



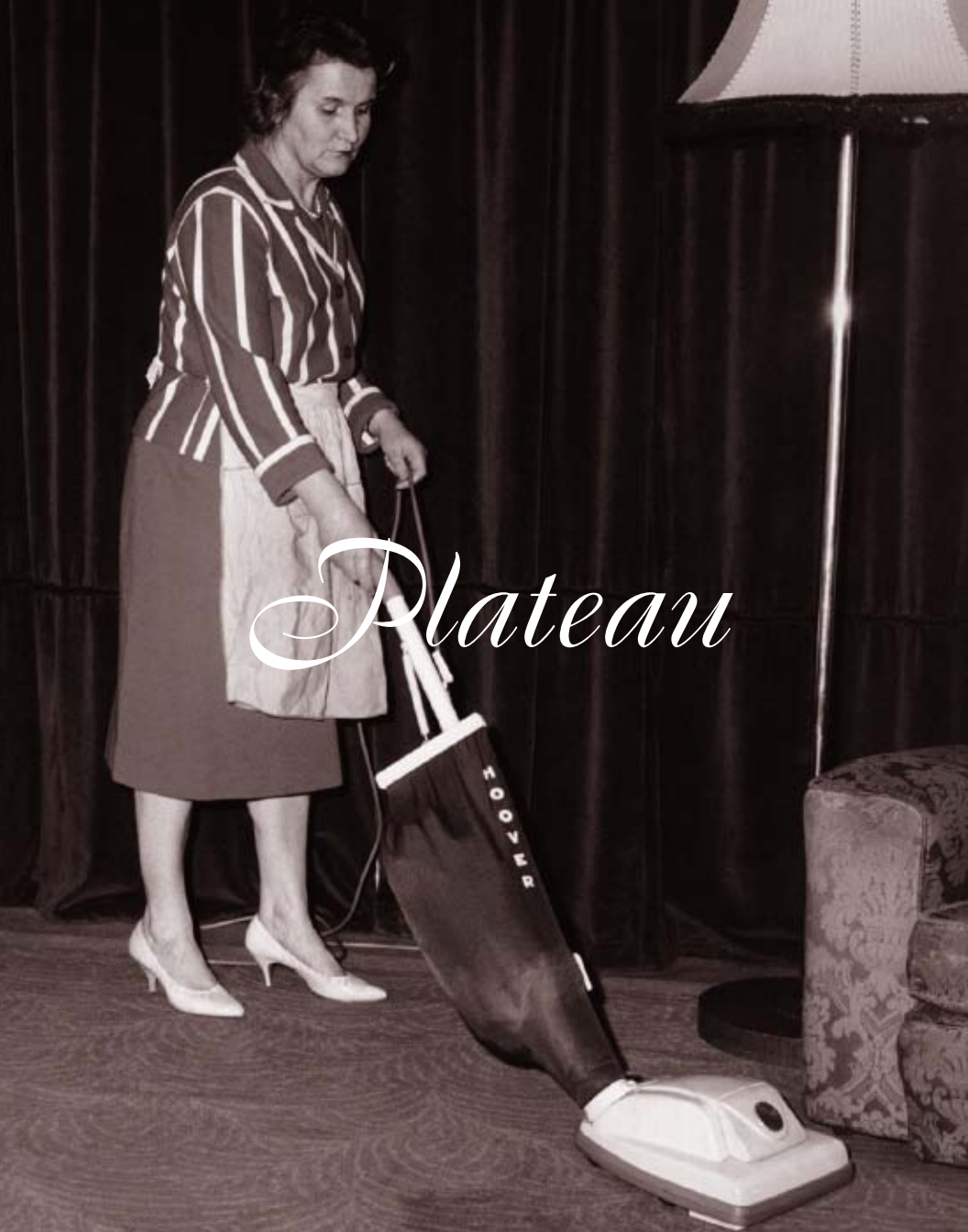
Arousal

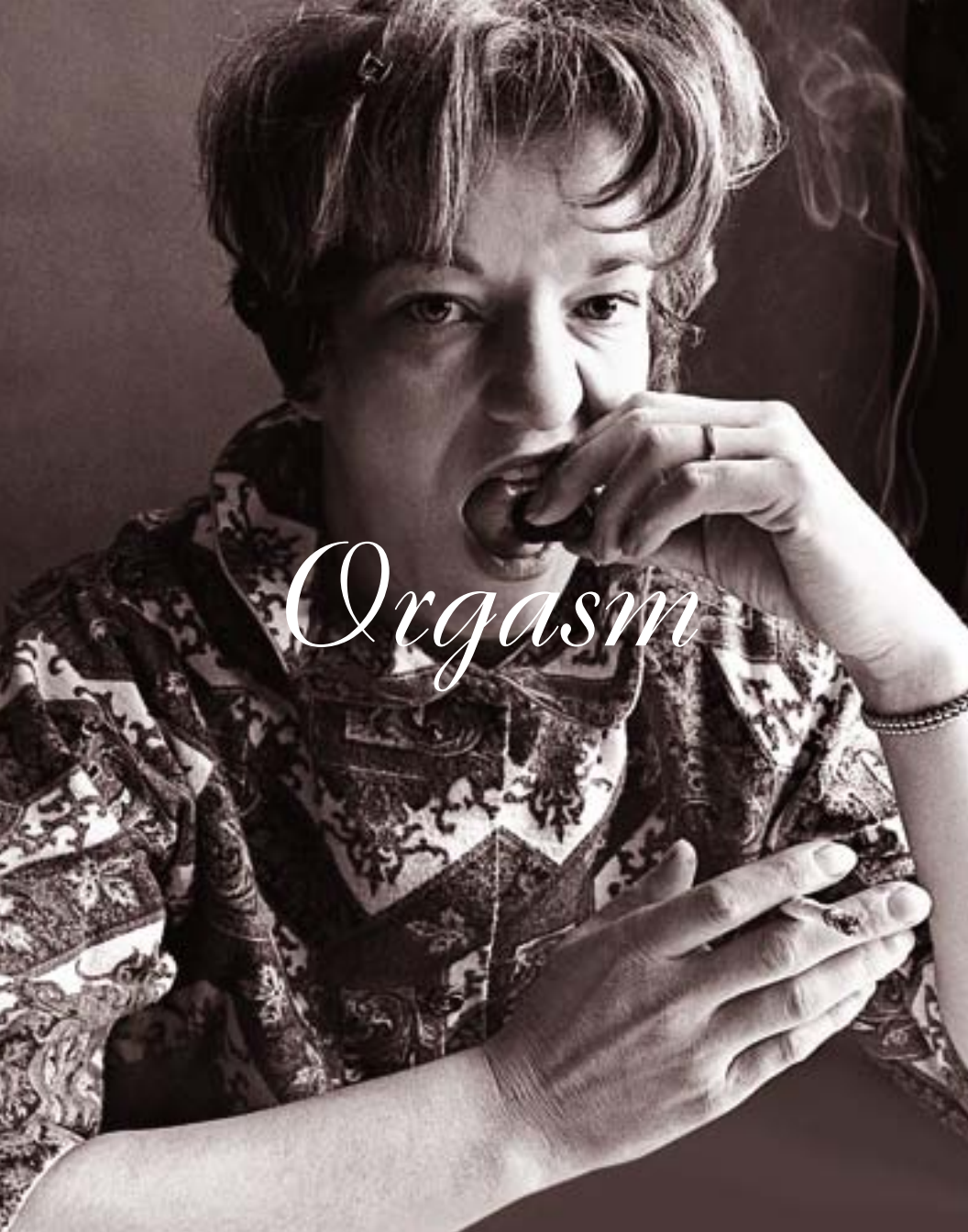
VIVUS 2004 Annual Report



Excitement

Plateau





Orgasm



Resolution

Female sexual dysfunction is divided into four distinct categories, each related to a particular phase of the sexual response cycle: desire, arousal, orgasmic and pain disorders. 43% of women identified themselves as afflicted with a sexual disorder, reporting that they most commonly experience problems affecting their arousal and desire. Research in understanding women's sexual response has lagged behind that of men. As a result, there have been major medical advances in treatment of male sexual dysfunction but not female sexual dysfunction.

VIVUS, the pioneer in its field, is engaged in developing innovative products to restore sexual function in women and men. We believe the market for the treatment of female sexual dysfunction is large and underserved. Our two products in development for female sexual dysfunction, ALISTA™ and Testosterone-MDTS®, address the disorders women are most concerned about, arousal and desire. We are also developing Evamist™ for menopausal vasomotor symptoms and avanafil for male erectile dysfunction.

Pipeline

ALISTA™ (topical alprostadil)
Female Sexual Arousal Disorder

Evamist™
Menopausal Vasomotor Symptoms

Testosterone MDTs®
Hypoactive Sexual Desire Disorder

Avanafil
Erectile Dysfunction

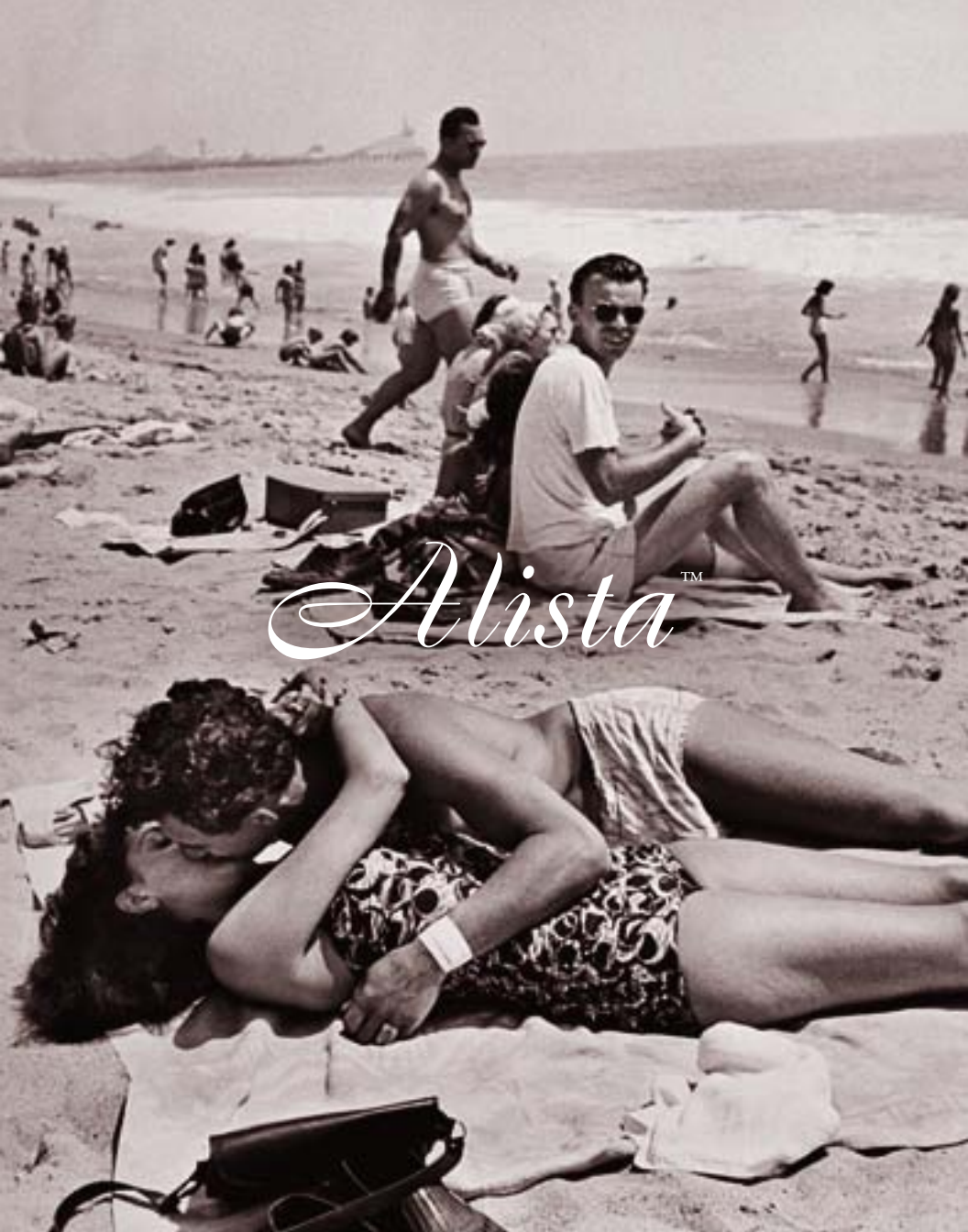
products representing major
areas of sexual dysfunction

Phase 3

Phase 3

Phase 2

Phase 2



Alista™

Indication:
Female Sexual Arousal Disorder

Female sexual arousal disorder (FSAD) is the persistent or recurrent inability to attain or maintain sufficient sexual excitement causing personal distress. Women may experience a lack of excitement, genital lubrication, swelling or other somatic responses, such as nipple sensitivity. Until recently, FSAD received little attention despite estimates that 13 million women in the United States experience symptoms.

