FNB CORP/FL/
Form 8-K
January 27, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 8-K
CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
Date of Report (Date of earliest event reported): January 26, 2009
F.N.B. CORPORATION

(Exact name of registrant as specified in its charter)
FLORIDA

(State or Other Jurisdiction of Incorporation)

001-31940	25-1255406
(Commission File Number)	(IRS Employer Identification No.)
One F.N.B. Boulevard, Hermitage, PA	16148
(Address of Principal Executive Offices)	(Zip Code)

(724) 981-6000

(Registrant s telephone number, including area code)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

INFORMATION TO BE INCLUDED IN THE REPORT

ITEM 2.02. RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On January 26, 2009, F.N.B. Corporation (the Corporation) announced financial results for the quarter ended December 31, 2008. A copy of the press release announcing the Corporation s results for the quarter ended December 31, 2008 is attached hereto as Exhibit ect to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

(Continued on the following page(s))

13G

CUSIP No.: 73179P106

1. NAME OF REPORTING PERSON

S.S. OR I.R.S. IDENTIFICATION NO. OF ABOVE PERSON

The Vanguard Group - 23-1945930

2. CHECK THE APPROPRIATE [LINE] IF A MEMBER OF A GROUP

A. B. X

3. SEC USE ONLY

4. CITIZENSHIP OF PLACE OF ORGANIZATION

Pennsylvania

(For questions 5-8, report the number of shares beneficially owned by each reporting person with:)

5. SOLE VOTING POWER

127,236

6. SHARED VOTING POWER

7. SOLE DISPOSITIVE POWER

5,073,388

8. SHARED DISPOSITIVE POWER

123,836

9. AGGREGATE AMOUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON

5,197,224

10. CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (9) EXCLUDES CERTAIN SHARES

N/A

11. PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW 9

5.83%

12. TYPE OF REPORTING PERSON

IA

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 13G

Under the Securities Act of 1934

Check the following [line] if a fee is being paid with this statement N/A

Item 1(a) - Name of Issuer:

PolyOne Corp

Item 1(b) - Address of Issuer's Principal Executive Offices:

33587 WALKER ROAD

AVON LAKE, OHIO 44012

Item 2(a) - Name of Person Filing:

The Vanguard Group - 23-1945930

Item 2(b) – Address of Principal Business Office or, if none, residence:

100 Vanguard Blvd.

Malvern, PA 19355

Item 2(c) – Citizenship:

Pennsylvania

Item 2(d) - Title of Class of Securities:

Common Stock

Item 2(e) - CUSIP Number

73179P106

Item 3 - Type of Filing:

This statement is being filed pursuant to Rule 13d-1. An investment adviser in accordance with §240.13d-1(b)(1)(ii)(E).

Item 4 - Ownership:

(a) Amount Beneficially Owned:

5,197,224

(b) Percent of Class:

5.83%

(c) Number of shares as to which such person has:

(i) sole power to vote or direct to vote: 127,236

(ii) shared power to vote or direct to vote:

(iii) sole power to dispose of or to direct the disposition of: 5,073,388

(iv) shared power to dispose or to direct the disposition of: 123,836

Comments:

Item 5 - Ownership of Five Percent or Less of a Class:

Not Applicable

Item 6 - Ownership of More Than Five Percent on Behalf of Another Person:

Not applicable

Item 7 - Identification and Classification of the Subsidiary Which Acquired The Security Being Reported on by the Parent Holding Company:

See Attached Appendix A

Item 8 - Identification and Classification of Members of Group:

Not applicable

Item 9 - Notice of Dissolution of Group:

Not applicable

Item 10 - Certification:

By signing below I certify that, to the best of my knowledge and belief, the securities referred to above were acquired in the ordinary course of business and were not acquired for the purpose of and do not have the effect of changing or influencing the control of the issuer of such securities and were not acquired in connection with or as a participant in any transaction having such purpose or effect.

Signature

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

Date: 02/07/13

By /s/ F. William McNabb III*

F. William McNabb III

President and Chief Executive Officer

*By: /s/ Glenn Booraem

Glenn Booraem, pursuant to a Power of Attorney filed January 29, 2010, see File Number 005-81485, Incorporated by Reference

Appendix A

Vanguard Fiduciary Trust Company ("VFTC"), a wholly-owned subsidiary of The Vanguard Group, Inc., is the beneficial owner of 123,836 shares or .13% of the Common Stock outstanding of the Company as a result of its serving as investment manager of collective trust accounts.

