



## **VIVUS Reports 2008 Fourth Quarter and Full-Year Financial Results**

### ***Significant Clinical Progress Made in Development of Qnexa to Treat Obesity and Type 2 Diabetes; Data from Two Phase 3 Trials Expected Mid-2009***

MOUNTAIN VIEW, Calif., Mar 09, 2009 (BUSINESS WIRE) -- VIVUS, Inc. (NASDAQ: VVUS), a biopharmaceutical company dedicated to the development and commercialization of novel therapeutic products, today reported its financial results for the fourth quarter and year ended December 31, 2008.

"In 2008, VIVUS made excellent progress with the clinical development of Qnexa, our novel, investigational drug in Phase 3 trials for the treatment of obesity and in Phase 2 trials for the treatment of type 2 diabetes," stated Leland Wilson, president and chief executive officer of VIVUS. "In addition, Qnexa has been well tolerated in our studies completed to date. We look forward to obtaining the results from our EQUIP and CONQUER pivotal Phase 3 trials of Qnexa mid-year, and potentially submitting a new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for Qnexa in the treatment of obesity by the end of 2009."

#### **Fourth Quarter Results**

Total revenue for the fourth quarter of 2008 was \$28.8 million, as compared to \$29.8 million for the fourth quarter of 2007. Product revenues from the sale of MUSE in the fourth quarter of 2008 were \$7.8 million as compared to \$8.8 million in the fourth quarter of 2007. The decrease in both total revenue and product revenues in the fourth quarter 2008 compared to the fourth quarter last year was primarily due to a slight decrease in both domestic and international shipments partially offset by an increase in domestic prices.

License and other revenue of \$21 million in each of the fourth quarters of 2008 and 2007 relates to the sale in 2007 of Evamist to K-V Pharmaceutical ("K-V") and will continue to 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 loss for the fourth quarter of 2008 was \$6.7 million or \$0.10 per share, compared to net income of \$10.4 million or \$0.17 per share on a fully-diluted basis for the same period last year. The net loss in the fourth quarter of 2008 as compared to the net income in the fourth quarter of 2007 was due to an increase in operating expenses of \$12.1 million and a \$4.6 million change in net interest expense. The increase in operating expenses was primarily due to an increase in research and development spending in support of Qnexa, our investigational product candidate for the treatment of obesity (currently in Phase 3 clinical studies) and the commencement of the Phase 3 clinical trials program for avanafil, our investigational product candidate for the treatment of erectile dysfunction. The change from net interest income to net interest expense was due to lower investment yields in the fourth quarter of 2008 as compared to last year including a \$2.6 million impairment non-cash loss on available-for-sale securities taken in the fourth quarter of 2008.

#### **Year End Results**

For 2008, total revenues were \$102.2 million, compared to \$54.7 million for 2007. The increase in total revenues is primarily due to the recognition of the K-V deferred license revenue. MUSE revenues for 2008 decreased by \$1.3 million to \$18.1 million from \$19.4 million in 2007. Net loss for 2008 was \$9.9 million, or \$0.16 per share, compared to a net loss of \$2.4 million or \$0.04 per share for 2007. The increase in the net loss is primarily due to an increase in operating expenses related to our phase 3 clinical trials of Qnexa for obesity. Research and development expenses in 2008 of \$77 million increased by \$50.3 million from \$26.7 million last year primarily due to the Phase 3 studies for Qnexa for obesity and the commencement of Phase 3 studies for avanafil.

#### **Cash, Cash Equivalents and Available for Sale Securities**

VIVUS had cash, cash equivalents and available-for-sale securities of \$189.2 million at December 31, 2008, as compared to \$179.5 million at December 31, 2007. The increase in cash, cash equivalents and available-for-sale securities of \$9.7 million consists of \$63.7 million in net proceeds received from a registered direct offering of our common stock and cash receipts of \$17.2 million from the previously reported Deerfield financing transactions offset by cash used in operations and other net cash

uses of \$71.2 million.

### Recent Clinical Development Highlights:

- **Obesity Program:** Qnexa Phase 3 development was initiated in 2007 in approximately 4,500 patients over three studies. EQUATE, the first of the three Phase 3 studies, evaluated 756 obese subjects at 32 sites. Top-line results reported in December 2008 showed that after 28 weeks weight loss in subjects treated with Qnexa was 9.2% with full-dose and 8.5% with mid-dose. Placebo subjects had weight loss of 1.7% ( $p < 0.001$ ). The proportion of patients losing 5% or more of their initial body weight was 66% for full-dose, 62% for mid-dose and 15% for placebo. Importantly, Qnexa was well-tolerated, with no drug-related serious adverse events.
- Results from two additional Phase 3 pivotal, one-year studies - EQUIP, evaluating 1,250 morbidly obese patients and CONQUER, evaluating 2,500 overweight and obese patients with at least two co-morbid conditions - are anticipated to be available mid-2009. The Company expects to submit a new drug application (NDA) for Qnexa with the FDA by the end of 2009.
- **Type 2 Diabetes Program:** A 56-week Phase 2 study of Qnexa for glycemic management in 130 obese type 2 diabetics demonstrated a 1.6% reduction in hemoglobin A1c (HbA1c). Subjects treated with Qnexa lost 9.4% of their baseline body weight, and also saw reductions in blood pressure, triglycerides and waist circumference. There were no drug-related serious adverse events.
- **Erectile Dysfunction Program:** VIVUS is developing its investigational drug candidate avanafil, a highly specific and selective phosphodiesterase type 5 (PDE5) inhibitor, for the treatment of erectile dysfunction (ED). Phase 2 data in 284 patients showed that patients were able to achieve erections sufficient for vaginal penetration in up to 84% of attempts. Late in 2008, VIVUS initiated the Phase 3 program for avanafil in ED. Initiated in December 2008, REVIVE is an efficacy and safety study of avanafil in men with a history of ED, with an expected enrollment of more than 600 patients at 40 sites in the U.S. Results from REVIVE are expected by the end of 2009. Initiated in February 2009, REVIVE-Diabetes is evaluating avanafil for the treatment of ED in men with diabetes; expected enrollment is approximately 375 patients at approximately 30 U.S. sites.