VIVUS is in Phase 3 development with ALISTA, a topical formulation of alprostadil (prostaglandin E1), for the treatment of FSAD. Alprostadil increases blood flow to the genital tissue in women, enhancing sensitivity and sexual arousal. Three Phase 2 clinical trials of ALISTA have demonstrated statistically significant increases in arousal and/or satisfying sexual encounters in pre- and post-menopausal women.

Indication:
Menopausal Vasomotor Symptoms

Menopause begins when a woman's level of the hormone estrogen starts to fall and the menstrual cycle becomes irregular; it can also be abrupt or immediate after surgical removal of the ovaries. Approximately 1.5 million American women between the ages of 45 and 60 enter menopause each year, and about 75 percent report troublesome vasomotor symptoms of varying severity. The most common vasomotor symptoms include hot flashes and night sweats; a significant number are also affected by vaginal atrophy (thinning of the vagina).

VIVUS is in Phase 3 clinical development with Evamist, our patent protected, low-dose, topical, estrogen-only treatment for vasomotor symptoms associated with menopause. Evamist utilizes our proprietary, metered-dose transdermal spray applicator that delivers a sustained release of estradiol.



*Evamist*TM



Testosterone
MDTS®

Indication:
Hypoactive Sexual Desire Disorder

Hypoactive sexual desire disorder (HSDD) has been defined as the persistent or recurrent deficiency (or absence) of sexual fantasies, and/or desire for, or receptivity to, sexual activity, which causes personal distress. While women may have adequate lubrication and even muscle tension in the genital area, they may lack an awareness of psychological excitement. In addition, women with testosterone and/or estrogen deficiency that accompanies aging, natural menopause or the surgical removal of the ovaries may experience HSDD.

VIVUS has completed Phase 2 clinical development with Testosterone MDTs, our patent-protected, transdermal treatment for HSDD. Testosterone MDTs utilizes our proprietary, metered-dose transdermal spray that delivers a sustained release of testosterone.

Indication:
Erectile Dysfunction

Erectile dysfunction (ED), or the persistent or repeated inability for at least three months to attain or maintain an erection sufficient for satisfactory sexual performance, is reported to affect 35% of men between the ages of 40 to 70 in the United States. Erectile dysfunction can impact physical and emotional well-being, as well as the health of a relationship. The current worldwide sales of oral erectile dysfunction treatments is \$2.4 billion.

VIVUS has completed enrollment of a Phase 2 study with avanafil, a specific, highly selective phosphodiesterase type 5 (PDE5) inhibitor, as an oral medication for the treatment of erectile dysfunction. We anticipate that results from this current Phase 2 study will allow us to finalize plans for Phase 3 studies.



Avanafil

DEAR SHAREHOLDERS

VIVUS remains a leading company focused on the development and commercialization of pharmaceuticals to treat female and male sexual health. Our late stage development pipeline focused on sexual dysfunction continues to grow and make progress. In 2004 each of our development candidates advanced in the clinic. In 2005 and beyond our goal will be to continue to advance these promising development candidates in the clinic towards our ultimate goal of approval and commercialization.

Specific progress for each of the developmental candidates includes:

ALISTA, our topical, non-hormonal therapy for Female Sexual Arousal Disorder or FSAD, completed Phase 2 development in the third quarter of 2004. In July 2004 we reported results from our clinical trial in pre-menopausal women diagnosed with FSAD. This trial demonstrated that the use of ALISTA significantly increased the percentage of satisfying sexual events when compared to placebo. This was the third double-blind, randomized, placebo controlled Phase 2 study that demonstrated the use of ALISTA to successfully treat FSAD. In September 2004 we initiated a Phase 3 clinical trial of ALISTA in post-menopausal women with FSAD. We anticipate completing enrollment by the end of 2005. We estimate that approximately 13 million women in the United States have FSAD and no FDA approve treatments exists to help these women. FSAD continues to have a serious impact on women affected by the condition and we are encouraged by the clinical trial results we have seen to date.

Testosterone MDTs, our metered dose transdermal testosterone spray for the treatment of Hypoactive Sexual Desire Disorder or HSDD made excellent progress in 2004. We acquired the US rights to Testosterone MDTs in early 2004 and completed enrollment of the Phase 2 trial in premenopausal women in late 2004. This trial demonstrated that the use of testosterone MDTs resulted in a statistically significant improvement in the number of satisfying sexual events in pre-menopausal women with HSDD. As many as 22 million women in the US are affected by HSDD. This trial, as well as several other published trials, demonstrates that testosterone has been proven effective in treating this condition. We continue to refine the requirements for the final Phase 3 clinical trials and look forward to the initiation of these trials once the final protocol has been agreed upon with the FDA.

Evamist, estradiol MDTs for the treatment of menopausal symptoms, began the pivotal Phase 3 clinical trial in late 2004. We received a special protocol assessment from the FDA for the design of this trial. We anticipate that enrollment for this trial will be complete by

the end of 2005. Evamist has the potential to be the first product from the current pipeline subject to a New Drug Application. It is estimated that 1.5 million women in the United States enter menopause each year. Transdermal estradiol has been approved as therapy for vasomotor symptoms such as hot flashes associated with menopause. Evamist should offer women a proven therapy in patient preferred delivery system.

Avanafil, our orally administered PDE5 inhibitor, completed a Phase 2 head-to-head study against Viagra® in early 2004. Both products demonstrated comparable results. We were also able to secure an \$8.5 million line of credit from Tanabe Seiyaku Co., Ltd. for the development of avanafil. We recently completed enrollment in a Phase 2, double-blind, placebo-controlled, dose ranging study for avanafil. We anticipate that results from this study will be available during the second half of 2005.

Financially, we reported a net loss of \$21.6 million in 2004 and ended the year with \$29.8 million in available cash and investments. The increase in the loss over last year is due primarily to increased clinical activities related to our four primary clinical development programs, lower product revenue and decreased demand for MUSE. We expect our loss to increase in 2005 as we continue to advance our clinical development candidates towards commercialization.

By capitalizing on our clinical and regulatory expertise and experience in the field of sexual health, 2004 has been an important year for VIVUS in reaching significant clinical milestones. Our innovation, dedication and hard work have been the key to our success in the past and will continue to guide us in the future towards accomplishing our goals and building shareholder value. To our shareholders, partners, employees and customers, we thank you for your support. We look forward to sharing our progress and continued success with you during the course of the coming year.

Sincerely,



Leland F. Wilson



Virgil A. Place, M.D.

Financials

Selected Financial Data

(In thousands, except per share)

Income Statement Data:

Product revenue—United States, net
Product revenue—International
Milestone and other revenue
Total revenue

Operating expenses:

Cost of goods sold
Research and development
Selling, general and administrative
Other restructuring (income)
Total operating expenses
Income (loss) from operations
Interest and other income, net
Income (loss) before taxes
Net income (loss)

Net income (loss) per diluted share.....

Shares used in per share computation.....

Balance Sheet Data (at year end):

Working capital
Total assets
Accumulated deficit
Stockholders' equity

Year Ended December 31

	2004	2003	2002	2001	2000
.....	\$ 16,419	\$ 18,953	\$ 20,962	\$ 19,560	\$ 21,293
.....	3,030	3,302	1,237	4,041	5,200
.....	152	5,183	150	—	—
.....	19,601	27,438	22,349	23,601	26,493
.....	11,283	10,993	11,207	12,933	8,066
.....	18,676	7,724	13,281	12,324	4,670
.....	11,730	9,839	10,556	9,314	8,655
.....	—	—	—	—	(903)
.....	41,689	28,556	35,044	34,571	20,488
.....	(22,088)	(1,118)	(12,695)	(10,970)	6,005
.....	511	773	1,211	2,171	2,541
.....	\$ (21,577)	\$ (345)	\$ (11,484)	\$ (8,799)	\$ 8,546
.....	\$ (21,583)	\$ (26)	\$ (10,566)	\$ (7,070)	\$ 7,691
.....	\$ (0.57)	\$ (0.00)	\$ (0.32)	\$ (0.22)	\$ 0.23
.....	38,010	35,884	32,907	32,572	33,428
.....	\$ 25,466	\$ 30,099	\$ 18,974	\$ 14,898	\$ 32,981
.....	\$ 54,389	\$ 66,732	\$ 49,681	\$ 58,574	\$ 69,174
.....	\$ (122,543)	\$ (100,960)	\$ (100,934)	\$ (90,368)	\$ (83,298)
.....	\$ 30,722	\$ 51,235	\$ 34,385	\$ 43,975	\$ 50,187

Management’s Discussion and Analysis of Financial Conditions and Results of Operations

This Management’s Discussion and Analysis of Financial Conditions and Results of Operations and other parts of this Form 10-K contain “forward-looking” statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as “believe,” “expect,” “intend,” “anticipate,” “should,” “planned,” “estimated,” and “potential,” among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligation to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a “safe harbor” for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the clinical trial development of products not yet approved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with United States Food and Drug Administration regulations; (8) risks related to the failure to protect our intellectual property and litigation in which we may become involved; and (9) other factors that are described from time to time in our periodic filings with the Securities and Exchange Commission, including those set forth in this filing as “Risk Factors Affecting Operations and Future Results.”

All percentage amounts and ratios were calculated using the underlying data in thousands. Operating results for the year ended December 31, 2004, are not necessarily indicative of the results that may be expected for future fiscal years. The following discussion and analysis should be read in conjunction with our historical financial statements and the notes to those financial statements that are included in Item 8. of Part II of this Form 10-K.

Overview

VIVUS, Inc. is a specialty pharmaceutical company focused on the research, development and commercialization of products to restore sexual function in women and men. Our product pipeline includes four clinical stage product candidates, each of which targets an estimated existing or potential market in excess of \$1 billion annually. ALISTA, currently in Phase 3 trials, is our product candidate for the treatment of female sexual arousal disorder. Testosterone-MDTS, which recently completed a positive Phase 2 trial, is our product candidate to treat hypoactive sexual desire disorder. Evamist, currently in Phase 3 development, is our product candidate to alleviate symptoms associated with menopause. Avanafil, currently in Phase 2 trials, is our phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction.

In 1997, we launched MUSE® (alprostadil) in the United States and, together with our partners in 1998, internationally. We market MUSE as a prescription product for the treatment of erectile dysfunction. For international markets, we have entered into supply and distribution agreements with established pharmaceutical companies to market and distribute MUSE in various foreign countries. MUSE was the first minimally invasive therapy for erectile dysfunction available at a time when only more invasive therapies existed. Developing and bringing MUSE to the market provided us with experience in clinical and regulatory matters when the market for erectile dysfunction was in its infancy.