Vanguard Investments Australia, Ltd. ("VIA"), a wholly-owned subsidiary of The Vanguard Group, Inc., is the beneficial owner of 3,400 shares or .00% of the Common Stock outstanding of the Company as a result of its serving as investment manager of Australian investment offerings.

By /s/ F. William McNabb III*

F. William McNabb III

President and Chief Executive Officer

*By: /s/ Glenn Booraem

Glenn Booraem, pursuant to a Power of Attorney filed on January 29, 2010, see File Number 005-81485, Incorporated by Reference

ace:none;">8,597

8,135

In June 2003, the Company announced the disposition of Busulfex (busulfan) Injection to ESP Pharma, Inc. for $29.3 million plus the book value of inventory, approximately $0.2 million. The Company announced the sale of the product Sucraid (sacrosidase) oral solution to a specialty pharmaceutical company in May 2003 for $1.5 million. The Company also divested a third product, Elliotts B Solution to the same specialty company for proceeds that were not material. Proceeds from these dispositions will be used for further development and marketing of Xyrem and for the creation of a stronger presence in the sleep and CNS markets. The Company recorded a gain of $30.3 million related to these transactions in the second quarter of 2003.

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

General

Orphan Medical, Inc. (the Company or we) acquires, develops, and markets products of high medical value intended to treat sleep disorders, pain and other central nervous system (CNS) disorders that are addressed by physician specialists. A drug has high medical value if it offers a major improvement in the safety or efficacy of patient treatment and has no substantially equivalent substitute. The Company has had six pharmaceutical products approved for marketing by the United States Food and Drug Administration (FDA). Three of these products have been divested, and the Company is now focusing its resources on Xyrem® (sodium oxybate) oral solution, a medication approved for cataplexy, a significant and debilitating symptom of narcolepsy. The Company has completed two clinical trials assessing Xyrem in treating excessive daytime sleepiness (EDS) and fragmented nighttime sleep, the other prominent symptoms of narcolepsy. In January 2005, the Company submitted an sNDA to the FDA requesting approval of an expanded label for Xyrem. The Company is also conducting a clinical trial assessing Xyrem in the treatment of symptoms of fibromyalgia syndrome (FMS) and is supporting several Phase IV studies. A new compound, Butamben (butyl-p-aminobenzoate) suspension for injection, is being evaluated for development as a treatment of pain. The Company is seeking other approved or development-stage products in the specialty CNS areas it serves. The Company also markets Antizol® (fomepizole) Injection, as a treatment for suspected or confirmed ethylene glycol or methanol poisonings and Cystadane® (betaine anhydrous for oral solution) for the treatment of homocystinuria, an inherited metabolic disease.

Since its inception, the Company has experienced recurring losses from operations and has generated an accumulated deficit through December 31, 2004 of $70.3 million. With the exception of 2003, when the accumulated deficit decreased as a result of the gain on the divestment of certain products, the accumulated deficit has increased each year as a result of incurring losses from operations. We expect that in 2005 we will also incur additional losses from operations.

Recent Developments

In January 2005, we submitted an sNDA to expand the Xyrem label to encompass improvement in the other primary symptoms of narcolepsy, specifically the reduction of EDS and the improvement in fragmented nighttime sleep, in addition to the established efficacy of Xyrem in treating cataplexy. We expect that the FDA will take action on this sNDA in late 2005. If approved, this sNDA may provide an expanded indication which could increase the market opportunity for the product in excess of $250 million.

In June 2004 the Company announced the initiation of a controlled clinical trial assessing Xyrem in the treatment of FMS. The protocol for the trial calls for 150 patients to complete a three-month trial with an eight-week active treatment period that will assess the impact of Xyrem on the symptoms of fibromyalgia, including the sleep disturbance that typically accompanies fibromyalgia. After a washout period, patients will be assigned in a randomized, blinded manner to one of two active Xyrem dosing arms or to a placebo arm. Trial sites are located throughout the United States and Canada with 22 participating centers. In December 2004, the Company announced that enrollment in this trial has been completed. We expect to announce the results of this trial in the third quarter of 2005.

