VIVUS Reports 2007 Fourth Quarter and Full-Year Financial Results and Highlights

MOUNTAIN VIEW, Calif., Mar 06, 2008 (BUSINESS WIRE) -- VIVUS, Inc. (NASDAQ: VVUS), a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today announced its financial results and highlights for the fourth quarter and year ended December 31, 2007.

Fourth Quarter Results

Total revenue for the fourth quarter of 2007 was $29.8 million, as compared to $8.3 million for the fourth quarter of 2006. The increase in revenue over the fourth quarter last year was primarily due to the recognition of $20.9 million in deferred license revenue earned from the sale of Evamist to K-V Pharmaceutical Company ("K-V"). MUSE revenues in the quarter increased to $8.8 million from $8.1 million for the same period last year.

License and other revenue will be significant on a quarterly basis until all of the revenue from the sale of Evamist is recognized, currently expected to be May 2009. Since we have received the $150 million in cash from the sale of Evamist and we have no related contingencies, the recognition of license revenue and the corresponding reduction of deferred revenue related to the Evamist sale will have no impact on our cash flows from operations in future periods.

Net income for the fourth quarter of 2007 was $10.4 million or $0.17 per share on a fully-diluted basis, compared to a net loss of $801,000 or $0.02 per share for the same period last year. The net income in the fourth quarter of 2007 as compared to the net loss in the fourth quarter of 2006 is primarily due to the recognition of the K-V deferred license revenue partially offset by an increase in operating expenses in the fourth quarter of 2007 as compared to the same period in 2006. The increase in operating expenses was attributable to spending related to our Qnexa development program and higher non-cash share-based compensation expenses. For the fourth quarter of 2007, the share-based compensation expense under FAS 123R is $1.1 million as compared to $464,000 in the same period last year. This amount has been allocated to cost of goods sold and manufacturing, research and development, and selling, general and administrative expenses.

Year End Results

For 2007, total revenues were $54.7 million, compared to $17.2 million for 2006. The increase in revenues is mainly due to the recognition of the K-V deferred license revenue. MUSE revenues for 2007 increased to $19.4 million from $16.7 million in 2006. Research and development expenses in 2007 of $26.7 million increased by $13.4 million from $13.3 million last year primarily due to the commencement of the Phase 3 studies for Qnexa. Net loss for 2007 was $2.4 million, or $0.04 per share, compared to a net loss of $21.6 million or $0.45 per share for 2006. The decrease in the net loss is primarily due to the recognition of the K-V deferred license revenue, increased MUSE revenues and interest income, partially offset by an increase in research and development expenses, income taxes and non-cash share-based compensation expense as compared to 2006. For 2007, the total share-based compensation expense under FAS 123R is $3.9 million, compared to $2.1 million last year.

The company recorded a provision for income taxes of $5.1 million in 2007, which relates to the U.S. alternative minimum tax ("AMT"), tax expense as a result of excess tax benefits related to share-based compensation plans and state income taxes. The utilization of tax loss carryforwards is limited in the calculation of AMT and as a result, a federal tax charge was recorded in the year ended December 31, 2007. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of the Company's net operating loss carryforward. The tax provision reflects tax recognition of the entire $150 million in non-refundable payments we received from K-V in 2007.

VIVUS had cash, cash equivalents and available-for-sale securities of $179.5 million at December 31, 2007, as compared to $58.9 million at December 31, 2006. The increase in cash, cash equivalents and available-for-sale securities of $120.6 million consists of cash receipts of $150 million from K-V and $2.4 million from exercises of stock options, offset by the repayment of the Tanabe loan of $6.7 million, and cash used in operations and other cash uses of $25.1 million.

2007 Highlights

2007 was another significant year for VIVUS where accomplishments from 2006 were built upon. Highlights for 2007 included:

Qnexa for Obesity

--Qnexa Scientific Advisory Board (SAB) - In order to help guide the phase 3 trials, the Qnexa SAB was formed in June. The SAB consists of six leading figures in the areas of obesity, trial design, psychology and diabetes.

--Completion of end of phase 2 meeting with FDA - In June, after meeting with the FDA, the company received approval to begin phase 3 trials and apply for a Special Protocol Assessment (SPA). Prior to the start of the pivotal trials, we reached agreement with the FDA through the SPA process on design of the phase 3 studies.