"We are enthusiastic about the potential role for Qnexa as not only an anti-obesity therapy, but also as a potential treatment for type 2 diabetes," added Mr. Wilson. "2009 will be an important year for VIVUS, and with a strong balance sheet, significant upcoming data events and an experienced management team, we believe we are well positioned for success."

### About VIVUS

VIVUS is a biopharmaceutical company developing innovative, next-generation therapies to address obesity, diabetes and sexual health. The company's lead product in clinical development, Qnexa(TM), is expected to complete Phase 3 clinical trials for the treatment of obesity in 2009. Qnexa is also in Phase 2 clinical development for the treatment of type 2 diabetes. In the area of sexual health, VIVUS is in Phase 3 development with avanafil, a potentially best-in-class PDE5 inhibitor, and in Phase 2 development of Luramist(TM) for the treatment of hypoactive sexual desire disorder (HSDD). For more information about the company, please visit [www.vivus.com](http://www.vivus.com).

### Note to Investors

As previously announced, VIVUS will hold a conference call to discuss the fourth quarter and year end financial results today, March 9, 2009, beginning at 1:30 p.m. Pacific Time. You can listen to this call by dialing 1-877-545-1415 and outside the U.S. 1-719-325-4858. A 30-day archive of the call can be accessed at <http://ir.vivus.com/>.

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, 2007 and periodic reports filed with the Securities and Exchange Commission.

### VIVUS, Inc.

### CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Three Months Ended		Years Ended	
	December 31, 2008	December 31, 2007	December 31, 2008	December 31, 2007*
	(unaudited)	(unaudited)	(unaudited)	
Revenue:				
US product, net	\$ 7,189	\$ 7,448	\$ 14,974	\$ 15,020
International product	565	1,329	3,076	4,332
License and other revenue	21,045	21,046	84,183	35,346
Total revenue	28,799	29,823	102,233	54,698
Operating expenses:				
Cost of goods sold and manufacturing	3,693	3,599	11,956	12,097
Research and development	22,700	11,071	76,996	26,681
Selling, general and administrative	5,805	5,386	18,904	17,374
Total operating expenses	32,198	20,056	107,856	56,152
Income (loss) from operations	(3,399 )	9,767	(5,623 )	(1,454 )
Interest (expense) income, net of other-than-temporary loss on impaired securities	(3,306 )	1,298	(4,314 )	4,165
Income (loss) before benefit (provision) for income taxes	(6,705 )	11,065	(9,937 )	2,711
Benefit (provision) for income taxes	12	(701 )	(3 )	(5,095 )
Net income (loss)	\$ (6,693 )	\$ 10,364	\$ (9,940 )	\$ (2,384 )
Net income (loss) per share:				
Basic	\$ (0.10 )	\$ 0.18	\$ (0.16 )	\$ (0.04 )
Diluted	\$ (0.10 )	\$ 0.17	\$ (0.16 )	\$ (0.04 )
Shares used in per share computation:				
Basic	69,454	58,738	63,724	58,522
Diluted	69,454	59,557	63,724	58,522

\*The Condensed Consolidated Statement of Operations at December 31, 2007 has been derived from the Company's audited financial statements at that date.

#### VIVUS, Inc.

#### CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value amount)

	December 31 2008	December 31 2007*
	(unaudited)	
Current assets:		
Cash and cash equivalents	\$ 66,121	\$ 37,838
Available-for-sale securities	121,789	141,672
Accounts receivable, net	4,157	4,202
Inventories, net	3,041	2,567
Prepaid expenses and other assets	3,744	4,893
Total current assets	198,852	191,172
Property and equipment, net	6,726	7,417
Restricted cash	700	700
Available-for-sale securities	1,344	-
Total assets	\$ 207,622	\$ 199,289
Current liabilities:		
Accounts payable	\$ 17,205	\$ 7,768
Deferred revenue	31,858	84,183
Accrued and other liabilities	14,909	8,991
Total current liabilities	63,972	100,942
Notes payable-net of current portion	11,177	5,062
Deferred revenue	1,260	33,118
Total liabilities	76,409	139,122
Commitments and contingencies		
Stockholders' equity:		

Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - 69,667 at December 31, 2008;		
58,873 at December 31, 2007	70	59
Additional paid-in capital	310,558	230,005
Accumulated other comprehensive income (loss)	354	(68 )
Accumulated deficit	(179,769 )	(169,829 )
Total stockholders' equity	131,213	60,167
Total liabilities and stockholders' equity	\$ 207,622	\$ 199,289

\*The Condensed Consolidated Balance Sheet at December 31, 2007 has been derived from the Company's audited financial statements at that date.

SOURCE: VIVUS, Inc.

**VIVUS, Inc.**

Timothy E. Morris, 650-934-5200

Chief Financial Officer

or

**Investor Relations:**

**The Trout Group**

Brian Korb, 646-378-2923

or

**Media Relations:**

**Pure Communications, Inc.**

Sheryl Seapy, 949-608-0841

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