



March 9, 2016

## VIVUS Reports Fourth Quarter and Year-End 2015 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) -- 03/09/16 -- 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 fourth quarter and year ended December 31, 2015. The net loss for the 2015 fourth quarter was \$12.2 million as compared to \$25.4 million in 2014. The net loss for the twelve months ended December 31, 2015 was \$93.1 million as compared to \$82.6 million in 2014. Cash, cash equivalents and available-for-sale securities was \$241.6 million at December 31, 2015.

"We have been pleased with the interest we have received for STENDRA<sup>®</sup> since announcing the return of the U.S. and Canadian commercialization rights in December 2015," said Seth H. Z. Fischer, VIVUS Chief Executive Officer. "We have initiated a process with a strategic advisor to assist us in evaluating not only our STENDRA alternatives, but our overall business strategy as well."

Mr. Fischer continued, "We are encouraged by the 21% growth in Qsymia annual net revenue in 2015 in a difficult branded anti-obesity market. We will continue to focus on efficiently commercializing Qsymia and managing our costs as we expect a continued difficult market in 2016."

#### Business Update

- | In December 2015, VIVUS announced the return of the U.S. and Canadian rights for STENDRA from Auxilium Pharmaceuticals, Inc., a subsidiary of Endo Pharmaceuticals, plc, on June 30, 2016, absent an agreement between Auxilium and VIVUS for an earlier termination date.
- | In November 2015, VIVUS presented the following posters at Obesity Week 2015.
  - | **Abstract Title: Effects of Phentermine and Topiramate Extended-Release (PHEN/TPM ER) on Weight Loss (WL) in Patients With a Baseline Body Mass Index (BMI)  $\geq$ 45 kg/m<sup>2</sup>**  
Authors: Scott Kahan, MD, MPH; W. Timothy Garvey, MD; Roman Dvorak, MD, PhD
  - | **Abstract Title: Budget Impact of Phentermine and Topiramate Extended-Release (PHEN/TPM ER) in Patients who are Overweight or Obese With Prediabetes or Type 2 Diabetes Mellitus (T2DM)**  
Authors: Sunil Karnawat, PhD; Sarah A. Odeh, BS
  - | **Abstract Title: Budget Impact Over 2 Years of Treatment With Phentermine and Topiramate Extended-Release (PHEN/TPM ER) in an Overweight/Obese Population**  
Authors: Sunil Karnawat, PhD; Sarah A. Odeh, BS
- | In October 2015, Mark K. Oki joined VIVUS in the role of Chief Financial Officer and Chief Accounting Officer. Mr. Oki was most recently at Alexza Pharmaceuticals, Inc., a publicly traded pharmaceutical company, where he most recently served as Alexza's Senior Vice President, Finance, Chief Financial Officer, Principal Accounting Officer and Secretary.

#### Financial Results

Total revenue, net for the quarter and year ended December 31, 2015 was \$15.3 million and \$95.4 million, respectively, compared to \$21.7 million and \$114.2 million in the same periods in 2014, respectively. Revenue consisted of the following:

	<b>Three Months Ended December 31,</b>		<b>Year Ended December 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Qsymia, net product revenue	\$ 13,970	\$ 12,702	\$ 54,622	\$ 45,277
License and milestone revenue	-	-	11,574	38,614

STENDRA/SPEDRA supply revenue	23	8,183	26,674	26,519
STENDRA/SPEDRA royalty revenue	1,350	847	2,560	3,771
Total revenue	<u>15,343</u>	<u>21,732</u>	<u>95,430</u>	<u>114,181</u>

Approximately 132,000 and 566,000 Qsymia prescriptions were dispensed in the quarter and year ended December 31, 2015, respectively, compared to 136,000 and 534,000 in the same periods in 2014, respectively.

Total cost of goods sold, excluding inventory impairment, was \$2.6 million and \$34.2 million in the quarter and year ended December 31, 2015, respectively, compared to \$9.6 million and \$33.4 million in the same periods of 2014, respectively. The changes in cost of goods sold were due to changes in net product and supply revenue in the respective periods and the mix between Qsymia and STENDRA/SPEDRA.

Total selling, general and administrative expense was \$13.7 million and \$79.4 million for the quarter and year ended December 31, 2015, respectively, compared to \$26.8 million and \$111.5 million in the same periods in 2014, respectively. Selling and marketing expense for the commercialization of Qsymia totaled \$8.6 million and \$53.0 million in the quarter and year ended December 31, 2015, respectively, compared to \$17.8 million and \$72.3 million in the same periods in 2014, respectively. The total decrease was the result of the realignment of our sales force, refinement of our marketing and promotional programs, and continued cost control initiatives.

