August 4, 2016

VIVUS Reports 2016 Second 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) -- 08/04/16 -- 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 second quarter ended June 30, 2016. The net loss for the 2016 second quarter was $11.4 million as compared to $49.4 million in 2015. Cash, cash equivalents and available-for-sale securities was $220.2 million at June 30, 2016.

"In the second quarter of 2016, we made significant strides to optimize the value of Qsymia and STENDRA," said Seth H. Z. Fischer, VIVUS' Chief Executive Officer. "Qsymia users now have a simplified savings program that better supports their long-term weight loss goals by providing them with three years of benefits. STENDRA is a unique and highly relevant brand in the erectile dysfunction (ED) market with a clinical profile that addresses many of the unmet needs among ED patients, including: a 15-minute onset-of-action, the ability to use STENDRA while consuming food and alcohol, and high selectivity resulting in lower side effects."

Mr. Fischer continued, "We are concurrently preparing to commercialize STENDRA in the U.S. while maintaining discussions to license or sell STENDRA's U.S. commercialization rights. On September 1, when the U.S. commercial rights are returned to us, we or a third party will assume STENDRA's promotion activities from Auxilium. We continue to explore opportunities to drive stockholder value through identifying commercial and development stage products to build our portfolio of offerings."

Business Update

- On June 4, 2016, VIVUS launched the new Qsymia Patient Savings Offer, an important program that is instrumental in driving brand trial and patient retention. The Savings Offer is designed to bring more new patients into the brand and support their weight loss effort for the long term. The new benefit will 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. Early feedback from healthcare providers and patients indicate that the new program design better supports Qsymia patients in achieving long-term success.
- On June 30, 2016, VIVUS announced an extension of the termination date of the license agreement between Auxilium Pharmaceuticals, Inc., a subsidiary of Endo International, plc, and VIVUS for STENDRA® (avanafil) U.S. and Canadian commercial rights through August 31, 2016. The termination date was originally June 30, 2016.
- On July 21, 2016, VIVUS announced that the United States District Court for the District of New Jersey had issued a claim construction (Markman) ruling governing patent litigation brought by VIVUS against Actavis Laboratories FL, Inc., Actavis Pharma, Inc., and Actavis Inc., collectively referred to as Actavis, and Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., collectively referred to as Teva. The lawsuits were filed in response to Abbreviated New Drug Applications (ANDA) filed by Actavis and Teva seeking to market and sell a generic version of Qsymia prior to the expiration of the U.S. Patents. The courts adopted VIVUS' proposed constructions for all but one of the disputed claim terms and adopted a compromise construction that was acceptable to VIVUS for the final claim term.
- On July 27, 2016, VIVUS filed a lawsuit in the U.S. District Court for the District of New Jersey against Hetero USA, Inc. and Hetero Labs Limited, collectively referred to as Hetero. The lawsuit was filed on the basis that Hetero's submission of their ANDA to obtain approval to manufacture, use, sell, or offer for sale generic versions of STENDRA prior to the expiration of the patents-in-suit constitutes infringement of one or more claims of those patents. In accordance with the Hatch-Waxman Act, as a result of having filed a timely lawsuit against Hetero, FDA approval of Hetero's ANDA will be stayed until the earlier of (i) up to 30 months from the expiration of STENDRA's New Chemical Entity exclusivity period (i.e., October 27, 2019) or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

Financial Results

Total revenue, net for the quarters ended June 30, 2016 and 2015, were $13.8 million and $23.0 million, respectively. Revenue consisted of the following:

	Three Months Ended June 30,	
	2016	2015
Qsymia, net product revenue	$ 12,749	$ 14,013
STENDRA/SPEDRA supply revenue	-	8,117
STENDRA/SPEDRA royalty revenue	1,027	855
Total revenue	$ 13,776	$ 22,985

Approximately 116,000 and 152,000 Qsymia prescriptions were dispensed in the quarters ended June 30, 2016 and 2015, respectively.