Our Product Pipeline

We currently have four research and development programs targeting female and male sexual health:

Product	Indication	Status	Patent Expiry and Number
ALISTA (topical alprostadil)	Female sexual arousal disorder (FSAD)	Phase 3 ongoing	2017 (US 5,877,216)
Testosterone-MDTS	Hypoactive sexual desire disorder (HSDD)	Phase 2 completed	2017 (US 6,818,226)
Evamist (estradiol-MDTS)	Menopausal symptoms	Phase 3 ongoing	2017 (US 6,818,226)
Avanafil (PDE5 inhibitor)	Erectile dysfunction (ED)	Phase 2 ongoing	2020 (US 6,656,935)

Our Corporate Strategy

Our goal is to become a leader in the development and commercialization of innovative proprietary products for the treatment of female and male sexual health. We intend to achieve this by:

- capitalizing on our clinical and regulatory expertise and experience in the field of sexual health to advance the development of product candidates in our pipeline;
- establishing strategic relationships with marketing partners to maximize sales potential for our products that require significant commercial support; and
- licensing complementary clinical stage products or technologies with competitive advantages from third parties for new and established markets.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to product returns, doubtful accounts, income taxes, restructuring, inventories and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Revenue Recognition: We recognize revenue when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable and collectibility is reasonably assured.

Product Returns: We record reserves for anticipated returns of expired or damaged product in the United States. We follow this method since reasonably dependable estimates of product returns can be made based on historical experience and our monitoring of inventory levels in the wholesale distribution channel. Revisions in returns estimates are charged to income in the period in which the facts that give rise to the revision become known. There is no right-of-return on product sold internationally subsequent to shipment, thus no returns reserve is needed.

Allowance for Doubtful Accounts: We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances could be required.

Income Taxes: We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. For all periods presented, we have recorded a full valuation allowance against our net deferred tax asset. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the

period such determination was made. We have also recorded income taxes payable for estimated current tax liabilities. We monitor these estimated liabilities and adjust them as conditions warrant.

Restructuring: In 1998, we experienced a significant restructuring and recorded restructuring related reserves for severance and employee costs, inventory obsolescence, raw material purchase commitments, property and related commitments, marketing commitments and other commitments. We monitor the adequacy of these liabilities and have made periodic adjustments as conditions have changed.

Inventories: We record inventory reserves for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. During the quarter ended September 30, 1998, we established significant reserves against its inventory to align with new estimates of expected future demand for MUSE. VIVUS had built up its inventory level prior to and after the launch of Viagra and had not anticipated the impact that Viagra would have on the demand for MUSE. As of December 31, 2004, the remaining inventory reserve balance is \$3.9 million. This remaining balance is related to the raw materials inventory that we previously estimated would not be used. Some portion of the fully reserved inventory was used in production in 2004, 2003 and 2002. In the fourth quarter of 2004, we stopped using this fully reserved inventory in production and determined that we would not likely use this inventory in future production. To the extent that this inventory was used in production in 2003 and 2004, it was charged to cost of goods sold at a zero basis, which had a favorable impact on cost of goods sold.

Available-for-Sale Securities: Available-for-sale securities represent investments in debt securities that are stated at fair value. We restrict our cash investments to:

- Direct obligations of the United States Treasury;
- Federal Agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate securities, including commercial paper, rated A1/P1 or better.

The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in “Accumulated Other Comprehensive (Loss) Income,” a separate component of stockholders’ equity until realized.

The Company's policy is to record investments in debt securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of debt securities are determined on a specific identification basis and are included in interest and other income in the accompanying consolidated statements of operations. Available-for-sale securities with original maturities beyond one year from the balance sheet date are classified as non-current.

Contingencies and Litigation: We are periodically involved in disputes and litigation related to a variety of matters. When it is probable that we will experience a loss, and that loss is quantifiable, we record appropriate reserves.

Results of Operations

Years Ended December 31, 2004 and 2003

For the year ended December 31, 2004, we reported a net loss of \$21.6 million, or \$0.57 net loss per share as compared to a net loss of \$26,000, or no net loss per share, during the same period in 2003. The net loss was higher in 2004 as compared to 2003 primarily due to lower product sales of MUSE in the United States and internationally and higher research and development expenses including an aggregate \$5.1 million in one time charges for licensing and milestone payments associated with three of the development programs in the pipeline, increased clinical trial and project activity for ALISTA, avanafil, estradiol and testosterone, as well as the lack of the \$5.0 million in other revenue resulting from the 2003 settlement of the Janssen Pharmaceutica arbitration claim.

We anticipate continued losses over the next several years because we expect MUSE sales to continue to decline, and we plan to continue to invest in clinical development of our current research and development product candidates to bring those potential products to market.

Revenue. Product revenue from the sales of MUSE in the United States for the year ended December 31, 2004 was \$16.4 million compared to \$19.0 million last year, a decrease of \$2.6 million. International product revenue was \$3.0 million for the year ended December 31, 2004, a decrease of \$272,000 compared to last year.

Worldwide product revenues from the sales of MUSE were \$19.4 million in 2004, a decrease of \$2.8 million, or 13%, from the worldwide sales of MUSE in 2003. The change in revenues is mainly due to decreased demand for MUSE. The launch of new PDE5 inhibitors and the associated direct-to-consumer advertising and aggressive sampling opportunities for all PDE5 inhibitors contributed to the decline in demand for MUSE. In addition, based on the current demand for MUSE, as measured by independent third party prescription data, we estimate purchases made by wholesalers

ahead of our annual price increase in the fourth quarter of 2004, represent approximately 6 to 7 months of demand. As a result of the decrease in demand and the strategic buying in the fourth quarter by our wholesalers, combined with the promotional efforts of all PDE5 inhibitors, we anticipate worldwide revenues of MUSE will decline in 2005.

Cost of goods sold. Cost of goods sold for 2004 was \$11.3 million, as compared to \$11.0 million for 2004, an increase of \$300,000. In accordance with GAAP, in 1998 we reduced the carrying cost of alprostadil, the active ingredient in MUSE, to zero due to excess quantities on hand at that time. Although the cost basis for alprostadil was reduced to zero we continued to use this active ingredient as allowed by the FDA in the production of MUSE, in 2004 and 2003. By utilizing the inventory that had previously been written down to zero, we lowered our cost of sales for 2004 and 2003 by \$844,000 and \$1.2 million, respectively. In the fourth quarter of 2004 we stopped using the alprostadil that had previously been reduced to a zero cost basis. The increase in cost of goods sold in 2004 as compared to 2003 is primarily due to use of recently purchased alprostadil that is expensed at its full cost of acquisition. We expect cost of goods sold to increase in 2005 as we are no longer using the zero cost basis alprostadil in production.

Research and development expenses. Research and development expenses for the year ended December 31, 2004 were \$18.7 million, as compared to \$7.7 million for the same period in 2003. During 2004, we entered into exclusive licensing agreements with a subsidiary of Acrux under which we will develop and commercialize, in the United States, an estradiol spray for the alleviation of the symptoms of menopause and a testosterone spray for the treatment of hypoactive sexual desire disorder in women. We expensed a total \$3.3 million of licensing fees under the terms of the agreements in 2004. A portion of these licensing fees was paid in February and September 2004, with the remainder, \$972,000, to be paid in June 2005. In addition, during the first half of 2004, we initiated a Phase 2 clinical trial with avanafil, our oral phosphodiesterase type 5 (PDE5) inhibitor being studied for the treatment of erectile dysfunction. Under the terms of our 2001 development, licensing and supply agreement with Tanabe we expensed a \$1.9 million milestone obligation to Tanabe in 2004. We intend to pay this milestone obligation in March 2006. The expenses associated with the avanafil Phase 2 clinical trials in 2004 resulted in an additional \$1.2 million expense. Increased clinical trial and project activity for ALISTA, estradiol and testosterone resulted in incremental spending for these projects of \$1.9 million during 2004. Additionally, salary, benefit and consulting expenses increased in support of our ongoing projects. We anticipate that our research and development expenditures will continue to increase in 2005 and we do not expect to recognize revenue from sales of any new product candidates being developed through our research and development efforts for several years.

Selling, general and administrative expenses. Selling, general and administrative expenses for 2004 were \$11.7 million as compared to \$9.8 million for 2003, or \$1.9 million higher than last year primarily due to an increase in spending for investor and public relations activities and marketing programs, as well as the absence of the reimbursement of previously incurred legal fees and other expenses related to the settlement of the Janssen Pharmaceutica arbitration claim in the third quarter of 2003.

Interest income and expense. Interest income for 2004 was \$622,000 as compared to \$708,000 for 2003. Declining balances of cash, cash equivalents and available-for-sale securities contributed to the reduction in interest income. Interest expense of \$143,000 in 2004 was related to the Acrux and Tanabe milestone liabilities. We did not have any interest expense in 2003.

Provision for income taxes. In 2004, we recorded a net tax provision of \$6,000 for minimum state income taxes and U.K. income taxes, both due for 2004. For the year ended December 31, 2003, we recorded a tax benefit based on an updated estimate of our tax liabilities.

Years Ended December 31, 2003 and 2002

For 2003, we reported a net loss of \$26,000, or no net loss per share as compared to a net loss of \$10.6 million or \$0.32 net loss per share for 2002. The decrease in the net loss in 2003 was due primarily to revenue recognized as the result of the resolution of our arbitration claim against Janssen Pharmaceutica in the third quarter of 2003. Reduced operating expenses also contributed to the lower loss.

Revenue. United States product revenue for 2003 was \$19.0 million, as compared to \$21.0 million for 2002. The decrease in revenue was due to a decrease in the number of MUSE units sold in 2003 versus 2002 due to declining demand.

International revenue was \$3.3 million for 2003, compared to \$1.2 million for 2002. Higher international product revenue in 2003 was due to a full year of sales to our international distribution partner, Meda. Initial shipments to Meda began in the fourth quarter of 2002.

Milestone and other revenue was \$5.2 million primarily due to \$5.0 million of other revenue resulting from the resolution of our arbitration claim against Janssen Pharmaceutica with the American Arbitration Association related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. \$3.7 million of other revenue represented amounts due from Janssen Pharmaceutica under the arbitration award. The remaining \$1.3 million resulted from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration.

Cost of Goods Sold. Cost of goods sold for 2003 was \$11.0 million, compared to \$11.2 million for the 2002. During 2003, we used certain raw material inventory of alprostadil, the cost basis of which had been reduced to zero in prior years. The use of this raw material which had a zero cost basis had a favorable impact on our cost of goods sold during 2003 of \$1.2 million. The 2002 amount includes a reduction in cost of goods sold of \$802,000 as a result of settlements of previously recognized purchase commitment liabilities for our major raw material, alprostadil.

Research and development expenses. Research and development expenses for the year ended December 31, 2003 were \$7.7 million, \$5.6 million lower than the same period in the previous year. The decrease was due to greater clinical trial activity in 2002 as compared to 2003.

Selling, general and administrative expenses. Selling, general and administrative expenses for 2003 were \$9.8 million, compared to \$10.6 million in 2002. The decrease was primarily due to the reimbursement in 2003 by Janssen Pharmaceutica of legal fees and other expenses totaling \$323,000 related to the Janssen Pharmaceutica arbitration that were previously expensed in 2002.

Interest income. Interest income for 2003 was \$708,000, as compared to \$1.3 million for 2002. Despite the increase in our investments, lower interest rates contributed to the reduction in interest income.

Benefit for income taxes. We recorded a tax benefit of \$319,000 for 2003 based on an estimate of our net tax liabilities. In 2002, we recorded a tax benefit of \$918,000 based on an estimate of our net tax liabilities as well as filing for a refund of previously paid alternative minimum taxes which became available due to a 2002 tax law change.

