



May 3, 2016

## Vivus Reports 2016 First Quarter Financial Results

### Management to Review Results and Provide Business Update in Conference Call Today at 4:30 p.m. Eastern Time

MOUNTAIN VIEW, CA -- (Marketwired) -- 05/03/16 -- VIVUS, Inc. (NASDAQ: VVUS) (the "Company"), 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, 2016. The net loss for the 2016 first quarter was \$12.7 million as compared to \$15.5 million in 2015. Cash, cash equivalents and available-for-sale securities was \$227.8 million at March 31, 2016.

"We and our advisor are engaged in a rigorous business evaluation process with the sole objective of optimizing the value of both STENDRA and Qsymia to VIVUS and our stockholders," said Seth H. Z. Fischer, VIVUS Chief Executive Officer. "We are actively evaluating all options as both brands represent significant advancements and opportunities in their respective markets. STENDRA, with a patent life through April 2025, boasts a 15-minute time-to-onset, benign safety profile and the ability to be taken with food and alcohol, and Qsymia, the best-in-class prescription weight loss brand, with its unsurpassed clinical profile and patent life through June 2029."

Mr. Fischer continued, "First quarter 2016 was unusual for the anti-obesity market. Historically, we have observed a return to growth following the holiday season of the fourth quarter. This year, however, the market did not experience that bounce back that has, over the past several years, been fueled by new prescribers in the category using new market entrants on a trial basis. We believe that recent reductions in promotional efforts within the category are behind the changes in market dynamics and will create an opportunity for Qsymia by shifting prescribing more toward obesity specialists where brand share is strongest."

#### **Business Update**

- 1 The Company received certification that the term for a key patent for STENDRA (US Patent No. 6,656,935) has been extended by 1,687 days as provided by 35 U.S.C. § 156. The expiration date of the patent, which is listed in the Orange Book for STENDRA, is now April 27, 2025.
- 1 The Qsymia Patient Savings Offer, an important program that is instrumental in driving brand trial and patient retention, will be upgraded late in the second quarter of 2016. The upcoming Savings Offer has been designed to bring more new patients into the brand and support their weight loss effort for the long term. The new benefit will continue to offer the two-week Free Trial but will now offer the alternative option of \$95 savings for a patient's first 30-day prescription. A subsequent monthly savings of \$65 will continue for an extended savings benefit of 36 months. We believe that the new program design better supports Qsymia patients in achieving long term success. The new offer will launch June 3, 2016.

#### **Financial Results**

Total revenue, net for the quarters ended March 31, 2016 and 2015 were \$15.3 million and \$32.2 million, respectively. Revenue consisted of the following:

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Qsymia, net product revenue	\$ 12,412	\$ 12,628
License and milestone revenue	-	11,574
STENDRA/SPEDRA supply revenue	1,526	8,478
STENDRA/SPEDRA royalty revenue	1,386	(514)
Total revenue	\$ 15,324	\$ 32,166

Approximately 116,000 and 136,000 Qsymia prescriptions were dispensed in the quarters ended March 31, 2016 and 2015, respectively.

Total cost of goods sold was \$3.7 million and \$9.9 million in the quarters ended March 31, 2016 and 2015, respectively. The change in cost of goods sold was due to changes in net product and supply revenue in the respective periods and the sales mix between Qsymia and STENDRA/SPEDRA.

Total research and development expense was \$1.0 million and \$2.7 million in the quarter ended March 31, 2016 and 2015, respectively. The decrease was primarily due to activity related to the Qsymia adolescent PK/PD study conducted in 2015 and the cost control initiatives implemented in 2015.

Total selling, general and administrative expense was \$15.1 million and \$26.4 million for the quarters ended March 31, 2016 and 2015, respectively. Selling and marketing expense for the commercialization of Qsymia totaled \$7.6 million and \$18.0 million in the quarters ended March 31, 2016 and 2015, respectively. The total decrease was the result of the realignment of our sales force in 2015, refinement of our marketing and promotional programs, and cost control initiatives implemented in 2015.

