

# VIVUS Reports Second Quarter 2006 Financial Results and Product Development Highlights

MOUNTAIN VIEW, Calif., July 27, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- VIVUS, Inc. (Nasdaq: VVUS), a pharmaceutical company dedicated to the development and commercialization of novel therapeutic products addressing obesity and sexual health, today announced its financial results and accomplishments for the second guarter of 2006.

Financial Results for the Quarter Ended June 30, 2006

Total revenue for the second quarter of 2006 was \$3.6 million, as compared to \$1.7 million for the second quarter of 2005. The increase in revenue over the second quarter last year was primarily due to increases in both domestic and international shipments of MUSE. The increase in MUSE revenues is a result of fluctuations in inventory levels at the wholesale level and is not indicative of any trend. Domestic demand for MUSE at the retail and government level remains consistent with prior periods averaging almost 200,000 units per quarter.

For the three months ended June 30, 2006, VIVUS reported a net loss of \$5.8 million, or \$0.12 per share, as compared to a net loss of \$8.7 million, or \$0.19 per share, in the second quarter of 2005. The reduction in the net loss is primarily the result of increased MUSE revenue and lower total operating expenses in three months ended June 30, 2006 compared to the same period of the prior year. Total operating expenses of \$9.7 million in the second quarter were \$900,000 lower than the second quarter of 2005, the net result of decreases in research and development spending offset by increases in both cost of goods sold and manufacturing and selling, general and administrative. Research and development spending in the second quarter of 2006 declined for the company's four clinical development programs for sexual health, partially offset by an increase in spending related to our obesity product candidate, Qnexa.

Effective January 1, 2006, VIVUS implemented the FASB revised statement No. 123 (FAS 123R) Share-Based Payment, which requires companies to expense the estimated fair value of employee stock options and similar awards. For the three months ended June 30, 2006, the stock compensation expense under FAS 123R is \$564,000. This amount has been allocated to cost of goods sold and manufacturing, research and development, and selling, general and administrative expenses, accordingly.

Financial Results for the Six Months Ended June 30, 2006

For the six-month period ending June 30, 2006, total revenues were \$4.9 million, compared to \$2.3 million for the same period in 2005. The increase in revenues is due to increased shipments of MUSE. Net loss for the six months ended June 30, 2006 was \$14.7 million, or \$0.32 per share, compared to a net loss of \$17.5 million or \$0.42 per share for the same period in 2005. The decrease in the net loss is primarily the result of increased MUSE revenues as compared to the first six months of 2005. For the six months ended June 30, 2006, the total stock compensation expense under FAS 123R is \$1.1 million, a non-cash charge.

Cash. Cash Equivalents and Available-for-Sale Securities

At June 30, 2006, VIVUS had cash, cash equivalents and available-for-sale securities of \$34.0 million, as compared to \$27.0 million at December 31, 2005. The increase in cash, cash equivalents and available-for-sale securities of \$7.0 million is the net result of the \$12.0 million in proceeds from our registered direct public offering, the \$5.4 million loan obtained from Crown Bank, N.A., the collection of amounts owed at December 31, 2005 from customers as measured by a decrease of \$6.2 million in accounts receivable offset by cash used in operations, investment and other financing activities of \$16.6 million for the first half of 2006. Exclusive of the cash received from the sale of common stock and proceeds from the loan, the decrease in cash, cash equivalents and available-for-sale securities for the first six months of 2006 was \$10.4 million.

Second Quarter 2006 Accomplishments

Highlights during the second quarter include:

-- Positive Phase 2 Clinical Trial Results with Qnexa, a Novel Therapy To Treat Obesity -- In May 2006, the company announced positive results from a Phase 2 study of Qnexa. The study, which was conducted by Duke University Medical Center, was a double-blind, randomized, placebo controlled trial. Findings from the study included:

- Over 50% of patients on Qnexa experienced 10% or more total body weight loss in 24 weeks.
- Patients on Qnexa achieved a placebo-adjusted weight loss of 20.3 pounds at week 24.
- Weight loss with Qnexa had not plateaued by 24 weeks.
- Qnexa was well tolerated. Only four patients (8%) dropped out of the Qnexa study arm for any reason, versus 19 patients (38%) on placebo.

