November 7, 2017

VIVUS Reports Third Quarter 2017 Financial Results

CAMPBELL, CA -- (Marketwired) -- 11/07/17 -- VIVUS, Inc. (NASDAQ: VVUS) (the "Company"), a biopharmaceutical company committed to the development and commercialization of innovative therapies focusing on treatments for patients with serious unmet medical needs, today reported financial results for the quarter ended September 30, 2017 and provided a business update.

"We achieved several key objectives for our marketed products and our lead pipeline program in the third quarter. We expanded the market opportunity for Qsymia® to South Korea and resolved the last of the patent litigation relating to generic versions of Qsymia," said Seth H. Z. Fischer, VIVUS' Chief Executive Officer. "We were pleased to see the promising clinical data in Class 1 and 2 pulmonary arterial hypertension (PAH) patients supporting the potential of tacrolimus in the treatment of PAH in a peer reviewed article in the *European Respiratory Journal*. Our pre-IND meeting with the U.S. Food and Drug Administration (FDA) provided us with clarity on the path forward for filing an IND for tacrolimus in the treatment of PAH, and we intend to file the IND in the first half of 2018. We continue to evaluate opportunities for expanding our product offerings and our product pipeline and continue with our goal of adding at least one new product candidate by the end of the year."

Recent Business Highlights

- ***VIVUS Resolves Qsymia IP Challenges***
  In July and August 2017, VIVUS announced settlement agreements with Actavis Laboratories FL (Actavis) and Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc. (Dr. Reddy's). The settlement agreements permit Actavis and Dr. Reddy's to begin selling a generic version of Qsymia on December 1, 2024 and June 1, 2025, respectively, or earlier under certain circumstances. In the event of a launch earlier than these dates, VIVUS will receive a royalty on net sales of the generic version of Qsymia.

- ***VIVUS Expands Qsymia Beyond the U.S.***
  In September 2017, VIVUS announced an agreement under which Alvogen Malta Operations (ROW) Ltd (Alvogen) will market Qsymia® in the Republic of Korea for the treatment of chronic weight management or weight-related conditions. Alvogen will be solely responsible for obtaining and maintaining regulatory approvals and for all sales and marketing activities in South Korea. VIVUS received an upfront payment and is eligible to receive additional future milestone payments. In addition, VIVUS will receive royalties on Alvogen's net sales of Qsymia.

- ***Tacrolimus Hits Key Milestones and Releases Clinical Data***
  In September 2017, VIVUS announced that the European Medicines Agency (EMA) has granted Orphan Designation to its lead clinical candidate tacrolimus, for the treatment of PAH.

  In October 2017, VIVUS announced that it held a pre-IND meeting with the FDA in October for its proprietary formulation of tacrolimus for the treatment of PAH. The FDA addressed VIVUS' questions related to preclinical, nonclinical and clinical data and planned design of clinical trials of tacrolimus in class III and IV PAH patients, and clarified the requirements needed to file an IND to initiate a clinical trial in this indication. VIVUS is on track to file this IND in the first half of 2018. As discussed with the FDA, VIVUS currently intends to design and conduct clinical trials that could qualify for Fast Track and/or Breakthrough Therapy designation.

  In September 2017, results of a clinical study of tacrolimus, VIVUS' lead product development candidate, in patients with PAH were published in the *European Respiratory Journal*. Study results demonstrate the safety of tacrolimus in patients with PAH, a chronic life-threatening disease characterized by elevated blood pressure in the pulmonary arteries (arteries between the heart and lungs) due to severe constriction of these blood vessels.

Financial Results

Net loss for the third quarter of 2017 was $6.0 million, as compared to $9.2 million in the third quarter of 2016. Cash, cash equivalents and available-for-sale securities were $236.0 million at September 30, 2017.

Total revenue, net for the third quarters of 2017 and 2016, was $15.2 million and $13.4 million, respectively. Revenue consisted of the following:

	Three Months Ended September 30,	
	2017	2016
Qsymia, net product revenue	$ 9,911	$ 12,294
License and milestone revenue	2,500	-
STENDRA/SPEDRA supply revenue	2,133	-
STENDRA/SPEDRA royalty revenue	649	1,059
Total revenue	$ 15,193	$ 13,353

Beginning in the first quarter of 2017, with 48 months of returns experience, VIVUS believed that it had sufficient data and experience from selling Qsymia to reliably estimate expected returns. As a result, VIVUS changed its revenue recognition methodology for Qsymia sales from a "sell-through" methodology to a "sell-in" methodology.

Approximately 97,000 and 109,000 Qsymia prescriptions were dispensed in the third quarters of 2017 and 2016, respectively. In the third quarter of 2017, VIVUS shipped approximately 92,000 units of Qsymia to the wholesalers as wholesalers reduced their Qsymia inventory levels. VIVUS recognized approximately $0.5 million less Qsymia revenue under the "sell-in" methodology than would have been recognized under the "sell-through" methodology. The "sell-in" methodology could continue to result in higher volatility of Qsymia sales, as wholesalers adjust inventory levels compared to those historically reported.

Total cost of goods sold was $3.5 million and $2.1 million in the third quarters of 2017 and 2016, respectively. The increase was primarily a result of higher STENDRA/SPEDRA supply revenue during the third quarter of 2017.

