



May 5, 2015

## VIVUS Reports First Quarter 2015 Financial Results

MOUNTAIN VIEW, CA -- (Marketwired) -- 05/05/15 -- VIVUS, Inc. (NASDAQ: VVUS) (the "Company"), 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 first quarter ended March 31, 2015.

"We have sharpened the focus of our Qsymia<sup>®</sup> commercial campaign, with new emphasis for the sales force on the most productive healthcare providers," said Seth H. Z. Fischer, CEO. "Pilot programs are underway that will offer targeted prescribers comprehensive value-added resources to help their appropriate patients manage obesity. We are amplifying our messages through digital media to information-seeking consumers, those most likely to take action and speak with their physicians about obesity treatment options. We believe our enhanced web-based strategies will deliver clear and compelling communications to potential patients. Early indicators suggest that implementation of these strategies is making an impact with the intended audience in terms of productive engagement and follow through."

Mr. Fischer continued, "Our commitment to the future of the Qsymia franchise is as strong as ever, as we begin the process of securing a new labeled indication in obstructive sleep apnea, or OSA. Our published Phase 2 data in OSA provide a strong foundation for this pathway, and the disorder represents a substantial unmet medical need. Current epidemiologic estimates show that OSA afflicts approximately 9% of men and 4% of women within the general population in the U.S. alone, with relatively severe cases affecting approximately two to four million people."

VIVUS is actively pursuing a commercial partnership for avanafil in Latin America, and the Company plans to make an announcement as soon as an alliance is secured. VIVUS is encouraged with the plans being executed by its STENDRA<sup>®</sup> and SPEDRA<sup>™</sup> commercialization partners to integrate the 15 minute onset of action data into their promotional campaigns. In parallel, the Company has begun examining pulmonary arterial hypertension as a potential additional indication for avanafil, both alone and in combination with another agent.

### **First Quarter 2015 Financial Results**

Total net revenue was \$32.2 million in the current quarter, compared to \$36.7 million in the first quarter of 2014. Of the total revenue, net product revenue was \$12.6 million from sales of Qsymia in the current quarter, compared to \$9.1 million in the first quarter of 2014. In addition, under our commercialization agreements for STENDRA<sup>®</sup> or SPEDRA<sup>™</sup>, we recognized \$11.6 million in license and milestone revenue in the current quarter, compared to \$19.4 million in the first quarter of 2014, and \$8.5 million in supply revenue in the current quarter, compared to \$7.4 million in the first quarter of 2014. We also recognized \$(0.5) million in net royalty revenue in the current quarter, compared to \$0.8 million in the first quarter of 2014. The decrease in net royalty revenue is due primarily to a change in estimate made by our U.S. commercialization partner for STENDRA return reserve related to sales made in 2014. As a result, in the current quarter, we recorded an adjustment of \$1.2 million to reduce our royalty revenue.

There were approximately 136,000 Qsymia prescriptions dispensed in the current quarter, compared to approximately 121,000 in the first quarter of 2014.

Total cost of goods sold was \$9.9 million in the current quarter, compared to \$9.5 million in the first quarter of 2014. The increase was due primarily to the cost of STENDRA supply in proportion to the increase in supply revenue.

Total selling, general and administrative expense was \$26.4 million in the current quarter, compared to \$28.6 million in the first quarter of 2014. Selling and marketing expense for the commercialization of Qsymia totaled \$18.0 million in the current quarter, compared to \$18.7 million in the first quarter of 2014. The decreases in selling and marketing expenses were due primarily to our targeted and more focused spending on marketing and promotional programs. The decreases in general and administrative expenses were due primarily to our continued cost cutting initiatives.

Total research and development expense was \$2.7 million in the current quarter, compared to \$4.4 million in the first quarter of 2014. The fluctuation was due primarily to the timing of clinical projects.

Net loss was \$15.5 million, or \$0.15 net loss per share, in the current quarter, compared to a net loss of \$15.6 million, or \$0.15

net loss per share, in the first quarter of 2014.

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

Cash, cash equivalents and available-for-sale securities (collectively cash) totaled \$287.3 million at March 31, 2015, as compared to \$299.6 million at December 31, 2014. The decrease of \$12.3 million is due primarily to cash used in operating activities, including a milestone payment of \$11.6 million related to the approval of the time to onset claim for SPEDRA in Europe.

### **Recent Business Updates**

On March 30, 2015, we announced an operational update that described certain key corporate decisions and plans regarding Qsymia commercialization investments and resource deployment.

On April 15, 2015, we announced the filing of a lawsuit in the U.S. District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd., collectively referred to as Teva. The lawsuit was filed in response to an Abbreviated New Drug Application, or ANDA, filed by Teva. In its application, Teva seeks to market and sell generic versions of the currently approved doses of Qsymia. VIVUS filed the lawsuit on the basis that Teva's proposed generic products infringe each of the patents held by VIVUS.