Liquidity and Capital Resources

Cash. Unrestricted cash, cash equivalents and available-for-sale securities totaled \$29.8 million at December 31, 2004, compared with \$48.3 million at December 31, 2003. The decrease was primarily due to decreased revenues in 2004 as well as increased research and development spending.

Since inception, we have financed operations primarily from the issuance of equity securities. Through December 31, 2004, we raised \$174.2 million from financing activities and had an accumulated deficit of \$122.5 million.

Available-for-sale securities. The Company focuses on liquidity and capital preservation in its investments in available-for-sale securities. The Company restricts its cash investments to:

- Direct obligations of the United States Treasury;
- Federal Agency securities which carry the direct or implied guarantee of the United States government; and
- Corporate securities, including commercial paper, rated A1/P1 or better.

The Company sequences the maturities of its investments consistent with its cash forecasts. The weighted average maturity of the portfolio is not to exceed 18 months. As investments mature, the Company re-invests the money by purchasing additional securities. As the Company needs cash for its operating expenses, it sells such investment securities. Because the Company sequences maturities consistent with its cash forecasts, realized gains and losses on the sales of securities are typically insignificant.

Accounts receivable. Accounts receivable (net of allowance for doubtful accounts) at December 31, 2004 was \$9.5 million, as compared to \$2.6 million at December 31, 2003. The increase in the accounts receivable balance at December 31, 2004 is due to 38% of the 2004 sales occurring in the month of December. Currently, the Company does not have any significant concerns related to accounts receivable or collections. As of February 25, 2005, we had collected all of the December 31, 2004 accounts receivable.

Liabilities. Total liabilities were \$23.7 million at December 31 2004, \$8.2 million higher than at December 31, 2003. Accrued research and clinical expenses and accrued licensing fees increased \$3.6 million due to liabilities for the future payment of milestones totaling \$2.8 million to Acrux and Tanabe and to increased liabilities for clinical trial expense in 2004. Notes payable increased \$3.2 million due to borrowing under the agreement we signed with Tanabe in the first quarter of 2004 for a line of credit of up to \$8.5 million to be used for the development of avanafil, and accrued chargeback reserves increased \$1.0 million due to the increase in December 2004 sales of MUSE as compared to December 2003.

Operating Activities. Our operating activities used \$22.7 million of cash during 2004 and provided \$1.9 million of cash in 2003. The cash used in 2004, can be attributed to our net operating loss of \$21.6 million, an increase in our accounts receivable balance of \$7.0 million offset by a \$3.6 million increase in accrued research and development expenses, non-cash depreciation expense of \$1.9 million, and a \$1.0 million increase in accrued chargeback reserves. The cash provided by operations in 2003 was due to a \$2.0 million decrease in our accounts receivable balance and \$2.1 million of non-cash depreciation expenses included in our \$26,000 net loss, offset by an increase in our inventories due to the purchase of \$2.1 million of alprostadil.

Investing Activities. Net cash provided by investing activities was \$13.5 million in 2004 as compared to the use of \$18.1 million in 2003, respectively. The fluctuations from period to period are due primarily to the timing of purchases, sales and maturity of investment securities.

Financing Activities. Financing activities provided cash of \$4.4 million and \$17.1 million during 2004 and 2003, respectively. These amounts include the proceeds from the exercise of stock options in 2004 and 2003, borrowings from Tanabe during 2004 and the private placement of 4,375,000 shares of common stock for aggregate net proceeds of \$16.4 million in 2003.

We anticipate that our existing capital resources combined with anticipated future cash flows will be sufficient to support our operating needs for at least the next two years. However, we anticipate that we will be required to obtain additional financing to fund the development of our research and development pipeline in future periods as well as to support the possible launch of any future products. In particular, we expect to make other substantial payments to Acrux and Tanabe in accordance with our agreements with them in connection with the licensing of certain compounds. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales.

In the first quarter of 2004, we signed an agreement for a secured line of credit with Tanabe, allowing us to borrow up to \$ 8.5 million to be used for the development of avanafil (formerly TA-1790), our erectile dysfunction compound currently in Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing has a 48-month term and bears interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. As of December 31, 2004 we had long-term notes payable to Tanabe of \$3.2 million, and \$5.3 million of available credit under this agreement.

On December 21, 2004, we filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission (SEC) which allows us to offer and sell up to an aggregate of \$50 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering. On February 22, 2005, we filed a prospectus supplement with the Securities and Exchange Commission relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf registration statement and supplement thereto. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of \$3.40 per share providing us with net proceeds of \$19.6 million. We also granted the underwriters a 30-day option to purchase up to an additional 937,500 shares to cover over-allotments.

To obtain additional capital when needed, we will evaluate alternative financing sources, including, but not limited to, the issuance of equity or debt securities, corporate alliances, assets sales, joint ventures and licensing agreements. However, there can be no assurance that funding will be available on favorable terms, if at all. If we are unable to obtain additional capital, management may be required to explore alternatives to reduce cash used by operating activities, including the termination of research and development efforts that may appear to be promising to us, the sale of certain assets and the reduction in overall operating activities. Our future capital requirements will depend upon numerous factors, including:

- the progress of our research and development programs;
- the scope, timing and results of pre-clinical testing and clinical trials;
- patient recruitment and enrollment in current and future clinical trials;
- results of operations;
- the cost, timing and outcome of regulatory reviews;
- the rate of technological advances;
- ongoing determinations of the potential commercial success of our products under development;
- the level of resources devoted to sales and marketing capabilities; and
- the activities of competitors.

Future Accounting Requirements

In December 2004, the Financial Accounting Standards Board (FASB) issued revised statement No. 123 (FAS 123R) which requires companies to expense the estimated fair value of employee stock options and similar awards. The accounting provisions of FAS 123R will be effective for the third quarter of fiscal 2005. We will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123. We are in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on our consolidated financial statements.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. This Statement is meant to eliminate any differences existing between the FASB standards and the standards issued by the International Accounting Standards Board by clarifying that any abnormal idle facility expense, freight, handling costs and spoilage be recognized as current-period charges. This Statement is required to be adopted by VIVUS, Inc. in the first quarter of 2006; however, early application is permitted. VIVUS, Inc. does not expect the adoption of this Statement to have a material impact on results of operations, financial position or cash flows as we currently do expense a portion of our manufacturing overhead as period cost due to excess capacity.

Overview of Contractual Obligations

Contractual Obligations	Payments Due by Period (in thousands)				
	Total	Less than 1 year	1–3 years	3–5 years	More than 5 years
Operating Leases ⁽¹⁾	\$ 2,793	\$ 1,318	\$ 1,475	\$ —	\$ —
Purchases ⁽²⁾	4,590	1,530	3,060	—	—
Notes Payable ⁽³⁾	3,239	—	3,239	—	—
Other Long Term Liabilities ⁽⁴⁾	6,293	300	2,350	325	3,318
Total	\$ 16,915	\$ 3,148	\$ 10,124	\$ 325	\$ 3,318

- (1) We lease our manufacturing facilities in Lakewood, New Jersey under a non-cancelable operating lease expiring in 2007 and have the option to extend this lease for one additional renewal term of five years. In January 2000, we entered into a seven-year lease for our corporate headquarters in Mountain View, California, which expires in January 2007.
- (2) In November 2002, we entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. In 2003 we purchased \$2.1 million of product and in 2004 we purchased \$762,000 of product. We are committed to purchase a minimum total of \$3.1 million of product from 2005 through 2008.
In January 2004, we entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. As of December 31, 2004, we have purchased \$475,000 of product from this supplier. We will be required to purchase a minimum total of \$1.8 million of product from 2005 through 2006.
- (3) In the first quarter of 2004, we signed an agreement for a secured line of credit with Tanabe, allowing us to borrow up to \$8.5 million to be used for the development of avanafil (formerly TA-1790), our erectile dysfunction compound currently in Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing will have a 48-month

term and will bear interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. As of December 31, 2004 we have \$5.3 million of available credit under this agreement.

- (4) Other Long Term Liabilities includes the restoration liability of \$3.0 million for our leased manufacturing facilities. This liability will remain in effect through the end of the lease term, including any renewals. We have exercised our first option to renew the original lease, thereby extending any cash payments to be made relating to this liability out to 2007. The second renewal term, if exercised, would then extend the liability out an additional five years, to 2012. We initially recorded \$1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda AB in September 2002. This amount is being recognized as income ratably over the term of the supply agreement. Through December 31, 2004, \$1,000,000 of long-term revenue remains deferred under this agreement. We will recognize \$150,000 of revenue under this agreement in 2005.

During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil. Under the terms of our 2001 development, licensing and supply agreement with Tanabe we accrued an expense of \$1.9 million for a milestone obligation to Tanabe during 2004. We intend to pay the entire milestone obligation, with a future value of \$2.0 million, in March 2006.

Off-Balance Sheet Financing and Related Party Transactions

VIVUS has not entered into any off-balance sheet financing arrangements and has not established any special purpose entities. VIVUS has not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets. The only transaction between VIVUS and a related party during 2004 was Mario M. Rosati, one of our directors, who is also a member of Wilson Sonsini Goodrich & Rosati, Professional Corporation, which has served as our outside corporate counsel since our formation and has received compensation at normal commercial rates for these services.

Dividend Policy

The Company has not paid any dividends since its inception and does not intend to declare or pay any dividends on its common stock in the foreseeable future. Declaration or payment of future dividends, if any, will be at the discretion of the Company's Board of Directors after taking into account various factors, including the Company's financial condition, operating results and current and anticipated cash needs.

Quantitative and Qualitative Disclosures about Market Risk

The Securities and Exchange Commission's rule related to market risk disclosure requires that we describe and quantify our potential losses from market risk sensitive instruments attributable to reasonably possible market changes. Market risk sensitive instruments include all financial or commodity instruments and other financial instruments that are sensitive to future changes in interest rates, currency exchange rates, commodity prices or other market factors. VIVUS is not exposed to market risks from changes in foreign currency exchange rates or commodity prices. We do not hold derivative financial instruments nor do we hold securities for trading or speculative purposes. At December 31, 2004, we had drawn \$3.2 million of the \$8.5 million secured line of credit with Tanabe. Each quarterly borrowing will have a 48-month term and will bear interest at the annual rate of 2%. We, however, are exposed to changes in interest rates on our investments in cash equivalents and available-for-sale securities. A significant portion of all of our investments in cash equivalents and available-for-sale securities are in money market funds that hold short-term investment grade commercial paper, treasury bills or other United States government obligations. Currently, this reduces our exposure to long-term interest rate changes.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of VIVUS, Inc.:

We have audited the accompanying consolidated balance sheets of VIVUS, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations and other comprehensive (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004. In connection with our audits of the consolidated financial statements, we also have audited financial statement schedule II. These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. Our audit included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of VIVUS, Inc. and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of VIVUS, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2005 expressed an unqualified opinion on management's unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/KPMG LLP
San Francisco, California
March 15, 2005

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of VIVUS, Inc.:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that VIVUS, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). VIVUS, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that VIVUS, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, VIVUS, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of VIVUS, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations and other comprehensive (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 15, 2005 expressed an unqualified opinion on those consolidated financial statements.

