VIVUS Reports 2005 Fourth Quarter and Full-Year Financial Results

Multiple Late-Stage Product Candidates Continue to Meet Key Development Milestones

MOUNTAIN VIEW, Calif., Feb. 23 /PRNewswire-FirstCall/ -- VIVUS, Inc. (Nasdaq: VVUS), a leading specialty pharmaceutical company focused on the development and commercialization of novel products to restore sexual function in women and men, today announced its accomplishments for 2005 and financial results for the fourth quarter and year ended December 31, 2005.

Fiscal Year 2005 Accomplishments

2005 was an important year for VIVUS. We achieved key clinical milestones with each program, and secured financing to advance each program. Some of the company's most significant 2005 highlights include:

First Quarter

- Completed enrollment of the avanafil Phase 2 clinical trial for the treatment of erectile dysfunction (ED) -- 298 patients were successfully enrolled in this multi-center study, the purpose of which is to evaluate the safety and efficacy of different doses of avanafil, an orally administered phosphodiesterase type 5 (PDE5) inhibitor.
- Positive Phase 2 data for Testosterone MDTS® for the treatment of Hypoactive Sexual Desire Disorder (HSDD) -- Data released during the first quarter of 2005 showed that treatment with the company's Testosterone MDTS, an investigational transdermal testosterone spray, significantly increased the number of satisfactory sexual events in pre-menopausal women with HSDD.
- Successful completion of financing raising $19.6 million -- VIVUS sold 6,250,000 shares of common stock in a public offering managed by SG Cowen & Co., LLC, with Wachovia Capital Markets, LLC acting as co- manager. The proceeds from this financing are being used to advance our clinical programs and to fund our operations.

Second Quarter

- Positive Phase 2 data for avanafil at-home study -- Results showed that up to 84 percent of avanafil doses resulted in erections sufficient for vaginal penetration, as compared to placebo ($p<0.001$). 284 patients were treated for 12 weeks with placebo or avanafil at various doses. Patients were instructed to attempt sexual intercourse 30 minutes after taking avanafil, with no restrictions on food or alcohol consumption. No serious adverse events were reported.
- Positive data from avanafil twice-daily dosing study -- The results showed no significant plasma accumulation of avanafil after the twice- a-day treatment regimen when compared to the single dose, indicating the drug was quickly removed from the blood stream.
- Positive data from avanafil nitrate interaction study -- Results of a clinical pharmacology study designed to evaluate the hemodynamic effects (blood pressure and heart rate) of glyceryl trinitrate (GTN) in subjects pretreated with placebo, avanafil, and sildenafil citrate showed that avanafil had less impact on blood pressure and heart rate than sildenafil citrate.
- Positive ALISTA™ data presented at the Annual Meeting of the American Urological Association -- ALISTA is being evaluated for the treatment of female sexual arousal disorder (FSAD). This study was the first to evaluate the use of ALISTA in pre-menopausal women in the home setting. The study showed that 64 percent of ALISTA doses resulted in satisfactory sexual events when compared to placebo, and that the use of ALISTA also resulted in significant improvement in orgasm. No serious adverse events were reported during this study.
- Positive clinical data demonstrates early MUSE® therapy following radical prostatectomy enhances penile recovery and function -- The study showed that 74 percent of patients who completed six months of MUSE treatment were able to resume sexual activity and 39 percent were able to achieve natural erections sufficient for intercourse without the use of erectogenic agents.

Third Quarter

- Completed enrollment in a pivotal Phase 3 clinical study of the investigational drug Evamist™ (Estradiol MDTS®) -- Evamist is an estradiol spray being developed for the treatment of vasomotor symptoms associated with menopause. Over 400 patients were enrolled at 43 centers throughout the United States. Results from this trial are expected in the second quarter of 2006.
- An end of Phase 2 meeting was held with the FDA regarding Testosterone MDTS for the treatment of HSDD -- Though final Phase 3 protocols have not been agreed upon, the FDA provided guidance regarding the size and duration requirements that would be necessary to support a filing for regulatory approval for the use of testosterone to treat HSDD.