This trial involved 200 subjects, 159 women and 41 men with an average age of 40 and a mean body mass index (BMI) of 38. (A BMI of >30.0 is classified as obese per guidelines from the U.S. Department of Health and Human Services.)

- -- Key Patent Issuance for Qnexa -- In June 2006, the U.S. Patent and Trademark Office issued the company's first patent for Qnexa. This patent, number U.S. 7,056,890 B2, broadly covers Qnexa and its use in the treatment of obesity. The term of this patent extends into 2019. Qnexa is the subject of multiple additional U.S. and foreign patent applications.
- Raising \$12 Million in Registered Direct Offering of Common Stock -- In May 2006, VIVUS entered into a purchase agreement for the sale of \$12 million of its common stock in a registered direct offering. The financing was led by new investor, OrbiMed Advisors, LLC. The company is using the proceeds from the financing to fund clinical trials, including certain studies required prior to the initiation of a Phase 3 clinical trial of Qnexa and for operating purposes.
- Positive Phase 3 Clinical Trial Results for Evamist -- The First Transdermal Spray for the Treatment of Menopausal Symptoms -- In May 2006, the company announced positive results from the pivotal Phase 3 clinical trial of Evamist. Evamist is a novel, once-a-day, transdermal spray that delivers estradiol, a naturally occurring estrogen, for the treatment of hot flashes in women. The study showed a statistically significant reduction in the number and severity of moderate and severe hot flashes. The Phase 3 trial, which was conducted at 43 clinical sites in the United States, was a 12-week, randomized, double-blind, placebo controlled study of 457 menopausal women. Evamist is a small, hand-held, simple-to-use spray that is designed to provide an easy and convenient means to deliver a preset dose of estradiol via the skin. Evamist is fast drying, non-irritating and invisible after application. Studies have shown that once administered, Evamist's formulation is not affected by washing and does not transfer to partners. Evamist is easily titratable between one, two or three sprays.
- Special Protocol Assessment (SPA) for Testosterone MDTS Submitted to the FDA -- In June 2006, the company submitted an SPA for the Phase 3 safety and efficacy study for Testosterone MDTS for the treatment of Hypoactive Sexual Desire Disorder ("HSDD").

"In the first half of 2006 we achieved some significant milestones highlighted by the clinical results for Qnexa and Evamist," commented Leland Wilson, president and chief executive officer of VIVUS. "In the second half of 2006 we look forward to filing the New Drug Application for Evamist."

## Outlook for 2006

VIVUS' 2006 goals, which provide for the continued advancement of each of our product candidates, have been updated to include milestones pertaining to Qnexa. Specific goals include:

- -- Qnexa for the treatment of obesity -- Initiate and complete toxicology and other studies required to initiate the pivotal Phase 3 studies.
- -- ALISTA (topical alprostadil) for the treatment of female sexual arousal disorder (FSAD) -- Complete Phase 2B clinical trial and announce results.
- -- Evamist for the treatment of symptoms associated with menopause -- File an NDA for Evamist in the second half of 2006.
- -- Testosterone MDTS for the treatment of HSDD -- In June 2006, the company successfully achieved its goal of defining a Phase 3 protocol design and submitting a Special Protocol Assessment (SPA) to the FDA for such trials.
- -- Avanafil for erectile dysfunction -- Complete the remaining preclinical and metabolism studies prior to advancing the compound into Phase 3. Submit an SPA for the Phase 3 trial design.

#### About VIVUS

VIVUS, Inc. is a pharmaceutical company dedicated to the development and commercialization of next-generation therapeutic products addressing obesity and sexual health. VIVUS has four products that are positioned to enter Phase 3 clinical trials, and

one product that has completed Phase 3 evaluation, for which an NDA is anticipated to be submitted to the U.S. Food and Drug Administration (FDA) in the second half of 2006. The investigational pipeline includes: Qnexa<sup>™</sup>, for which a Phase 2 study has been completed for the treatment of obesity; ALISTA<sup>™</sup>, for which a Phase 2B study is ongoing for the treatment of Female Sexual Arousal Disorder (FSAD); Testosterone MDTS®, for which a Phase 2 study has been completed for the treatment of Hypoactive Sexual Desire Disorder (HSDD); Evamist<sup>™</sup>, for which a Phase 3 study has been completed for the treatment of menopausal symptoms; avanafil, for which a Phase 2 study has been completed for the treatment of erectile dysfunction (ED); and, MUSE®, which 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 www.vivus.com.