/s/KPMG LLP

San Francisco, California

March 15, 2005

Consolidated Balance Sheets

(In thousands, except par value)

	December 31	
	2004	2003
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,304	\$ 13,097
Available-for-sale securities	16,739	21,488
Accounts receivable (net of allowance for doubtful accounts of \$104 and \$68 at December 31, 2004 and 2003, respectively)	9,544	2,623
Inventories, net	3,855	3,109
Prepaid expenses and other assets	1,459	1,108
Total current assets	39,901	41,425
Property and equipment, net	6,394	8,220
Restricted cash	3,324	3,324
Available-for-sale securities, non-current	4,770	13,763
Total assets	\$ 54,389	\$ 66,732
Liabilities And Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,120	\$ 2,917
Product returns	2,848	2,932
Accrued research and clinical expenses	2,164	458
Accrued chargeback reserve	1,989	1,035
Accrued employee compensation and benefits	1,442	1,249
Income taxes payable	1,214	1,216
Accrued royalties	764	629
Accrued and other liabilities	894	890
Total current liabilities	14,435	11,326
Notes payable	3,239	—
Accrued restructuring reserve	3,021	3,021
Deferred revenue	1,110	1,150
Accrued licensing fees	1,862	—
Total liabilities	23,667	15,497
Stockholders' equity:		
Preferred stock; \$1.00 par value; shares authorized— 5,000 at December 31, 2004 and 2003; shares issued and outstanding—0 at December 31, 2004 and 2003	—	—
Common stock; \$.001 par value; shares authorized— 200,000 at December 31, 2004 and 2003; shares issued and outstanding—38,127 at December 31, 2004 and 37,788 at December 31, 2003	38	38
Additional paid-in capital	153,275	152,093
Accumulated other comprehensive income (loss)	(48)	64
Accumulated deficit	(122,543)	(100,960)
Total stockholders' equity	30,722	51,235
Total liabilities and stockholders' equity	\$ 54,389	\$ 66,732

See accompanying notes to consolidated financial statements.

Consolidated Statements of Operations And Other Comprehensive (Loss)

(In thousands, except per share data)

	Year Ended December 31		
	2004	2003	2002
Revenue:			
United States product, net	\$ 16,419	\$ 18,953	\$ 20,962
International product	3,030	3,302	1,237
Milestone and other revenue	152	5,183	150
Total revenue	19,601	27,438	22,349
Operating expenses:			
Cost of goods sold	11,283	10,993	11,207
Research and development	18,676	7,724	13,281
Selling, general and administrative	11,730	9,839	10,556
Total operating expenses	41,689	28,556	35,044
Loss from operations	(22,088)	(1,118)	(12,695)
Interest and other income:			
Interest income	622	708	1,312
Gain (loss) on disposal of property and equipment	(7)	26	(134)
Foreign exchange gain	39	39	33
Interest expense	(143)	—	—
Loss before benefit for income taxes	(21,577)	(345)	(11,484)
Benefit (provision) for income taxes	(6)	319	918
Net loss	\$ (21,583)	\$ (26)	\$ (10,566)
Other comprehensive loss:			
Unrealized loss on securities, net of taxes	(112)	(217)	(41)
Comprehensive loss	\$ (21,695)	\$ (243)	\$ (10,607)
Net loss per share:			
Basic and diluted	\$ (0.57)	\$ (0.00)	\$ (0.32)
Shares used in per share computation:			
Basic and diluted	38,010	35,884	32,907

See accompanying notes to consolidated financial statements.

Consolidated Statements of Stockholders' Equity

(In thousands)

Balances, December 31, 2001
Sale of common stock through employee stock purchase plan
Exercise of common stock options for cash
Stock compensation costs
Change in unrealized gain on securities, net of taxes
Net loss
Balances, December 31, 2002
Sale of common stock through employee stock purchase plan
Exercise of common stock options for cash
Stock compensation costs
Proceeds from private placement of common stock
Issue costs for private placement of common stock
Change in unrealized gain on securities, net of taxes
Net loss
Balances, December 31, 2003
Sale of common stock through employee stock purchase plan
Exercise of common stock options for cash
Stock compensation costs
Change in unrealized gain on securities, net of taxes
Net loss
Balances, December 31, 2004

See accompanying notes to consolidated financial statements.

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount				
.....	32,693	\$ 33	\$ 133,988	\$ 322	\$ (90,368)	\$ 43,975
.....	106	—	289	—	—	289
.....	200	—	624	—	—	624
.....	—	—	104	—	—	104
.....	—	—	—	(41)	—	(41)
.....	—	—	—	—	(10,566)	(10,566)
.....	32,999	33	135,005	281	(100,934)	34,385
.....	108	—	325	—	—	325
.....	306	—	312	—	—	312
.....	—	—	39	—	—	39
.....	4,375	5	17,500	—	—	17,505
.....	—	—	(1,088)	—	—	(1,088)
.....	—	—	—	(217)	—	(217)
.....	—	—	—	—	(26)	(26)
.....	37,788	38	152,093	64	(100,960)	51,235
.....	84	—	283	—	—	283
.....	255	—	859	—	—	859
.....	—	—	40	—	—	40
.....	—	—	—	(112)	—	(112)
.....	—	—	—	—	(21,583)	(21,583)
.....	38,127	\$ 38	\$ 153,275	\$ (48)	\$ (122,543)	\$ 30,722

Consolidated Statements of Cash Flows

(In thousands)

Cash flows from operating activities:

Net loss
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:	
Provision for doubtful accounts
Depreciation
Stock compensation costs
(Gain) loss on disposal of property and equipment
Changes in assets and liabilities:	
Accounts receivable
Inventories
Prepaid expenses and other assets
Accounts payable
Accrued research and clinical expenses
Accrued chargeback reserve
Accrued employee compensation and benefits
Accrued and other liabilities
Net cash provided by (used for) operating activities

Cash flows from investing activities:

Property and equipment purchases
Proceeds from sale of property and equipment
Investment purchases
Proceeds from sale/maturity of securities
Net cash provided by (used for) investing activities

Cash flows from financing activities:

Sale of common stock through employee stock purchase plan
Borrowing under note agreements
Exercise of common stock options
Proceeds of issuance of common stock
Common stock issuance costs
Net cash provided by financing activities

Net increase (decrease) in cash and cash equivalents

Cash and cash equivalents:

Beginning of year
End of year

Non-cash investing and financing activities:

Unrealized loss on securities
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Supplemental cash flow disclosure:

Income taxes paid (received)
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See accompanying notes to consolidated financial statements.

Year Ended December 31

	2004	2003	2002
.....	\$ (21,583)	\$ (26)	\$ (10,566)
.....	36	(77)	(87)
.....	1,936	2,074	2,288
.....	40	39	104
.....	7	(26)	134
.....	(6,957)	1,955	(1,766)
.....	(746)	(1,751)	1,742
.....	(351)	389	(717)
.....	203	1,051	625
.....	1,706	(905)	245
.....	954	126	575
.....	193	120	(356)
.....	1,875	(1,100)	183
.....	<u>(22,687)</u>	<u>1,869</u>	<u>(7,596)</u>
.....	(118)	(225)	(169)
.....	1	41	41
.....	(20,451)	(42,798)	(10,567)
.....	<u>34,081</u>	<u>24,860</u>	<u>18,129</u>
.....	<u>13,513</u>	<u>(18,122)</u>	<u>7,434</u>
.....	283	325	289
.....	3,239	—	—
.....	859	312	624
.....	—	17,500	—
.....	—	(1,083)	—
.....	<u>4,381</u>	<u>17,054</u>	<u>913</u>
.....	(4,793)	801	751
.....	13,097	12,296	11,545
.....	<u>\$ 8,304</u>	<u>\$ 13,097</u>	<u>\$ 12,296</u>
.....	\$ (112)	\$ (217)	\$ (41)
.....	\$ 13	\$ (494)	\$ (6)

Notes To Consolidated Financial Statements

Note 1. Business and Significant Accounting Policies

Business

VIVUS, Inc. is a specialty pharmaceutical company, incorporated in 1991, focused on the research, development and commercialization of products to restore sexual function in women and men. The Company's product pipeline includes four clinical stage product candidates. ALISTA, currently in Phase 3 trials, is a product candidate for the treatment of female sexual arousal disorder. Testosterone-MDTS, which recently completed a positive Phase 2 trial, is a product candidate to treat hypoactive sexual desire disorder. Evamist, currently in Phase 3 development, is a product candidate to alleviate symptoms associated with menopause. Avanafil, currently in Phase 2 trials, is a phosphodiesterase type 5, or PDE5, inhibitor product candidate for the treatment of erectile dysfunction. The Company also markets MUSE (alprostadil), a transurethral applicator used for treating erectile dysfunction, in the United States and internationally through distribution partners.

At December 31, 2004, the Company's accumulated deficit was approximately \$122.5 million. Based on current plans, management expects to incur further losses for the foreseeable future. Management believes that the Company's cash, cash equivalents, and short-term investments at December 31, 2004, will be sufficient to meet the Company's obligations through at least the end of 2006. Until the Company can generate sufficient levels of cash from its operations, the Company expects to continue to finance future cash needs primarily through proceeds from equity or debt financing, loans and collaborative agreements with corporate partners.

The Company primarily sells its products through wholesale channels in the United States. International sales are made only to the Company's international distributors. All transactions are denominated in United States dollars and the Company operates in a single segment reporting to the chief executive officer, based on the criteria of Statement of Financial Accounting Standards, or SFAS, No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

Significant Accounting Policies

Principles of Consolidation: The consolidated financial statements include the accounts of VIVUS, Inc., VIVUS International Limited, a wholly owned subsidiary, and VIVUS Ireland Limited, VIVUS U.K. Limited and VIVUS B.V. Limited, wholly owned subsidiaries of VIVUS International Limited. All significant inter-company transactions and balances have been eliminated in consolidation. On February 20, 2004, VIVUS Ireland was officially dissolved.

Use of Estimates: The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents: The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents.

Available-for-Sale Securities: Available-for-sale securities represent investments in debt securities that are stated at fair value. The difference between amortized cost (cost adjusted for amortization of premiums and accretion of discounts which are recognized as adjustments to interest income) and fair value, representing unrealized holding gains or losses, are recorded in Accumulated Other Comprehensive (Loss) Income, a separate component of stockholders' equity until realized. The change in unrealized (losses) gains on investments included in accumulated other comprehensive loss for 2004, 2003 and 2002, in thousands, are \$112, \$217, and \$41, respectively.

The Company's policy is to record investments in debt securities as available-for-sale because the sale of such securities may be required prior to maturity. Any gains and losses on the sale of debt securities are determined on a specific identification basis and are included in interest and other income in the accompanying consolidated statements of operations and other comprehensive (loss). Available-for-sale securities with original maturities beyond one year from the balance sheet date are classified as non-current.

Inventories: Inventories are stated at the lower of cost (first-in, first-out basis) or market and consist of raw materials, work in process and finished goods. Cost includes material and conversion costs.

During the quarter ended September 30, 1998, the Company established significant reserves against its inventory to align with new estimates of expected future demand for MUSE. The Company had built up its inventory level prior to and after the launch of Viagra and had not anticipated the impact that Viagra would have on the demand for MUSE. The Company had anticipated sales to ultimately increase as a result of an expanding market for impotence products. Given the decline in demand for MUSE, in 1998 the Company recorded reserves of \$16.0 million related to excess raw materials and future inventory purchase commitments for raw materials.

As of December 31, 2004, the remaining inventory reserve balance is \$3.9 million. This remaining balance is related to the raw materials inventory that the Company previously estimated would not be used.

Some portion of the fully reserved inventory has been used in production. In 2004, 2003 and 2002, the Company used \$844,000, \$1.2 million and \$163,000 of its fully reserved raw materials inventory. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.

Prepaid Expenses and Other Assets: Prepaid expenses and other assets generally consist of deposits and prepayments for future services. Prepayments are expensed when the services are received.