Fourth Quarter

- Appointment of Wesley W. Day, Ph.D., as vice president of clinical development -- Dr. Day comes to VIVUS after more than 12 years experience with Pfizer, Inc. where he was instrumental in the creation and development of compounds designed to treat women's health issues including sexual dysfunction.
- Presentation of positive results from five key avanafil studies at the Sexual Medicine Society of North America's (SMSNA) 2005 fall meeting -- The positive study results presented addressed the following aspects of avanafil: enzyme selectivity; pharmacokinetics and pharmacology; the hemodynamic effects of co-administration of avanafil with nitrates in men; and, Phase 2 human safety and efficacy.
- Completed enrollment in Phase 2B study of ALISTA -- Over 300 women who have undergone a hysterectomy and who have been diagnosed with female sexual arousal disorder (FSAD) were enrolled at 45 centers throughout the United States. Patients are expected to complete the trial late in 2006.

"2005 was an important clinical year for VIVUS," commented Leland Wilson, president and chief executive officer of VIVUS. "During the year, we saw positive clinical results with each of our product candidates spanning multiple health indications. As we begin 2006, we are increasingly enthusiastic about the continued progress of these clinical programs, and the potential commercialization of ALISTA, Evamist, Testosterone MDTS and avanafil."

Financial Results for the Quarter Ended December 31, 2005

Total revenues for the fourth quarter of 2005 were $9.0 million compared to $10.1 million in the fourth quarter of 2004. Net loss for the fourth quarter of 2005 was $1.0 million or $0.02 per share, compared to a net loss of $887,000 or $0.02 per share for the same period last year. Decreased U.S. product revenues of $2.3 million were partially offset by increased international product revenues of $1.2 million in the fourth quarter of 2005 as compared to the fourth quarter of 2004. The decrease in U.S. product revenues is primarily due to decreased purchases made by U.S. wholesalers in advance of a price increase late in the fourth quarter of 2005 as compared to the strategic buying which took place late in the fourth quarter of 2004. The increased net loss in the fourth quarter of 2005 as compared to 2004 is attributable to the decline in product revenues partially offset by decreased expenses, mainly research and development, primarily due to the completion of the Phase 2 avanafil trial, completion of the initial formulation work for Testosterone MDTS and completion of patient enrollment in the Phase 2B trial for ALISTA.

Financial Results for the Year Ended December 31, 2005

For 2005, total revenues were $14.7 million, compared to $19.6 million for 2004. Net loss for 2005 was $24.5 million or $0.57 per share, compared to a net loss of $21.6 million or $0.57 per share, for 2004. The increase in the net loss in 2005 is primarily due to lower product revenue, as a result of decreased strategic buying in the fourth quarter of 2005 for MUSE and increased clinical activities related to the Company's four primary clinical development programs which were more than offset by $5.1 million in licensing fees included in research and development expenses in 2004.

VIVUS had cash, cash equivalents and available-for-sale securities of $27.0 million at December 31, 2005, a decrease of $2.8 million from December 31, 2004.

MUSE Performance

Worldwide product revenues from the sales of MUSE were $14.5 million in 2005, a decrease of $5.0 million from the worldwide sales of MUSE in 2004. The change in revenues is mainly due to destocking of inventory at the wholesale level that occurred prior to the fourth quarter of 2005. Demand for MUSE, as measured by independent third-party prescription data, has begun to stabilize, but is down from the demand in 2004. Similar to prior years, wholesalers made purchases in the fourth quarter of 2005 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 2005 represent approximately 4 months of excess demand. Given the stabilization of the

demand and the strategic buying in the fourth quarter of 2005 we anticipate worldwide revenues of MUSE in 2006 will remain consistent with those seen in 2005.

Outlook for 2006

In 2006, VIVUS plans to continue the advancement of each of our product candidates. Specific goals include:

- ALISTA 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 -- Complete Phase 3 clinical trial and announce results. If the results are positive we intend to file an NDA for Evamist in 2006.
- Testosterone MDTS for the treatment of HSDD -- Continue to work with the FDA to define the Phase 3 protocol design and request a Special Protocol Assessment (SPA) from the FDA for the Phase 3 trials.
- Avanafil for erectile dysfunction -- Complete the remaining Phase 2 studies required to advance the compound into Phase 3. Request a SPA for the Phase 3 trial design. Enter into a partnership to fund Phase 3 development.