--Initiation of the phase 3 studies - In the fourth quarter we initiated all of the pivotal studies. The co-primary endpoints for these studies will evaluate the differences between treatments from baseline to the end of the treatment period, in mean percent weight loss and in the percentage of subjects achieving weight loss of 5% or more. Specifically, the phase 3 studies include:

- --EQUATE (OB-301), a 28-week study, has enrolled 700 patients with Body Mass Index ("BMI") ranging from 30 to 45.
- --EQUIP (OB-302), a 56-week study, is enrolling 1,250 morbidly obese patients with BMI that equals or exceeds 35.
- --CONQUER (OB-303), a 56-week study enrolling 2,500 patients with a BMI ranging from 27 to 45 and two related co-morbidities. Patients with type 2 diabetes will be enrolled regardless of BMI.

Qnexa for Diabetes

-- Initiated an initial phase 2 study in obese patients with type 2 diabetes - In June, we began a randomized, double blind, parallel-designed, 28-week study to measure the effects of Qnexa on obese patients with type 2 diabetes mellitus. The primary endpoint of the study is glycemic control as measured by reduction in HbA1c. The study will also measure changes in various secondary endpoints such as weight loss and waist circumference. Obese patients with type 2 diabetes often respond less favorably to weight-management products and may face unique safety issues such as hypoglycemia. The phase 2 study contains specific treatment algorithms for the lowering or elimination of diabetes medications and rescue therapy for patients that experience increases in levels of HbA1c.

-- Completion of enrollment in diabetes study - In September, enrollment in OB-202 was completed. A total of 210 patients were enrolled at 10 centers in the United States. Results from this study are expected in the second quarter of 2008.

Evamist

-- Sale of commercial rights - In May, we transferred our exclusive rights and assets related to Evamist, a metered dose transdermal estradiol spray for the treatment of menopause symptoms, to K-V Pharmaceutical Company, in a transaction valued up to $180 million. Under the terms of the transaction, VIVUS received an upfront payment of $10 million upon the closing.

-- NDA approval - On July 27, 2007, the FDA approved the NDA for Evamist for the treatment of menopausal symptoms. Upon approval, the company received a $140 million payment from K-V.

Avanafil

-- Completion of the SPA process - We completed the SPA for our investigational product candidate, avanafil, an oral PDE5i for the treatment of erectile dysfunction. Under this procedure, a sponsor may seek the FDA's agreement on the design and analysis of a clinical trial intended to form the primary basis of an efficacy claim. If the FDA agrees in writing, its agreement may not be changed after the trial begins except in limited circumstances, such as the FDA determining that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the trial had begun. If the outcome of the trial is successful, the sponsor will ordinarily be able to rely on it as the basis for approval with respect to effectiveness.

While we have received the FDA's agreement on a SPA for avanafil, there can be no assurance that this trial will have a successful outcome or that we will ultimately receive approval for this product. For more information about the Agency's Special Protocol Assessment process see http://www.fda.gov/cder/guidance/3764fnl.htm.

MUSE Revenues

Worldwide product revenues from the sales of MUSE were $19.4 million in 2007, an increase of $2.7 million from $16.7 million in 2006. The increase in revenues in 2007 is mainly due to increases in both prices and shipment volume. Similar to prior years, wholesalers made purchases in the fourth quarter of 2007 that were greater than the current demand. Based on the fourth quarter demand for MUSE, we estimate purchases made by wholesalers in the fourth quarter of 2007 represent approximately 3 to 4 months of excess demand.

"I am delighted with the progress we have made in 2007," stated Leland Wilson, president and chief executive officer of VIVUS. "With the sale of Evamist to K-V Pharmaceuticals in the summer, we strengthened our balance sheet and positioned ourselves to start multiple clinical trials with our lead compound, Qnexa. These trials are already underway, including a phase 2 trial in diabetes, and we anticipate being able to share results from this trial in the second quarter of 2008."