Property and Equipment: Property and equipment is stated at cost and includes machinery and equipment, computers and software, furniture and fixtures and building improvements. For financial reporting, depreciation is computed using the straight-line method over estimated useful lives of two to seven years. Leasehold improvements are amortized using the straight-line method over the lesser of the estimated useful lives or remaining lease term, which may include option renewal periods if the Company determines that it is likely that the renewal options will be exercised. Expenditures for repairs and maintenance, which do not extend the useful life of the property and equipment, are expensed as incurred. Upon retirement, the asset cost and related accumulated depreciation are relieved from the accompanying consolidated financial statements. Gains and losses associated with dispositions or impairment of equipment, and leasehold improvements are reflected as a component of other income, net in the accompanying consolidated statements of operations and other comprehensive (loss).

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, long-lived assets, such as property, plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to an estimate of undiscounted future cash flows expected to be generated by the asset. If the carrying amount of the asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposed group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet.

Restricted Cash: The Company issued an irrevocable standby letter of credit for \$3.3 million during the fourth quarter of 2000, in connection with its leased manufacturing facilities. The Company purchased a certificate of deposit as collateral for this letter of credit, which is restricted and not available for use in operations, and is presented accordingly as restricted cash in the non-current asset section of the accompanying consolidated balance sheets. This restriction will remain through the end of the lease term, including any renewals. The Company has exercised its first option to renew the original lease, thereby extending its commitment to 2007. The second renewal term, if exercised, would then extend the lease for an additional five years, to 2012.

Revenue Recognition: The Company recognizes revenue when the following four criteria are met:

- persuasive evidence of an arrangement exists;
- delivery has occurred;
- the sales price is fixed or determinable; and
- collectibility is reasonably assured.

The Company recognizes revenue upon shipment when title passes to the customer and risk of loss is transferred to the customer. The Company does not have any post shipment obligations.

United States: The Company primarily sells its products through the wholesale channel in the United States. The Company provides for discounts, rebates, returns and other adjustments in the same period the related product sales are recorded. Provisions for discounts, rebates, returns and other adjustments are based upon analysis of historical data. Each period the Company reviews its reserves for discounts, rebates, returns and other adjustments based on data available at that time. Any adjustment to these reserves results in changes to the amount of product sales revenue recognized in the period.

International: The Company has supply agreements with Meda AB to market and distribute MUSE internationally in some Member States of the European Union. In Canada, we have entered into a license and supply agreement with Paladin Labs, Inc. for the marketing and distribution of MUSE. Sales to our distribution partner, who supplies MUSE in the European marketplace, for 2004, 2003 and 2002 were 96.7%, 92.1%, and 81.4% of international sales, respectively. The balance of international sales was made to our Canadian distribution partner.

The Company invoices its international distributors based on an agreed transfer price per unit, which is subject to revision based on contractual formulas upon quarterly reconciliations. Final pricing for product shipments to international distributors is subject

to contractual formulas based on the distributor's net realized price to its customers. The Company recognizes revenue at the lowest possible price, upon shipment, in accordance with contractual formulas. The Company recognizes additional revenue, if any, upon finalization of pricing with its international distributors. International distributors generally do not have the right to return products unless the products are damaged or defective.

The Company initially recorded \$1.5 million of unearned revenue related to an upfront payment in accordance with the international supply agreement signed with Meda AB in September 2002. This amount is being recognized as income ratably over the term of the supply agreement. Through December 31, 2004, \$350,000 has been recognized as revenue.

In 2003, we recorded other revenue of \$5.0 million due to the resolution of the Company's arbitration claim against Janssen Pharmaceutica with the American Arbitration Association related to payments owing to VIVUS under a previously terminated distribution agreement between the companies. \$3.7 million represents amounts received from Janssen Pharmaceutica under the arbitration award. The remaining \$1.3 million results from recognizing Janssen Pharmaceutica related revenue that was previously deferred pending the outcome of the arbitration.

In November 2004, the Company recorded \$123,000 of unearned revenue related to an upfront licensing payment in accordance with an amendment to its international supply and distribution agreement with Paladin Labs, Inc. This amount is being recognized as income ratably over the term of the supply and distribution agreement. Through December 31, 2004, \$2,000 has been recognized as revenue.

Stock Option Plans: The Company applies the intrinsic-value-based method of accounting prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations including Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25*, issued in March 2000, to account for its fixed-plan stock options. Under this method, compensation expense is recorded on the date of the grant only if the current market price of the underlying stock exceeded the exercise price. SFAS No. 123, *Accounting for Stock Based Compensation*, established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic-value-based method of accounting described above, and has adopted only the disclosure requirements of SFAS No. 123. The following table illustrates the effect on the net loss if the fair-value-based method has been applied to all outstanding and unvested awards in each period.

(In thousands, except per share data)	2004	2003	2002
Net (loss), as reported	\$ (21,583)	\$ (26)	\$ (10,566)
Deduct total stock-based employee compensation expense determined under fair-value-based method for all rewards, net of tax	(1,970)	(1,763)	(1,820)
Pro forma net (loss)	<u>\$ (23,553)</u>	<u>\$ (1,789)</u>	<u>\$ (12,386)</u>
Pro forma net (loss) per share:			
Basic and diluted	\$ (0.62)	\$ (0.05)	\$ (0.38)

The weighted-average fair value of options granted in 2004, 2003 and 2002 was \$3.17, \$2.63 and \$5.64, respectively.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used for grants in 2004, 2003 and 2002: no dividend yield, expected volatility of 64%, 66% and 75%, respectively, risk-free interest rates of between 2% to 4%, 1% to 4% and 2% to 6%, respectively and an expected life of 5 years for all years.

Effective February 28, 2005, the vesting of the 359,682 outstanding stock options granted on January 21, 2002, of which 82,479 were unvested options, was accelerated to that date. The options were originally scheduled to vest during the period from January 2002 to January 2012. On the accelerated vesting date, the per share market value of VIVUS stock of \$3.98 was less than the strike price of the options, which was \$8.08 per share.

Income Taxes: Income taxes are accounted for under the asset and liability method. The realization of deferred tax assets and liabilities is based on historical tax positions and expectations about future taxable income. Deferred income tax assets and liabilities are computed for differences between the financial statement carrying amount and tax basis of assets and liabilities based on enacted tax laws and rates applicable to the period in which differences are expected to be recovered or settled. Valuation allowances are established, when necessary, to reduce deferred tax assets to amounts that are more likely than not to be realized.

License Agreements: The Company has obtained rights to patented technologies under several licensing agreements. Non-refundable licensing payments made on technologies that are yet to be proven are expensed to research and development. Royalties paid associated with existing products are expensed to cost of goods sold when the liability is generated upon sale of product. We incurred royalty expense of \$952,000 in 2004 and \$950,000 in 2003.

Net (Loss) Income Per Share: Basic (loss) earnings per share, or EPS, is computed using the weighted average number of common shares outstanding during the periods. Diluted EPS is based on the weighted average number of common and common equivalent shares, which represent shares that may be issued in the future upon the exercise of outstanding stock options under the treasury stock method. The computation of basic and diluted EPS for the years ended December 31, 2004, 2003 and 2002 are as follows:

(In thousands, except per share data)	2004	2003	2002
Net (loss)	\$ (21,583)	\$ (26)	\$ (10,566)
Net (loss) per share—basic	\$ (.57)	\$ (.00)	\$ (.32)
Effect of dilutive securities (stock options)	—	—	—
Net (loss) per share—diluted	\$ (.57)	\$ (.00)	\$ (.32)
Shares used in the computation of net (loss) per share—basic	38,010	35,884	32,907
Effect of dilutive securities (stock options)	—	—	—
Diluted shares	38,010	35,884	32,907

Potentially dilutive options outstanding of 696,815, 481,437 and 1,153,276 at December 31, 2004, 2003 and 2002, respectively, are excluded from the computation of diluted EPS for 2004, 2003 and 2002 because the effect would have been antidilutive.

Future Accounting Requirements: In December 2004, 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. The accounting provisions of FAS 123R will be effective for the third quarter of fiscal 2005.

The Company will adopt the provisions of FAS 123R using a modified prospective application. Under modified prospective application, FAS 123R, which provides certain changes to the method for valuing stock-based compensation among other changes, will apply to new awards and to awards that are outstanding on the effective date and are subsequently modified or cancelled. Further compensation expense for outstanding awards for which the requisite service had not been rendered as of the effective date will be recognized over the remaining service period using the compensation cost calculated for pro forma disclosure purposes under FAS 123 (Note 1). The Company is in the process of determining how the new method of valuing stock-based compensation as prescribed in FAS 123R will be applied to valuing stock-based awards granted after the effective date and the impact the recognition of compensation expense related to such awards will have on its consolidated financial statements.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, an amendment of ARB No. 43, Chapter 4*. This Statement is meant to eliminate any differences existing between the FASB standards and the standards issued by the International Accounting Standards Board by clarifying that any abnormal idle facility expense, freight, handling costs and spoilage be recognized as current-period charges. This Statement is required to be adopted by VIVUS, Inc. in the first quarter of 2006; however, early application is permitted. VIVUS, Inc. does not expect the adoption of this Statement to have a material impact on results of operations, financial position or cash flows.

Reclassifications: Certain reclassifications have been made to the Company's 2003 and 2002 consolidated financial statements to conform to the current period presentations.

Note 2. Available-for-Sale Securities

The fair value and the amortized cost of available-for-sale securities at December 31, 2004 and 2003 are presented in the tables that follow. Fair values are based on quoted market prices obtained from an independent broker. For each category of investment securities, the table presents gross unrealized holding gains and losses.

As of December 31, 2004 (in thousands):	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
United States government securities	\$ 16,646	\$ 16,600	\$ 0	\$ (46)
Corporate debt	4,911	4,909	0	(2)
Total	21,557	21,509	0	(48)
Amount classified as short-term	(16,756)	(16,739)	0	17
Amount classified as long-term	\$ 4,801	\$ 4,770	\$ 0	\$ (31)

As of December 31, 2003 (in thousands):	Amortized Cost	Fair Market Value	Unrealized Holding Gains	Unrealized Holding Losses
United States government securities	\$ 25,520	\$ 25,587	\$ 68	\$ (1)
Corporate debt	9,667	9,664	4	(7)
Total	35,187	35,251	72	(8)
Amount classified as short-term	(21,428)	(21,488)	(68)	8
Amount classified as long-term	\$ 13,759	\$ 13,763	\$ 4	\$ (0)

Maturity dates for long-term investments range from April 2006 through May 2006.

Note 3. Inventories

Inventories are recorded net of reserves of \$3.9 million and \$5.6 million as of December 31, 2004 and 2003, respectively, and consist of (in thousands):

	2004	2003
Raw materials	\$ 3,260	\$ 2,370
Work in process.	22	81
Finished goods	573	658
Inventory, net	<u>\$ 3,855</u>	<u>\$ 3,109</u>

Inventory balances at December 31, 2004 were \$3.8 million as compared to \$3.1 million at December 31, 2003. The increase is attributable to increased purchases of alprostadiol, the active ingredient in MUSE.

As noted above, the Company has recorded significant reserves against the carrying value of its inventory of raw material. The reserves relate primarily to raw materials inventory that the Company previously estimated would not be used. Some portion of the fully reserved inventory has been used in production. In 2004, 2003 and 2002, the Company used \$844,000, \$1.2 million and \$163,000 of its fully reserved raw materials inventory, respectively. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.

Note 4. Property and Equipment

Property and equipment as of December 31, 2004 and 2003, respectively, consist of (in thousands):

	2004	2003
Machinery and equipment	\$ 18,160	\$ 18,168
Computers and software	2,504	2,523
Furniture and fixtures	1,254	1,251
Building improvements	11,947	11,941
	<u>33,865</u>	<u>33,883</u>
Accumulated depreciation	(27,471)	(25,663)
Property and equipment, net.	<u>\$ 6,394</u>	<u>\$ 8,220</u>

For the years ended December 31, 2004, 2003 and 2002, depreciation expense was \$1,936, \$2,074 and \$2,288, respectively.