Research and development expense was $0.9 million and $1.7 million in the third quarters of 2017 and 2016, respectively. Research and development expenses wereimpacted by a decrease in efforts surrounding our Qsymia regulatory requirements partially offset by development efforts of tacrolimus for the treatment of PAH.

General and administrative expense was $5.6 million and $6.0 million for the third quarters of 2017 and 2016, respectively, while selling and marketing expense for the commercialization of Qsymia totaled $2.8 million and $4.4 million in the third quarters of 2017 and 2016, respectively. The decreases were due to the continued cost control initiative and the result of the realignment of our sales force, and refinement of our marketing and promotional programs.

Additional Information

As previously announced, VIVUS will hold a conference call to discuss the quarter ended September 30, 2017 financial results and to provide a business update beginning at 4:30PM ET / 1:30PM PT today. Investors may listen to this call by dialing 877-359-2916 in the U.S. and 224-357-2386 from outside the U.S. The passcode is 7997677. To listen via webcast, please visit http://ir.vivus.com/ or click here. A webcast replay will be available on the VIVUS website for 30 days.

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^2 or greater (obese) or 27 kg/m^2 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® (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; 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. Metuchen Pharmaceuticals LLC has exclusive marketing rights to STENDRA in the U.S., Canada, South America and India.

STENDRA is available through retail and mail order pharmacies.

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.

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.

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 committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs. For more information about the Company, please visit 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, including the evaluation of development opportunities; risks and uncertainties related to our, or our partner's, ability to successfully commercialize Qsymia; risks and uncertainties related to our ability to successfully develop or acquire a proprietary formulation of tacrolimus as a precursor to the clinical development process; risks and uncertainties related to our ability to identify, acquire and develop new product pipeline candidates; risks and uncertainties related to our ability to develop a proprietary formulation and to demonstrate through clinical testing the quality, safety, and efficacy of our current or future investigational drug candidates; risks and uncertainties related to the timing, strategy, tactics and success of the commercialization of STENDRA (avanafil) by our sublicensees; 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 a commercial collaboration; risks and uncertainties related to the failure to obtain FDA or foreign authority clearances or approvals and noncompliance with FDA or foreign authority regulations; and risks and uncertainties related to our ability to protect our intellectual property and litigation in which we are involved or may become involved. 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' Form 10-K for the year ended December 31, 2016 as filed on March 8, 2017, and as amended by the Form 10-K/A filed on April 26, 2017, 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)

	Three Months Ended September 30,		***Nine Months Ended September 30,***	
	2017	***2016***	***2017***	***2016***
Revenue:				
Net product revenue	$ 9,911	$ 12,294	$ 36,049	$ 37,455
License and milestone revenue	2,500	-	7,500	-
Supply revenue	2,133	-	8,064	1,526
Royalty revenue	649	1,059	1,819	3,472
Total revenue	15,193	13,353	53,432	42,453
Operating expenses:				
Cost of goods sold	3,514	2,065	13,251	8,416
Research and development	865	1,696	4,059	3,821
Selling, general and administrative	8,388	10,440	31,449	39,254
Total operating expenses	12,767	14,201	48,759	51,491
Income (loss) from operations	2,426	(848)	4,673	(9,038)
Interest expense and other expense, net	8,412	8,313	25,112	24,209
Loss before income taxes	(5,986)	(9,161)	(20,439)	(33,247)
Provision (benefit) for income taxes	8	(9)	(3)	14
Net loss	$ (5,994)	$ (9,152)	$ (20,436)	$ (33,261)
Basic and diluted net loss per share	$ (0.06)	$ (0.09)	$ (0.19)	$ (0.32)
Shares used in per share computation:				
Basic and diluted	105,826	104,484	105,674	104,228

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

	September 30, 2017	***December 31, 2016****
ASSETS	***(Unaudited)***	
Current assets:		
Cash and cash equivalents	$ 73,151	$ 84,783
Available-for-sale securities	162,872	184,736
Accounts receivable, net	11,806	9,478
Inventories	13,442	16,186
Prepaid expenses and other assets	3,754	8,251
Total current assets	265,025	303,434
Property and equipment, net	606	788
Non-current assets	1,108	1,554
Total assets	$ 266,739	$ 305,776
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 4,430	$ 4,707
Accrued and other liabilities	19,806	15,686
Deferred revenue	1,884	19,174
Current portion of long-term debt	9,357	8,708
Total current liabilities	35,477	48,275
Long-term debt, net of current portion	225,354	232,610
Deferred revenue, net of current portion	5,205	6,449
Non-current accrued and other liabilities	348	257
Total liabilities	266,384	287,591
Commitments and contingencies		
Stockholders' (deficit) equity:		
Common stock and additional paid-in capital	834,102	831,855
Accumulated other comprehensive loss	(257)	(616)
Accumulated deficit	(833,490)	(813,054)
Total stockholders' (deficit) equity	355	18,185
Total liabilities and stockholders' (deficit) equity	$ 266,739	$ 305,776

* The Condensed Consolidated Balance Sheets have been derived from the Company's audited financial statements at that date, as adjusted.

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