.1 million. For the first quarter of 2013, we reported a net loss of \$53.6 million or \$0.53 net loss per share, as compared to a net loss \$18.8 million or \$0.20 net loss per share during the first quarter of 2012. The increased net loss in the first quarter of 2013, as compared to the first quarter of 2012, is primarily attributable to increased selling, general and administrative expenses of \$32.2 million related to commercialization activities for Qsymia. Additionally, included in the net loss was a charge of \$5.8 million to write off inventory in excess of demand. A substantial portion of the excess amount relates to the initial production of Qsymia, which has a shelf life of 24 months. With additional stability data to support a longer shelf life, we have submitted an application to the FDA to extend the shelf life to 36 months for current and future production.

The table below presents the cash, cash equivalents and available-for-sale securities at March 31, 2013 on a GAAP basis and on a non-GAAP basis to include the proceeds from the first closing of the BioPharma transaction, net of facility and funding fees (in thousands):

	March 31, 2013
GAAP <sup>1</sup> cash, cash equivalents and available-for-sale securities	\$ 150,308
Adjustment — Net proceeds from BioPharma initial closing	48,900
Non-GAAP cash, cash equivalents and available-for-sale securities	\$ 199,208

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

#### Note to Investors

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the first quarter financial results

today, May 8, 2013, beginning at 8:30am 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 <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

STENDRA<sup>™</sup> (avanafil) is approved by the FDA for the treatment of erectile dysfunction, or ED, in the U.S. VIVUS, through collaboration arrangements with third parties, intends to market and sell STENDRA in the U.S., and if approved, under the trade name SPEDRA<sup>™</sup> 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 is currently in discussions with potential partners to commercialize STENDRA in the United States and other territories throughout the world.

It is recommended that STENDRA should be taken approximately 30 minutes before sexual activity. STENDRA should not be taken more than once per day. 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 atazanir (Reyataz); some types of oral antifungal medicines, such as ketoconazole (Nizoral), and itraconozale (Sporonox); 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 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 the implementation of the modified REMS program and our ability to certify and sell Qsymia through certified retail pharmacies in the anticipated time, or at all; risks and uncertainties related to our ability to develop and deploy effective educational programs and direct-to-consumer advertising that along with increased access to Qsymia and ongoing improvements in reimbursement will result in the accelerated adoption of Qsymia; risks and uncertainties related to the completion of our avanafil 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. 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 periodic reports filed with the Securities and Exchange Commission. VIVUS does not undertake an obligation to update or revise any forward-looking statements.

## **Important Additional Information**

VIVUS, its directors and certain of its executive officers may be deemed to be participants in the solicitation of proxies from VIVUS stockholders in connection with the matters to be considered at VIVUS's 2013 Annual Meeting of Stockholders. VIVUS intends to file a proxy statement with the U.S. Securities and Exchange Commission (the "SEC") in connection with any such solicitation of proxies from VIVUS stockholders. INVESTORS AND STOCKHOLDERS ARE STRONGLY ENCOURAGED TO READ ANY SUCH PROXY STATEMENT AND ACCOMPANYING PROXY CARD AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION. Information regarding the identity of potential participants, and their direct or indirect interests, by security holdings or otherwise, will be set forth in the proxy statement and other materials to be filed with the SEC in connection with VIVUS's 2013 Annual Meeting of Stockholders. Information regarding the direct and indirect beneficial ownership of VIVUS's directors and executive officers in VIVUS securities is included in their SEC filings on Forms 3, 4 and 5, and additional information can also be found in VIVUS's Annual Report on Form 10-K for the year ended December 31, 2012, filed with the SEC on February 26, 2013, Amendment No. 1 to VIVUS's Annual Report on Form 10-K/A, filed with the SEC on April 30, 2013, and in VIVUS's definitive proxy statement on Schedule 14A in connection with VIVUS's 2012 Annual Meeting of Stockholders, filed with the SEC on April 25, 2012. Stockholders will be able to obtain any proxy statement, any amendments or supplements to the proxy statement and other documents filed by VIVUS with the SEC for no charge at the SEC's website at www.sec.gov. Copies will also be available at no charge at the Investor Relations section of VIVUS's corporate website at www.vivus.com.

#### VIVUS, Inc.

#### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

(Unaudited)

	Three Months Ended	
	March 31	March 31
	2013	2012
Revenue:		
Net product revenue	\$ 4,112	\$
Operating expenses:		
Cost of goods sold	390	
Inventory charge	5,777	
Research and development	7,046	6,291
Selling, general and administrative	44,696	12,481
Total operating expenses	57,909	18,772
Loss from operations	(53,797)	(18,772)
Interest and other income, net	35	17
Loss from continuing operations before income taxes	(53,762)	(18,755)
Provision for income taxes	(6)	(7)
Loss from continuing operations	(53,768)	(18,762)
Income (loss) from discontinued operations	192	(16)
Net loss	\$ (53,576)	\$ (18,778)
Basic and diluted net income (loss) per share:		
Continuing operations	\$ (0.53)	\$ (0.20)
Discontinued operations		
Net loss per share	\$ (0.53)	\$ (0.20)
Shares used in per share computation:		
Basic and diluted	100,660	92,267

# VIVUS, Inc. CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amount)

	March 31	December 31	
	2013	2012*	
	(unaudited)		
Current assets:			
Cash and cash equivalents	\$ 90,606	\$ 58,605	
Available-for-sale securities	59,702	155,981	
Accounts receivable, net	4,878	2,778	
Inventories	27,564	25,353	

Prepaid expenses and other assets	24,324	19,159
Total current assets	207,074	261,876
Property and equipment, net	2,867	1,951
Non-current assets	992	287
Total assets	\$ 210,933	\$ 264,114
Current liabilities:		
Accounts payable	\$ 18,670	\$ 25,375
Accrued and other liabilities	14,656	13,777
Deferred revenue	1,546	1,150
Current liabilities of discontinued operations	506	903
Total current liabilities	35,378	41,205
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	715,263	709,022
Accumulated other comprehensive income	14	33
Accumulated deficit	(539,722)	(486,146)
Total stockholders' equity	175,555	222,909
Total liabilities and stockholders' equity	\$ 210,933	\$ 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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