Total cost of goods sold was $2.6 million and $9.9 million in the quarters ended June 30, 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 $1.1 million and $2.6 million in the quarters ended June 30, 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 $13.7 million and $22.2 million for the quarters ended June 30, 2016 and 2015, respectively. Selling and marketing expense for the commercialization of Qsymia totaled $6.0 million and $15.3 million in the quarters ended June 30, 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 second quarter financial results today, August 4, 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 4946 5837. 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^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 (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. In December 2015, Auxilium notified us of its intention to return the U.S. and Canadian commercial rights for STENDRA to us, and Auxilium provided its contractually required six-month notice of termination. Given this, the supply agreement terminated on June 30, 2016, and absent an agreement to the contrary, the license agreement would have terminated on June 30, 2016. On June 30, 2016, we and Auxilium agreed to extend the termination date of the license agreement until August 31, 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.

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 (NASDAQ: VVUS) 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.

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; 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, Latin America and India; risks and uncertainties related to our ability to protect our intellectual property and litigation in which we are involved or may become involved; and risks and uncertainties related to our ability to continue to identify, acquire and develop innovative investigational drug candidates and drugs. 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, 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)

	Three Months Ended June 30,		***Six Months Ended June 30,***	
	2016	***2015***	***2016***	***2015***
Revenue:				
Net product revenue	$ 12,749	$ 14,013	$ 25,161	$ 26,641
License and milestone revenue	-	-	-	11,574
Supply revenue	-	8,117	1,526	16,595
Royalty revenue	1,027	855	2,413	341
Total revenue	13,776	22,985	29,100	55,151
Operating expenses:				
Cost of goods sold	2,647	9,870	6,351	19,766
Research and development	1,096	2,599	2,125	5,293
Selling, general and administrative	13,692	22,201	28,814	48,601
Inventory impairment and other non-recurring charges	-	29,522	-	29,522
Total operating expenses	17,435	64,192	37,290	103,182
Loss from operations	(3,659)	(41,207)	(8,190)	(48,031)
Interest expense and other expense, net	7,735	8,139	15,896	16,775
Loss before income taxes	(11,394)	(49,346)	(24,086)	(64,806)
Provision for income taxes	7	6	23	12
Net loss	$ (11,401)	$ (49,352)	$ (24,109)	$ (64,818)

Basic and diluted net loss per share	$ (0.11)	$ (0.48)	$ (0.23)	$ (0.62)
Shares used in per share computation:				
Basic and diluted	104,126	103,845	104,099	103,821

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

	June 30, 2016	***December 31, 2015****
ASSETS	***(Unaudited)***	
Current assets:		
Cash and cash equivalents	$ 82,545	$ 95,395
Available-for-sale securities	137,662	146,168
Accounts receivable, net	11,042	8,997
Inventories	10,809	13,602
Prepaid expenses and other assets	6,919	9,430
Total current assets	248,977	273,592
Property and equipment, net	792	994
Non-current assets	2,242	2,616
Total assets	$ 252,011	$ 277,202
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 8,200	$ 7,060
Accrued and other liabilities	9,032	15,891
Deferred revenue	19,472	22,142
Current portion of long-term debt	15,516	14,356
Total current liabilities	52,220	59,449
Long-term debt, net of current portion	220,848	217,034
Deferred revenue, net of current portion	7,284	6,508
Non-current accrued and other liabilities	1,103	1,296
Total liabilities	281,455	284,287
Commitments and contingencies		
Stockholders' equity:		
Common stock and additional paid-in capital	830,655	829,532
Accumulated other comprehensive (loss) income	366	(261)
Accumulated deficit	(860,465)	(836,356)
Total stockholders' deficit	(29,444)	(7,085)
Total liabilities and stockholders' deficit	$ 252,011	$ 277,202

* 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 June 30, 2016 formats.

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