About VIVUS

VIVUS, Inc. is a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products. The current portfolio includes investigational products addressing obesity and sexual health. The pipeline includes: Qnexa™, which is in phase 3, for the treatment of obesity and phase 2 for the treatment of type 2 diabetes; Luramist™ (Testosterone MDTS®), for which a phase 2 study has been completed for the treatment of Hypoactive Sexual Desire Disorder (HSDD); and avanafil, for which a phase 2 study has been completed for the treatment of erectile dysfunction (ED). MUSE® is approved and currently on the market for the treatment of ED. For more information on clinical trials and products, please visit the company's web site at http://www.vivus.com/.

Note to Investors

As previously announced, VIVUS will hold a conference call to discuss the third quarter financial results today, March 6, 2008, beginning at 1:30 p.m. Pacific Time. You can listen to this call by dialing 1-866-271-6130 and outside the U.S. 1-617-213-8894, and entering passcode 84938350. A 30-day archive of the call can be accessed at http://ir.vivus.com/.

A replay of the conference call will be available beginning at 3:30 p.m. PT on March 6, 2008 through 6:30 p.m. PT on March 20, 2008. Access numbers for this replay are: 1-888-286-8010 (U.S./Canada) and 1-617-801-6888 (international). The access code for the replay is 59027298.

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimated" and "intend," among others. These forward-looking statements are based on VIVUS' current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; reliance on sole source suppliers; limited sales and marketing efforts and dependence upon third parties; risks related to the development of innovative products; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical studies discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. VIVUS does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in VIVUS' Form 10-K for the year ended December 31, 2006 and periodic reports filed with the Securities and Exchange Commission.

(in thousands, except per share amounts)

	Three Months Ended		Year Ended	
	December 31, 2007	December 31, 2006	December 31, 2007	December 31, 2006
	(unaudited)	(unaudited)	(unaudited)	
Revenue:				

US product, net	$ 7,448	$ 7,332	$15,020	$ 14,280
International product	1,329	734	4,332	2,377
License and other revenue	21,046	241	35,346	588
Total revenue	29,823	8,307	54,698	17,245
Operating expenses:				
Cost of goods sold and manufacturing	3,599	3,391	12,097	11,933
Research and development	11,071	2,154	26,681	13,316
Selling, general and administrative	5,386	3,901	17,374	14,579
Total operating expenses	20,056	9,446	56,152	39,828
Income (loss) from operations	9,767	(1,139)	(1,454)	(22,583)
Interest and other income, net	1,298	340	4,165	979
Income (loss) before provision for income taxes	11,065	(799)	2,711	(21,604)
Provision for income taxes	(701)	(2)	(5,095)	(20)
Net income (loss)	$10,364	$ (801)	$(2,384)	$(21,624)
Net income (loss) per share:				
Basic	$ 0.18	$ (0.02)	$ (0.04)	$ (0.45)
Diluted	$ 0.17	$ (0.02)	$ (0.04)	$ (0.45)
Shares used in per share computation:				
Basic	58,738	52,505	58,522	48,103
Diluted	59,557	52,505	58,522	48,103

VIVUS, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except par value amount)

	December 31 2007	December 31 2006*

	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 37,838	$ 44,628
Available-for-sale securities	141,672	14,243
Accounts receivable, net	4,202	4,359
Inventories, net	2,567	3,327
Prepaid expenses and other assets	5,313	2,408
Total current assets	191,592	68,965
Property and equipment, net	7,417	8,549
Restricted cash	700	700
Total assets	$ 199,709	$ 78,214
Current liabilities:		
Accounts payable	$ 7,768	$ 2,102
Deferred revenue-short term	84,183	594
Accrued and other liabilities	9,411	8,705
Total current liabilities	101,362	11,401
Notes payable-long term	5,062	11,488
Deferred revenue-long term	33,118	2,185
Total liabilities	139,542	25,074
Commitments and contingencies		
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 58,873 at December 31, 2007; 58,144 at December 31, 2006	59	58
Additional paid-in capital	230,005	221,744
Accumulated other comprehensive loss	(68)	(11)
Accumulated deficit	(169,829)	(168,651)
Total stockholders' equity	60,167	53,140
Total liabilities and stockholders' equity	$ 199,709	$ 78,214

* The Condensed Consolidated Balance Sheet at December 31, 2006 has been derived from the Company's audited financial statements at that date.

SOURCE: VIVUS, Inc.

VIVUS, Inc.

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