"In recent years, VIVUS has made significant progress with the development of multiple promising compounds," commented Peter Tam, senior vice president of product and corporate development. "Such efforts have resulted in the broad pipeline we have today. With late-stage clinical products addressing multiple sexually-related indications, we believe VIVUS has emerged as a leader in this growing market. We look forward to continued clinical success as we bring these products closer to the market."

About VIVUS

VIVUS, Inc. is a pioneer in the research and development of proprietary products to restore sexual function for women and men. VIVUS' current product pipeline includes four investigational products in late stage clinical development. For women, VIVUS has initiated a Phase 3 program for Evamist™ for the treatment of vasomotor symptoms associated with menopause and a Phase 2B program with ALISTA™ for female sexual arousal disorder. Additionally, the company has completed Phase 2 development of Testosterone MDTS® for the treatment of hypoactive sexual desire disorder (HSDD). The MDTS system is a patented new-generation, transdermal drug delivery technology that delivers drugs directly through the skin.

For men, VIVUS has completed Phase 2 development of avanafil for erectile dysfunction. The company currently markets MUSE® (alprostadil) suppository for the treatment of erectile dysfunction in the U.S. and internationally through distributors. For more information on clinical trials and products, please visit the company's web site at www.vivus.com.

Note to Investors

As previously announced, VIVUS will hold a conference call to discuss the fourth quarter and full-year financial results today, February 23, 2006, beginning at 4:30 p.m. Eastern Time. You can listen to this call by dialing (877) 660-0983 and entering reservation number 5317282. 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 February 23rd at approximately 7:30 p.m. (EST) by dialing (800)-642-1687 and entering reservation number 5317282.

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, 2004 and periodic reports filed with the Securities and Exchange Commission.

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Tables to follow

VIVUS, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share amounts)

	Three Months Ended		Year Ended	
	December 31, 2005 (unaudited)	December 31, 2004 (unaudited)	December 31, 2005 (unaudited)	December 31, 2004
Revenue:				
US product, net	$7,442	$9,722	$11,697	$16,419
International product	1,559	364	2,794	3,030
Other revenue	41	40	163	152
Total revenue	9,042	10,126	14,654	19,601
Operating expenses:				
Cost of goods sold and manufacturing	4,402	4,045	11,018	11,283
Research and development	2,925	4,047	17,005	18,676
Selling, general and administrative	2,975	3,045	11,916	11,730
Total operating expenses	10,302	11,137	39,939	41,689
Loss from operations	(1,260)	(1,011)	(25,285)	(22,088)
Interest and other income, net	225	125	826	511
Loss before provision for income taxes	(1,035)	(886)	(24,459)	(21,577)
Provision for income taxes	(2)	(1)	(25)	(6)
Net loss	$(1,037)	$(887)	$(24,484)	$(21,583)
Net loss per share:				
Basic and diluted	$(0.02)	$(0.02)	$(0.57)	$(0.57)

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

	December 31, 2005 (unaudited)	December 31, 2004*

Current assets:		
Cash and cash equivalents	$22,236	$8,304
Available-for-sale securities	4,770	16,739
Accounts receivable	7,604	9,544
Inventories	4,504	3,855
Prepaid expenses and other assets	1,024	1,459
Total current assets	40,138	39,901
Property and equipment	9,144	6,394
Restricted cash	--	3,324
Available-for-sale securities, non-current	--	4,770
Total assets	$49,282	$54,389
Current liabilities:		
Accounts payable	$3,779	$3,120
Accrued and other liabilities	12,790	11,315
Total current liabilities	16,569	14,435
Notes payable	5,164	3,239
Accrued and other long-term liabilities	948	5,993
Total liabilities	22,681	23,667
Stockholders' equity:		
Common stock; $.001 par value; shares authorized 200,000; shares outstanding - 44,642 at December 31, 2005; 38,127 at December 31, 2004	45	38
Additional paid-in capital	173,613	153,275
Accumulated other comprehensive loss	(30)	(48)
Accumulated deficit	(147,027)	(122,543)
Total stockholders' equity	26,601	30,722
Total liabilities and stockholders' equity	$49,282	$54,389

*The Condensed Consolidated Balance Sheet at December 31, 2004 has been derived from the Company's audited financial statements at that date.

SOURCE VIVUS, Inc.
02/23/2006
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