### **Note to Investors**

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the 2016 first quarter financial results today, May 3, 2016, beginning at 4:30PM Eastern Time. Investors may listen to this call by dialing toll-free 1-877-359-2916 in the U.S. and 1-224-357-2386 from outside the U.S. The audience passcode is 8875 9885. 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<sup>®</sup> (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. In December 2015, Auxilium notified us of its intention to return the U.S. and Canadian commercial rights for STENDRA to us. Auxilium has provided its contractually required six-month notice of termination which, absent an agreement between Auxilium and us for an earlier termination date, will result in the termination of the license agreement and supply agreement on June 30, 2016.

STENDRA is available through retail and mail order pharmacies. Auxilium 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® (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 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 potential

change in our business strategy to enhance long-term stockholder value; 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 the impact of the return of the U.S. and Canadian rights for the commercialization of STENDRA; risks and uncertainties related to our ability, either by ourselves or through a third party, to successfully commercialize STENDRA in the U.S. and Canada; risks and uncertainties related to our ability to successfully commercialize Qsymia including risks and uncertainties related to expansion to retail distribution, the broadening of payor reimbursement, the expansion of Qsymia's primary care presence, changing market dynamics shifting prescribing towards obesity specialists, and the outcomes of our discussions with pharmaceutical companies and our strategic and franchise-specific pathways for Qsymia; risks and uncertainties related to our ability to commercialize Qsymia efficiently in 2016; and risks and uncertainties related to our ability to successfully complete on acceptable terms, and on a timely basis, avanafil partnering discussions for territories under our license with MTPC in which we do not have or will be ending a commercial collaboration, including the U.S., Canada and Latin America. 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, 2015 as filed on March 9, 2016 and as amended by the Form 10-K/A filed on April 22, 2016, 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)*

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2016</b>	<b>2015</b>
Revenue:		
Net product revenue	\$ 12,412	\$ 12,628
License and milestone revenue	-	11,574
Supply revenue	1,526	8,478
Royalty revenue	1,386	(514)
Total revenue	<u>15,324</u>	<u>32,166</u>
Operating expenses:		
Cost of goods sold	3,704	9,896
Selling, general and administrative	15,122	26,400
Research and development	1,029	2,694
Total operating expenses	<u>19,855</u>	<u>38,990</u>
Loss from operations	(4,531)	(6,824)
Interest expense and other expense, net	(8,161)	(8,636)
Loss before income taxes	<u>(12,692)</u>	<u>(15,460)</u>
Provision for (benefit from) income taxes	16	6
Net loss	<u>\$ (12,708)</u>	<u>\$ (15,466)</u>
Basic and diluted net loss per share	<u>\$ (0.12)</u>	<u>\$ (0.15)</u>
Shares used in per share computation:		
Basic and diluted	<u>104,071</u>	<u>103,797</u>

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

	<b>March 31,</b>		<b>December 31,</b>	
	<b>2016</b>		<b>2015*</b>	
	<b>(Unaudited)</b>			
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents	\$ 83,701	\$	95,395	
Available-for-sale securities	144,109		146,168	
Accounts receivable, net	11,855		8,997	
Inventories	11,424		13,602	
Prepaid expenses and other assets	5,335		9,430	

Total current assets	256,424	273,592
Property and equipment, net	884	994
Non-current assets	2,426	2,616
Total assets	<u>\$ 259,734</u>	<u>\$ 277,202</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 7,664	\$ 7,060
Accrued and other liabilities	10,300	15,891
Deferred revenue	18,223	22,142
Current portion of long-term debt	14,944	14,356
Total current liabilities	<u>51,131</u>	<u>59,449</u>
Long-term debt, net of current portion	218,782	217,034
Deferred revenue, net of current portion	7,682	6,508
Non-current accrued and other liabilities	1,243	1,296
Total liabilities	<u>278,838</u>	<u>284,287</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	829,784	829,532
Accumulated other comprehensive (loss) income	176	(261)
Accumulated deficit	(849,064)	(836,356)
Total stockholders' deficit	<u>(19,104)</u>	<u>(7,085)</u>
Total liabilities and stockholders' deficit	<u>\$ 259,734</u>	<u>\$ 277,202</u>

\* The Condensed Consolidated Balance Sheet at December 31, 2015 has been derived from the Company's audited financial statements at that date. Certain amounts have been reclassified to be consistent with March 31, 2016 formats.

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