On April 21, 2015, we announced that the United States Patent and Trademark Office has issued U.S. Patent Nos. 9,011,905, covering compositions of Qsymia, and 9,011,906, covering methods for effecting weight loss using Qsymia. The newly issued patents are assigned to VIVUS and will be submitted for listing in the FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book) and add to the existing patents listed in the Orange Book that provide market exclusivity for Qsymia.

On April 28, 2015, we announced that effective May 1, 2015, Qsymia is the sole anti-obesity agent participating in the Sam's Club Extra Value Drug List (EVDL) program. Qsymia patients paying cash who are premium members of Sam's Club, known as Sam's Plus Members, will pay lower out-of-pocket costs for Qsymia therapy than those offered through current discount card programs.

### **Note to Investors**

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the first quarter ended March 31, 2015 financial results today, May 5, 2015, beginning at 4:30PM Eastern Time. Investors may listen to this call by dialing toll-free (888) 771-4371 in the U.S. and (847) 585-4405 from 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. In January 2015, Auxilium was purchased by Endo International, plc., or Endo.

STENDRA is available through retail and mail order pharmacies. Endo currently offers programs that 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 our ability to focus

our promotional efforts, including digital media projects, on healthcare providers and on patient education 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 impact of promotional programs for Qsymia on our net product revenue and net income (loss) in future periods; risks and uncertainties related to our ability to successfully commercialize Qsymia and STENDRA/SPEDRA, as well as risks and uncertainties related to our failure to continue to develop innovative investigational drug candidates and drugs and new indications for our approved drugs, including securing for Qsymia a new labeled indication in obstructive sleep apnea; risks and uncertainties related to the timing, strategy, tactics and success of the launches and commercialization of STENDRA (avanafil) or SPEDRA (avanafil) by our sublicensees in the United States, Canada, the EU, Australia, New Zealand, Africa, the Middle East, Turkey, and the Commonwealth of Independent States, including Russia, as well as the timing and success of a commercial partnership for STENDRA (avanafil) or SPEDRA (avanafil) in Latin America; and risks and uncertainties related to the timing of initiation and completion of the proof-of-concept study with avanafil as a treatment for pulmonary arterial hypertension. 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 ended December 31, 2014 as filed on February 25, 2015 and as amended by the Form 10-K/A filed on April 30, 2015, 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 data)*  
*(Unaudited)*

	<i>Three Months Ended</i>	
	<i>March 31,</i>	
	<u>2015</u>	<u>2014</u>
Revenue:		
Net product revenue	\$ 12,628	\$ 9,138
License and milestone revenue	11,574	19,363
Supply revenue	8,478	7,370
Royalty revenue	(514)	820
Total revenue	<u>32,166</u>	<u>36,691</u>
Operating expenses:		
Cost of goods sold	9,896	9,533
Selling, general and administrative	26,400	28,609
Research and development	2,694	4,423
Non-recurring charges	-	2,054
Total operating expenses	<u>38,990</u>	<u>44,619</u>
Loss from operations	(6,824)	(7,928)
Total interest expense and other expense (income), net	8,636	8,058
Loss from continuing operations before income taxes	(15,460)	(15,986)
Provision for (benefit from) income taxes	6	(436)
Net loss	<u>\$ (15,466)</u>	<u>\$ (15,550)</u>
Basic and diluted net loss per share	<u>\$ (0.15)</u>	<u>\$ (0.15)</u>
Shares used in per share computation:		
Basic and diluted	103,797	103,289

**VIVUS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
*(In thousands)*

	<u>March 31,</u>	<u>December 31,</u>
	<u>2015</u>	<u>2014*</u>
	<i>(Unaudited)</i>	
Current assets:		
Cash and cash equivalents	\$ 98,888	\$ 83,174
Available-for-sale securities	188,363	216,397
Accounts receivable, net	11,712	11,595

Inventories	35,930	34,447
Prepaid expenses and other assets	12,182	12,824
Total current assets	<u>347,075</u>	<u>358,437</u>
Property and equipment, net	1,189	1,346
Non-current assets	6,464	7,155
Total assets	<u>\$ 354,728</u>	<u>\$ 366,938</u>
Current liabilities:		
Accounts payable	\$ 9,357	\$ 10,430
Accrued and other liabilities	17,130	17,037
Deferred revenue	18,934	19,445
Current portion of long-term debt	14,058	10,459
Total current liabilities	<u>59,479</u>	<u>57,371</u>
Long-term debt, net of current portion	217,522	217,324
Deferred revenue, net of current portion	8,334	8,876
Non-current accrued and other liabilities	725	849
Total liabilities	<u>286,060</u>	<u>284,420</u>
Commitments and contingencies	-	-
Stockholders' equity:		
Common stock and additional paid-in capital	827,345	825,795
Accumulated other comprehensive income (loss)	38	(28)
Accumulated deficit	<u>(758,715)</u>	<u>(743,249)</u>
Total stockholders' equity	<u>68,668</u>	<u>82,518</u>
Total liabilities and stockholders' equity	<u>\$ 354,728</u>	<u>\$ 366,938</u>

\* The Condensed Consolidated Balance Sheet at December 31, 2014 has been derived from the Company's audited financial statements at that date.

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