Critical Accounting Policies

Revenue Recognition

Sales for all products, except Xyrem, are recognized at the time a product is shipped to the Company s customers and are recorded net of reserves for discounts for prompt payment. Sales of Xyrem are recognized at the time product is shipped from the specialty pharmacy to the patient and are recorded net of discounts for prompt payment. Except for Xyrem, the Company is obligated to accept, for exchange only, from all domestic customers products that have reached their expiration date, which range from three to five years depending on the product. The Company is not obligated to accept exchange of outdated product from its international distribution partners. The Company establishes a reserve for the estimated cost of the exchanges. Management bases these reserves on historical experience and these estimates are subject to change.

Deferred revenue represents the initial payment received by the Company per the terms of the Company s license agreement with UCB Pharma (formerly Celltech. Pharmaceuticals). The Company is recognizing this payment ratably over the expected regulatory approval period. Future milestone payments are expected to be recognized as earned based on the achievement of the milestone as indicated in the license agreement. See Note 5 to the financial statements for additional details regarding the UCB Pharma transaction.

Accounts Receivable Allowance

The Company determines an allowance amount based upon an analysis of the collectibility of specific accounts and the aging of the accounts receivable. There is a concentration of sales to larger medical wholesalers and distributors. The Company performs periodic credit evaluations of its customers financial conditions. Domestic receivables are due within 30 days of the invoice date. International receivables are generally due within 60 to 90 days of invoice date. Credit losses relating to customers have not been material since the Company s inception.

Inventories

Inventories are valued at the lower of cost or market determined using the first-in, first-out (FIFO) method. The Company s policy is to establish an excess and obsolete reserve for its products in excess of the expected demand for such products. Inventory used in clinical trials is expensed at the time of production and included in the reserve until used.

Income Taxes

As part of the process of preparing its financial statements, the Company is required to estimate its income taxes in each of the jurisdictions in which it operates. This process involves estimating its actual current tax exposure, together with assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities.

The Company records a valuation allowance to reduce the carrying value of its net deferred tax asset to the amount that is more likely than not to be realized. For the year ended December 31, 2004, the Company recorded a $38.8 million valuation allowance related to its net deferred tax assets of $38.8 million. In the event the Company were to determine that it would be able to realize its deferred tax assets in the future, an adjustment to the deferred tax asset would increase net income in the period such determination is made. On a quarterly basis, the Company evaluates the realizability of its deferred tax assets and assesses the requirement for a valuation allowance.

Results of Operations

Twelve Months ended December 31, 2004 Vs. Twelve Months Ended December 31, 2003

Product Revenue Summary

The following is a summary of product revenue for the year ended December 31, 2004 compared to product revenue for the year ended December 31, 2003:

	Year ended December 31,		Variance	
	2004	2003	$	%
Antizol	$ 9,051	$ 6,622	$ 2,429	37%
Antizol-Vet	278	274	4	1%
Cystadane	1,438	1,186	252	21%
Xyrem	10,570	3,931	6,639	169%
Busulfex (1)		3,321	(3,321)	(100)%
Elliotts B (1)		15	(15)	(100)%
Sucraid (1)		177	(177)	(100)%
Total	$ 21,337	$ 15,526	$ 5,811	37%

(1) These products were divested during the second quarter of 2003.

Product revenue increased $5.8 million or 37% to $21.3 million for the year ended December 31, 2004 compared to $15.5 million the prior year. The increase is the result of the growth in revenues of all products, Xyrem, Antizol and Cystadane. Revenue from Xyrem was $10.6 million for the year ended December 31, 2004 compared to $3.9 million in fiscal 2003. This increase is the result of increased prescription volume for the product resulting from continued market penetration. Over 2,100 physicians have prescribed Xyrem as of December 31, 2004. Antizol revenue increased $2.4 million or 37% as hospital stocking of the product rose slightly, along with an increase in the number of uses resulting from poisonings during the year. Despite the expiration of the initial orphan drug protection in December 2004, the Company expects Antizol to contribute approximately 30 35% of product revenue in 2005 and would expect that percentage to decrease in future periods as Xyrem revenues continue to grow. Cystadane revenue increased $0.3 million or 21% as a result of increased prescriptions during the year. The divested products contributed $3.5 million of revenue through the divestment date in 2003. The Company expects total product revenue in fiscal 2005 to be in the $30.0 million range with Xyrem contributing approximately $20.0 million.