Note 5. Notes Payable

In the first quarter of 2004, the Company signed an agreement for a secured line of credit with Tanabe Holding America, Inc., a subsidiary of Tanabe Seiyaku Co., Ltd., or Tanabe, allowing it to borrow up to \$8.5 million to be used for the development of avanafil (formerly TA-1790), an erectile dysfunction compound currently in Phase 2 clinical trials. The secured line of credit may be drawn upon quarterly and each quarterly borrowing has a 48-month term and bears interest at the annual rate of 2%. There are no financial covenants associated with this secured line of credit. As of December 31, 2004 we had long-term notes payable to Tanabe of \$3.2 million, and \$5.3 million of available credit under this agreement. All the assets of the Company serve as collateral for this line of credit.

The amount of each quarterly borrowing and its due date are (in thousands):

Date of Note	Amount of Note	Due Date
March 31, 2004	\$ 315	March 31, 2008
June 30, 2004	883	June 30, 2008
September 30, 2004	1,007	September 30, 2008
December 31, 2004	1,034	December 31, 2008
Total	<u>\$ 3,239</u>	

Note 6. Restructuring and Related Charges

In 1998, the Company restructured its operations and recorded related costs and write-downs in accordance with Emerging Issues Task Force, or EITF, 94-3. The property write-downs were calculated in accordance with the provisions of SFAS No. 121 and represent the excess of the carrying value of property and equipment, primarily the Company's New Jersey manufacturing leaseholds and equipment, over the projected future discounted cash flows for the Company.

Restructuring reserve and related balances at December 31, 2004 were \$3.0 million. There was no change in the restructuring and related reserves accounts in 2004 and 2003.

The remaining balance in the restructuring reserve is related to the restoration liability for our leased manufacturing facilities. This liability will remain in effect through the end of the lease term, including any renewals. The Company has exercised its first option to renew the original lease, thereby extending any cash payments to be made relating to this liability out to 2007. The second renewal term, if exercised, would then extend the liability out an additional five years, to 2012.

Note 7. Stockholders' Equity

Common Stock

The Company is authorized to issue 200 million shares of common stock. As of December 31, 2004 and 2003, there were 38,126,962 and 37,788,365 shares, respectively, issued and outstanding.

Preferred Stock

The Company is authorized to issue 5 million shares of undesignated preferred stock with a par value of \$1.00 per share. As of December 31, 2004 and 2003, there are no preferred shares issued or outstanding. The Company may issue shares of preferred stock in the future, without stockholder approval, upon such terms as the Company's management and Board of Directors may determine.

Note 8. Stock Option and Purchase Plans

Stock Option Plan

Under the 2001 Stock Option Plan, or the 2001 Plan, which was approved by the stockholders at the annual meeting held on June 5, 2002, the Company may grant incentive or non-statutory stock options or stock purchase rights, or SPRs. The maximum aggregate number of shares that may be optioned and sold under the 2001 Plan is 1,000,000 shares plus (a) any shares that have been reserved but not issued under the Company's 1991 Incentive Stock Option Plan, or the 1991 Plan; (b) any shares returned to the 1991 Plan as a result of termination of options or repurchase of shares issued under the 1991 Plan; and (c) an annual increase to be added on the first day of the Company's fiscal year beginning 2003, equal to the lesser of (i) 1,000,000 shares, (ii) 2.5% of the outstanding shares on such date, or (iii) a lesser amount determined by the Board. The 2001 Plan allows the Company to grant incentive stock options to employees at not less than 100% of the fair market value of the stock (110% of fair market value for individuals who control more than 10% of the Company stock) at the date of grant, as determined by the Board of Directors. The 2001 Plan allows the Company to grant non-statutory stock options to employees, directors and consultants at a price to be determined by the Board of Directors. The term of the option is determined by the Board of Directors on the date of grant but shall not be longer than ten years. The 2001 Plan allows the Company to grant SPRs to employees and consultants. Sales of stock under SPRs are made pursuant to restricted stock purchase agreements containing provisions established by the Board of Directors. The Company has a right, but not the obligation, to repurchase the shares at the original sale price, which expires at a rate to be determined by the Board of Directors. As of December 31, 2004, no SPRs have been granted under the 2001 Plan.

Under the 2001 Plan, non-employee directors will receive an option to purchase 32,000 shares of common stock when they join the Board of Directors. These options vest 25% after one year and 25% annually thereafter. Each non-employee director shall automatically receive an option to purchase 8,000 shares of the Company's common stock annually upon their reelection and these options are fully exercisable ratably over eight months. Non-employee directors are also eligible to receive additional stock option grants.

Details of option activity under these plans are as follows:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2001	3,445,899	\$ 3.63
Granted	503,645	7.59
Exercised	(200,240)	3.12
Cancelled	(77,429)	5.03
Outstanding, December 31, 2002	3,671,875	\$ 4.16
Granted	642,526	4.04
Exercised	(306,631)	1.02
Cancelled	(31,344)	4.95
Outstanding, December 31, 2003	3,976,426	\$ 4.38
Granted	868,126	4.82
Exercised	(251,212)	3.41
Cancelled	(478,555)	4.14
Outstanding, December 31, 2004	4,114,785	\$ 4.56

Options Outstanding		Options Exercisable			
Range of Exercise Prices	Number Outstanding at December 31, 2004	Weighted- Average Remaining Contractual Life	Weighted- Average Exercise Price	Number Exercisable December 31, 2004	Weighted- Average Exercise Price
\$2.00 – \$4.00	1,854,653	5.1 years	\$ 3.38	1,592,992	\$ 3.28
\$4.03 – \$5.23	1,387,090	5.9 years	\$ 4.57	841,954	\$ 4.57
\$5.67 – \$8.08	873,042	6.1 years	\$ 7.04	566,502	\$ 7.35
\$2.00 – \$8.08	<u>4,114,785</u>	5.5 years	\$ 4.56	<u>3,001,448</u>	\$ 4.41

At December 31, 2004, 2,532,198 options remain available for grant.

During 2004, an option to purchase 15,000 shares of common stock was granted to a research consultant. The fair value of the option was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility of 46%, risk-free interest rate of 3.02% and an expected life of 10 years.

During 2003, an option to purchase 15,000 shares of common stock was granted to a research consultant. The fair value of the option was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility of 72%, risk-free interest rate of 2.93% and an expected life of 10 years.

During 2002, an option to purchase 15,000 shares of common stock was granted to a research consultant. The fair value of the option was estimated on the date of grant using the Black-Scholes option-pricing model with the following assumptions: no dividend yield, expected volatility of 86%, risk-free interest rate of 3.84% and an expected life of 10 years.

As permitted under SFAS No. 123, the Company accounts for these plans under APB Opinion No. 25. Except for compensation expense recognized for options granted to research consultants as discussed above, no compensation cost has been recognized because the exercise price equaled the market value of stock on the date of grant. Options under these plans generally vest over four years, and all options expire after ten years.

Stock Purchase Plan

Under the 1994 Employee Stock Purchase Plan, or the Stock Purchase Plan, the Company reserved 800,000 shares of common stock for issuance to employees pursuant to the Stock Purchase Plan, under which eligible employees may authorize payroll deductions of up to 10% of their base compensation (as defined) to purchase common stock at a price equal to 85% of the lower of the fair market value as of the beginning or the end of the offering period.

At the annual meeting held on June 4, 2003, the stockholders approved amendments to the Stock Purchase Plan to (i) extend the original term of the Stock Purchase Plan by an additional 10 years such that the Stock Purchase Plan will now expire in April 2014 (subject to earlier termination as described in the Stock Purchase Plan) and (ii) increase the number of shares of Common Stock reserved for issuance under the Stock Purchase Plan by 600,000 shares to a new total of 1,400,000 (collectively referred to herein as the 1994 Purchase Plan Amendments).

As of December 31, 2004, 800,549 shares have been issued to employees and there are 599,451 available for issuance under the Stock Purchase Plan. During 2004, the weighted average fair market value of shares issued under the Stock Purchase Plan was \$3.90 per share.

Note 9. License Agreements

During the first quarter of 2004, we initiated a Phase 2 clinical trial with avanafil, our oral PDE5 inhibitor being studied for the treatment of erectile dysfunction. Under the terms of our 2001 development agreement, we accrued a \$1.9 million milestone obligation to Tanabe for the year ended December 31, 2004. We intend to pay this milestone obligation, with a future value of \$2.0 million, in March 2006. We expect to make other substantial payments to Tanabe in accordance with our agreements with them. These payments are based on certain development, regulatory and sales milestones. In addition, we are required to make royalty payments on any future product sales.

In February 2004, the Company entered into exclusive licensing agreements with Acrux Limited and a subsidiary of Acrux under which it has agreed to develop and commercialize testosterone-MDTS and Evamist in the United States for various female health applications. Under the terms of the agreements, VIVUS agreed to pay to Acrux combined licensing fees of \$3.0 million over the 17 month period beginning in February 2004, up to \$4.3 million for the achievement of certain clinical development milestones, up to \$6.0 million for achieving product approval milestones, and royalties on net sales in the United States upon commercialization of each product. The Company expensed a total \$3.3 million of licensing fees under the terms of the agreements in 2004. A portion of these licensing fees was paid in February and September 2004, with the remainder, \$972,000, to be paid in June 2005.

The Company has entered into several agreements to license patented technologies that are essential to the development and production of the Company's transurethral products for the treatment of ED. These agreements generally required milestone payments during the development period. In connection with these agreements, the Company is obligated to pay royalties on product sales covered by the license agreements (4% of United States and Canadian product sales and 3% of sales elsewhere in the world). In 2004, 2003 and 2002, the Company recorded royalty expenses, in thousands, of \$949, \$952, and \$978, respectively, as cost of goods sold based on product sales.

Note 10. Commitments

The Company leases its manufacturing facilities in Lakewood, New Jersey under a non-cancelable operating lease expiring in 2007 and has the option to extend this lease for one additional renewal term of five years. In January 2000, the Company entered into a seven-year lease for its corporate headquarters in Mountain View, California, which expires in January 2007.

Future minimum lease payments under operating leases are as follows (in thousands):

2005	\$ 1,318
2006	1,359
2007	116
	<u>\$ 2,793</u>

Rent expense, in thousands, under operating leases totaled \$1,486, \$1,252, and \$1,342 for the years ended December 31, 2004, 2003, and 2002, respectively.

In November 2002, the Company entered into a manufacturing agreement to purchase raw materials from a supplier beginning in 2003 and ending in 2008. In 2004, the Company purchased \$762,000 of product. The Company is committed to purchase a minimum total of \$3.1 million of product from 2005 through 2008.

In January 2004, the Company entered into a manufacturing agreement to purchase raw materials from an additional supplier beginning in 2004 and ending in 2006. As of December 31, 2004, the Company had purchased \$475,000 of product from this supplier and will be required to purchase a minimum total of \$1.8 million of product from 2005 through 2006.

Note 11. Income Taxes

Deferred income taxes result from differences in the recognition of expenses for tax and financial reporting purposes, as well as operating loss and tax credit carry forwards. Significant components of the Company's deferred income tax assets as of December 31 are as follows (in thousands):

	2004	2003
Deferred tax assets:		
Net operating loss carry forwards	\$ 26,718	\$ 21,164
Research and development credit carry forwards	6,033	5,955
Inventory reserve	1,528	2,166
Accruals and other	5,853	4,048
Depreciation	1,979	706
	<u>42,111</u>	<u>34,039</u>
Valuation allowance	(42,111)	(34,039)
Total	<u>\$ —</u>	<u>\$ —</u>

For federal and California income tax reporting purposes, respective net operating loss, or NOL, carry forwards of approximately \$74.9 million and \$8.4 million are available to reduce further taxable income, if any. For federal and California income tax reporting purposes, respective credit carry forwards of approximately \$4.1 million and \$2.9 million are available to reduce future taxable income, if any. The carry forwards, except for the California research and development credit, expire on various dates through 2024. The California research and development credits do not expire. The Internal Revenue Code of 1986, as amended, contains provisions that may limit the net operating loss and credit carry forwards available for use in any given period upon the occurrence of certain events, including a significant change in ownership interest.