Total research and development expense was \$3.3 million and \$10.1 million in the quarter and year ended December 31, 2015, respectively, compared to \$2.7 million and \$13.8 million in the same periods in 2014, respectively. The increase in the quarter was primarily due to the initiation of the Qsymia adolescent PK/PD study.

Inventory impairment and other non-recurring charges were \$32.1 million in 2015 compared to \$6.2 million in 2014. The charges in the current year were for inventory impairment, in addition to charges for a corporate restructuring plan. The charges in 2014 were for inventory impairment, patent settlement, and a cost reduction plan.

### **Note to Investors**

As previously announced, VIVUS will hold a conference call and an audio webcast to discuss the fourth quarter and year ended December 31, 2015 financial results today, March 9, 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 5812 2612. 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.

SPEEDRA<sup>™</sup>, 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 SPEEDRA 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 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 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, 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; risks and uncertainties related to our ability to work with leading cardiovascular outcome trial experts in planning substantial revisions to the original design and execution of the CVOT with the goal of reducing costs and obtaining FDA agreement that the revised CVOT would fulfill the requirement of demonstrating the long-term cardiovascular safety of Qsymia; 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 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>Year Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Revenue:				
Net product revenue	\$ 13,970	\$ 12,702	\$ 54,622	\$ 45,277
License and milestone revenue	-	-	11,574	38,614
Supply revenue	23	8,183	26,674	26,519
Royalty revenue	1,350	847	2,560	3,771
Total revenue	<u>15,343</u>	<u>21,732</u>	<u>95,430</u>	<u>114,181</u>
Operating expenses:				
Cost of goods sold	2,626	9,571	34,157	33,387
Selling, general and administrative	13,657	26,836	79,387	111,539
Research and development	3,277	2,710	10,102	13,793
Inventory impairment and other non-recurring charges	-	-	32,061	6,173
Total operating expenses	<u>19,560</u>	<u>39,117</u>	<u>155,707</u>	<u>164,892</u>
Loss from operations	(4,217)	(17,385)	(60,277)	(50,711)
Interest expense and other expense, net	7,976	8,031	32,827	32,565
Loss before income taxes	(12,193)	(25,416)	(93,104)	(83,276)
Provision for (benefit from) income taxes	(10)	31	3	(629)
Net loss	<u>\$ (12,183)</u>	<u>\$ (25,447)</u>	<u>\$ (93,107)</u>	<u>\$ (82,647)</u>
Basic and diluted net loss per share	<u>\$ (0.12)</u>	<u>\$ (0.25)</u>	<u>\$ (0.90)</u>	<u>\$ (0.80)</u>
Shares used in per share computation:				
Basic and diluted	<u>104,046</u>	<u>103,703</u>	<u>103,926</u>	<u>103,456</u>

**VIVUS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands)

	<b>December 31, 2015</b>	<b>December 31, 2014*</b>
<b>ASSETS</b>	<b>(Unaudited)</b>	
Current assets:		
Cash and cash equivalents	\$ 95,395	\$ 83,174
Available-for-sale securities	146,168	216,397
Accounts receivable, net	8,997	11,595
Inventories	13,602	34,447
Prepaid expenses and other assets	10,624	12,824
Total current assets	274,786	358,437
Property and equipment, net	994	1,346
Non-current assets	4,801	7,155
Total assets	\$ 280,581	\$ 366,938
<b>LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 7,060	\$ 10,430
Accrued and other liabilities	15,891	16,314
Deferred revenue	22,142	19,445
Current portion of long-term debt	15,550	10,459
Total current liabilities	60,643	56,648
Long-term debt, net of current portion	219,219	217,324
Deferred revenue, net of current portion	6,508	8,876
Non-current accrued and other liabilities	1,296	1,572
Total liabilities	287,666	284,420
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	829,532	825,795
Accumulated other comprehensive (loss) income	(261)	(28)
Accumulated deficit	(836,356)	(743,249)
Total stockholders' (deficit) equity	(7,085)	82,518
Total liabilities and stockholders' (deficit) equity	\$ 280,581	\$ 366,938

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

VIVUS, Inc.  
Mark Oki  
Chief Financial Officer  
[oki@vivus.com](mailto:oki@vivus.com)  
650-934-5200

Investor Relations: The Trout Group  
Brian Korb  
Managing Director  
[bkorb@troutgroup.com](mailto:bkorb@troutgroup.com)  
646-378-2923

Source: VIVUS, Inc.

News Provided by Acquire Media