Notes to Investors

Financial Results Conference Call:

As previously announced, VIVUS will hold a conference call to discuss the second quarter financial results today, July 27, 2006, beginning at 4:30 p.m. Eastern. You can listen to this call by dialing 877-660-0983 and entering reservation number 3182451. A live webcast and 30-day archive of the call can be accessed at www.vivus.com.

A telephone replay of the conference call will be available for 24 hours beginning July 27th at approximately 7:30 p.m. (EDT) by dialing 800-642-1687 and entering reservation number 3182451.

**Qnexa Program Update Conference Call:** 

VIVUS will hold a Qnexa question and answer conference call on Wednesday, August 16th at 10:00 a.m. Eastern. During the call, investors will have an opportunity to pose questions to:

- Dr. Kishore Gadde, Principal Investigator for the Phase 2 Qnexa study
- Dr. Thomas Najarian, Principal Scientist and Inventor of Qnexa
- VIVUS Management

You can listen to this call by dialing 877-660-0983 and entering reservation number 3584580. A live webcast and 30-day archive of the call can be accessed at www.vivus.com .

A telephone replay of the conference call will be available for 24 hours beginning August 16th at approximately 2:00 p.m. Eastern by dialing 800-642-1687 and entering reservation number 3584580.

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, 2005 and periodic reports filed with the Securities and Exchange Commission.

VIVUS, Inc. Timothy E. Morris Chief Financial Officer 650-934-5200 Vida Communication Stephanie Diaz Tim Brons 415-675-7400

VIVUS, Inc.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except per share data)

2006	2005	2006	2005		
<pre>(unaudited)(unaudited)(unaudited)</pre>					

Revenue:						
United States product, net	\$2,637	\$1,321	\$3,600	\$1,717		
International product	888	355	1,076	547		
Other revenue	115	40	231	81		
Total revenue	3,640	1,716	4,907	2,345		
Operating expenses:						
Cost of goods sold and						
manufacturing	2,895	2,049	5,915	4,139		
Research and development Selling, general and	3,301	5,661	6,861	9,926		
administrative	3,496	2,894	7,168	6,115		
Total operating expenses	9,692	10,604	19,944	20,180		
Loss from operations	(6,052)	(8,888)	(15,037)	(17,835)		
Interest and other income, net	221	246	386	369		
Loss before provision for income						
taxes	(5,831)	(8,642)	(14,651)	(17,466)		
Provision for income taxes	(6)	(8)	(12)	(21)		
Net loss	\$(5,837)	\$(8,650)	\$(14,663)	\$(17,487)		
Net loss per share:						
Basic and diluted	\$(0.12)	\$(0.19)	\$(0.32)	\$(0.42)		
Shares used in per share						
computation:  Basic and diluted	46,776	44,508	45,715	41,958		
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## VIVUS, Inc.

# CONDENSED CONSOLIDATED BALANCE SHEETS (In thousands, except par value)

	June 30 2006 (unaudited)	December 31 2005*
Current assets:		
Cash and cash equivalents	\$26,545	\$22,236
Available-for-sale securities	7,451	4,770
Accounts receivable, net	1,490	7,604
Inventories, net	4,172	4,504
Prepaid expenses and other assets	1,221	1,024
Total current assets	40,879	40,138
Property and equipment, net	8,901	9,144
Restricted cash	700	
Total assets	\$50,480	\$49,282
Current liabilities:		
Accounts payable	\$2,679	\$3,779
Accrued and other liabilities	8,917	12,790
Total current liabilities	11,596	16,569
Notes payable	11,282	5,164
Deferred revenue	2,417	948
Total liabilities	25,295	22,681
Common stock; \$.001 par value; shares authorized 200,000; shares outstanding - 48,383 at June 30, 2006 and 44,642 at		
December 31, 2005	48	45
Additional paid-in capital	186,827	173,613
Accumulated other comprehensive loss		(30)
Accumulated deficit	(161,690)	(147,027)
Total stockholders' equity	25,185	26,601
Total liabilities and stockholder's eq	quity \$50,480	\$49,282

<sup>\*</sup> The Condensed Consolidated Balance Sheet at December 31, 2005 has been derived from the Company's audited financial statements at that date.

SOURCE VIVUS, Inc.

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