A valuation allowance has been recorded for the entire deferred tax asset as a result of uncertainties regarding the realization of the asset balance due to the history of losses and the variability of operating results. The net change in the valuation allowance from December 31, 2003 to December 31, 2004 was \$8.1 million. As of December 31, 2004 and 2003, the Company had no significant deferred tax liabilities.

The (benefit)/provision for income taxes attributable to continuing operations is based upon (loss)/income before (benefit)/provision for income taxes as follows, for the years ended December 31, 2004, 2003 and 2002 (in thousands):

	2004	2003	2002
Loss before income taxes:			
Domestic	\$ (20,388)	\$ (2,188)	\$ (6,386)
International	(1,189)	1,843	(5,098)
Total	<u>\$ (21,577)</u>	<u>\$ (345)</u>	<u>\$ (11,484)</u>

The (benefit)/provision for income taxes consists of the following components for the years ended December 31, 2004, 2003 and 2002 (in thousands):

	2004	2003	2002
Current			
Federal	\$ —	\$ (311)	\$ (842)
State	2	(14)	(85)
Foreign	4	6	9
Total (benefit)/provision for income taxes ..	<u>\$ 6</u>	<u>\$ (319)</u>	<u>\$ (918)</u>

The (benefit)/provision for income taxes differs from the amount computed by applying the statutory federal income tax rates as follows, for the years ended December 31, 2004, 2003 and 2002:

	2004	2003	2002
(Benefit) provision computed at federal statutory rates	(35)%	(35)%	(35)%
State income taxes, net of federal tax effect ...	(4)	(4)	(3)
Change in valuation allowance	38	39	30
Refund of taxes	—	(2)	(5)
Adjustment of income tax payable	—	(90)	(3)
Tax credits	1	—	(5)
Loss/(income) not subject to federal and state taxation	—	—	17
Other	—	—	(4)
(Benefit)/provision for income taxes	<u>0%</u>	<u>(92)%</u>	<u>(8)%</u>

The 2003 tax benefit was based on updated estimate of net tax liabilities. The 2002 tax benefit relates primarily to a filing for a refund of previously paid alternative minimum taxes which became available due to a 2002 tax law change, as well as an updated estimate of net tax liabilities.

Note 12. Concentration of Customers and Suppliers

Sales to significant customers as a percentage of total revenues are as follows:

	2004	2003	2002
Customer A	46%	23%	17%
Customer B	27%	21%	30%
Customer C	0%	18%	17%
Customer D	12%	16%	20%
Customer E	12%	11%	0%

Accounts receivable by significant customer as a percentage of the total gross accounts receivable balance are as follows:

	2004	2003
Customer A	51%	45%
Customer B	36%	18%
Customer C	0%	15%
Customer D	4%	15%

Customer C merged with Customer A in 2004. The Company did not have any suppliers making up more than 10% of operating costs.

Note 13. 401(k) Plan

All of the Company’s employees are eligible to participate in the VIVUS 401(k) Plan. Employer-matching contributions for the years ended December 31, 2004, 2003 and 2002, in thousands were \$261, \$241, and \$246, respectively. The employer-matching portion of the 401(k) plan began on July 1, 2000.

Note 14. Legal Matters

In the normal course of business, the Company receives and makes inquiries regarding patent infringement and other legal matters. The Company believes that it has meritorious claims and defenses and intends to pursue any such matters vigorously. The Company is not aware of any asserted or unasserted claims against it where an unfavorable resolution would have an adverse material impact on the operations or financial position of the Company.

Note 15. Subsequent Events (Unaudited)

On January 7, 2005, the Securities and Exchange Commission (SEC) declared effective the shelf Registration Statement the Company filed on Form S-3 on December 21, 2004. The shelf Registration Statement (File Number 333-12159) allows the Company to offer and sell up to an aggregate of \$50 million of common stock from time to time in one or more offerings. The terms of any such future offering would be established at the time of such offering.

On February 22, 2005, the Company filed a prospectus supplement with the Securities and Exchange Commission relating to an underwritten public offering of 7,500,000 shares of common stock under the existing shelf Registration Statement (File Number 333-12159) and supplement thereto. On March 15, 2005, we sold 6,250,000 shares of our common stock at a price of \$3.40 per share providing us with net proceeds of \$19.6 million. We also granted the underwriters a 30-day option to purchase up to an additional 937,500 shares to cover over-allotments.

Effective February 28, 2005, the vesting of the 359,682 outstanding stock options granted on January 21, 2002, of which 82,479 were unvested options, was accelerated. The options were originally scheduled to vest during the period from January 2002 to January 2012. On the accelerated vesting date, the per share market value of VIVUS stock of \$3.98 was less than the strike price of the options, which was \$8.08 per share. When considering this action, the Compensation Committee took into account that accelerating the vesting of these out-of-the money options prior to June 30, 2005, when the Company currently expects to adopt SFAS 123R, will further reduce the amount of compensation expense that the Company will be required to record in 2005 and beyond as a result of the previously granted equity incentive awards. In addition, by accelerating these options before the implementation of SFAS 123R the expenses associated with the implementation of SFAS 123R will be lower in future periods. The acceleration of these out-of-the money options will not cause any additional compensation expense in 2005. Under SFAS 123R the compensation expense associated with these out-of-the-money options would have been significant.

Note 16. Selected Financial Data (Unaudited)

Selected Quarterly Financial Data (in thousands)

	Quarter Ended,			
	March 31	June 30	September 30	December 31
2004				
Total revenue	\$ 1,942	\$ 3,202	\$ 4,331	\$ 10,126
Net loss	\$ (10,899)	\$ (4,880)	\$ (4,917)	\$ (887)
Net loss per share:				
Basic and diluted	\$ (0.29)	\$ (0.13)	\$ (0.13)	\$ (0.02)
2003				
Total revenue	\$ 4,269	\$ 3,648	\$ 10,530	\$ 8,991
Net income (loss)	\$ (3,191)	\$ (2,925)	\$ 3,873	\$ 2,217
Net income (loss) per share:				
Basic and diluted	\$ (0.10)	\$ (0.08)	\$ 0.10	\$ 0.08

Schedule II - Valuation and Qualifying Accounts

(in thousands)

	Balance at Beginning of Period	Charged to Operations	Charges Utilized	Balance at End of Period
Allowance for Doubtful Accounts				
Fiscal year ended December 31, 2002 . . .	\$ 232	\$ 33	\$ (120)	\$ 145
Fiscal year ended December 31, 2003 . .	145	(24)	(53)	68
Fiscal year ended December 31, 2004 . .	68	42	(6)	104
Inventory Reserve				
Fiscal year ended December 31, 2002 . .	7,484	192	(455) ⁽¹⁾	7,221
Fiscal year ended December 31, 2003 . .	7,221	56	(1,724) ⁽²⁾	5,553
Fiscal year ended December 31, 2004 . .	5,553	158	(1,794) ⁽³⁾	3,917
Product Returns				
Fiscal year ended December 31, 2002 . .	1,523	2,020	(1,263)	2,280
Fiscal year ended December 31, 2003 . .	2,280	1,815	(1,163)	2,932
Fiscal year ended December 31, 2004 . .	\$ 2,932	\$ 1,640	\$ (1,724)	\$ 2,848

- (1) The Company used \$163,000 of its fully reserved raw materials inventory in production. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.
- (2) The Company used \$1.2 million of its fully reserved raw materials inventory in production. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.
- (3) The Company used \$844,000 of its fully reserved raw materials inventory in production. The fully reserved raw materials are charged to cost of goods sold at a zero basis when used, which has a favorable impact on gross profit. In the fourth quarter of 2004, the Company determined that it will likely not use the fully reserved inventory in future production.

Forward-Looking Statements

Except for the historical information contained herein, the matter discussed in this annual report to shareholders contains “forward-looking” statements that involve risks and uncertainties. These statements typically may be identified by the use of forward-looking words or phrases such as “believe,” “expect,” “intend,” “anticipate,” “should,” “planned,” “estimated,” and “potential,” among others. All forward-looking statements included in this document are based on our current expectations, and we assume no obligations to update any such forward-looking statements. The Private Securities Litigation Reform Act of 1995 provides a “safe-harbor” for such forward-looking statements. In order to comply with the terms of the safe harbor, we note that a variety of factors could cause actual results and experiences to differ materially from the anticipated results or other expectations expressed in such forward-looking statements. The risks and uncertainties that may affect the operations, performance, development, and results of our business include but are not limited to: (1) our history of losses and variable quarterly results; (2) substantial competition; (3) risks related to the failure to protect our intellectual property and litigation in which we may become involved; (4) our reliance on sole source suppliers; (5) our limited sales and marketing efforts and our reliance on third parties; (6) failure to continue to develop innovative products; (7) risks related to noncompliance with the United States Food and Drug Administration regulations; and (8) other factors that are described from time to time in our periodic filing with the Securities and Exchange Commission, including those set forth in this filing as “Risk Factors Affecting Operations and Future Results.”

Corporate Information

Directors

Virgil A. Place, M.D.
Chairman and
Chief Scientific Officer,
VIVUS, Inc.

Leland F. Wilson
President and
Chief Executive Officer,
VIVUS, Inc.

Mark B. Logan⁽¹⁾⁽²⁾
Former Chairman and
Chief Executive Officer,
VISX, Inc.

Mario M. Rosati⁽²⁾⁽³⁾
Partner
Wilson, Sonsini, Goodrich & Rosati, P.C.

Linda M. Dairiki Shortliffe, M.D.⁽¹⁾⁽²⁾⁽³⁾
Professor and Chair of Urology,
Stanford University School of Medicine

Graham Strachan⁽¹⁾
Principal Owner of
GLS Business Development, Inc.

⁽¹⁾ Member Audit Committee

⁽²⁾ Member Compensation Committee

⁽³⁾ Member Nominating and
Governance Committee

Officers

Virgil A. Place, M.D.
Chairman of the Board
Chief Scientific Officer

Leland F. Wilson
President and
Chief Executive Officer

John Dietrich, Ph.D.
Vice President,
Research and Development

Guy P. Marsh
Vice President,
U.S. Operations and
General Manager

Timothy E. Morris, CPA
Vice President,
Finance and
Chief Financial Officer

Terry M. Nida
Vice President,
Corporate Development and
International Marketing

Peter Y. Tam
Senior Vice President, Product
and Corporate Development

Legal Counsel

Wilson, Sonsini, Goodrich & Rosati, P.C.
Palo Alto, CA

Independent Public Accountants

KPMG, LLP
San Francisco, CA

Transfer Agent

For stockholder services such as address changes or lost stock certificates, contact:
Computershare Investor Services
(312) 588-4993

Annual Meeting

The annual meeting of stockholders will be held on June 15, 2005 at 10:00 a.m. local time at VIVUS's headquarters, 1172 Castro Street, Mountain View, CA 94040

Corporate Contact

Investor Relations
1172 Castro Street
Mountain View, CA 94040
(650) 934-5200
ir@vivus.com

Form 10K

A copy of the Company's Form 10K, as filed with the Securities and Exchange Commission, is available upon request.

Product Information

Consumers
(888) 367-6873
Health Care Professionals
(888) 345-6873

Website: www.vivus.com

Trademarks

MUSE, ACTIS, ALISTA, Evamist and MDTS are licensed trademarks of VIVUS, Inc. Viagra is a licensed trademark of Pfizer Inc.

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Palo Alto, CA

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