Licensing and royalty revenue was $2.4 million for the year ended December 31, 2004. This included $2.3 million related to the Company s license agreement for European registration and marketing of Xyrem for narcolepsy. In addition, the Company also received $0.1 million of royalties mainly related to Sucraid which was divested in the prior year. The Company expects licensing and royalty revenue to be in the $4.0 million range in 2005

Cost of product revenues increased $0.5 million or 22% to $3.0 million for the twelve months ended December 31, 2004 from $2.4 million for the twelve months ended December 31, 2003. The increase is primarily attributable to the increase in product revenues in 2004. The gross margin for 2004 was 86% compared to 84% the prior year. The increase in the gross margin percentage is the result of the change in the product mix after the divestment of products in 2003. The products divested had a lower average gross margin. Cost of sales as a percentage of revenues will fluctuate from quarter to quarter and from year to year depending on, among other factors, demand for the Company s products, new product

introductions and the mix of approved products shipped. The Company expects its gross margins for Xyrem as well as its other products to be in the 85% range in 2005.

Product development expense increased $2.4 million or 22% to $13.2 million for the year ended December 31, 2004 compared to $10.8 million for the prior year. This increase is attributable to increased clinical trial activity in 2004 compared to the prior year. During 2004 the Company completed two Phase III(b) trials assessing Xyrem in the treatment of symptoms associated with narcolepsy and the Company initiated a proof-of-principle trial assessing Xyrem in the treatment of fibromyalgia (FMS). We expect product development expense in 2005 to increase from 2004. Development spending is expected to increase in the first half of 2005 compared to the fourth quarter of 2004 as a result of the Company s clinical trial evaluating Xyrem as a treatment for fibromyalgia and continued spending for other development programs, including the ongoing Xyrem extended release formulation activities and the continued evaluation of Butamben as a treatment for chronic malignant pain.

Sales and marketing expense increased $0.2 million or 1% to $16.6 million from the $16.4 million of expense recorded in 2003. The primary reason for the increase is a full-year of expense associated with the commercialization of Xyrem. The costs of the sales force, sales administration and the design and execution of several marketing programs approximated the same costs in the prior year. The Company expects sales and marketing spending during 2005 to be approximately $4.5 million per quarter, which includes spending in preparation for the anticipated approval of the Xyrem sNDA.

General and administrative expense decreased $0.5 million or 11% to $4.2 million for the year ended December 31, 2004 compared to $4.8 million the prior year. This decrease is the result of cost savings associated with the divestment of products in the second quarter of 2003. The Company expects general and administrative expenses in 2005 to be consistent with or slightly less than expense levels in 2004.

Interest income increased from the prior year as the rate of investment return on the Company s excess cash increased slightly from 2003.

We recorded minimum interest expense associated with our line of credit facility, capital lease and the amortization of warrants issued in connection with the line of credit facility entered into in March 2003. The amortization of warrants is over the initial term of the credit facility or one year.

We have a history of pre-tax losses and had not generated taxable income since inception until 2003. While the Company had pre-tax income in 2003, the Company utilized a portion of its net operating loss carryforward and therefore, only recorded income tax expense for the alternative minimum taxes that were owed.

As of December 31, 2004, we had $38.8 million of net deferred tax assets available to offset future taxable income. The primary components of the net deferred tax assets are net operating loss carryforwards, which begin to expire in 2010, along with orphan drug and research and development credits which also begin to expire in 2010. In addition, under the Tax Reform Act of 1986, the amounts of and benefits from net operating loss carryforwards may be impaired or limited in certain circumstances, including significant changes in ownership interests. Future use of the Company s net operating loss carryforwards may be restricted due to changes in ownership or from future tax legislation.

The Company has established a valuation allowance against the entire amount of its deferred tax asset because it has not been able to conclude that it is more likely than not that it

will be able to realize the deferred tax asset, due primarily to its history of operating losses.

Preferred stock dividends relate to the Senior Convertible Preferred Stock that was issued on July 23, 1998 and Series B Convertible Preferred Stock issued on August 2, 1999. Both have dividend rates of 7.5%. Preferred stock dividends were $1.0 million and $0.9 million for the twelve months ended December 31, 2004 and 2003, respectively. Preferred stock dividends, which commenced on February 1, 1999, are payable in arrears on August 1 and February 1 of each year. Prior to February 2001, the Company satisfied its dividend payment obligation by issuing additional preferred stock, as permitted by the terms of the Senior Convertible Stock. Subsequent to February 2001, the Company intends to continue to satisfy its future dividend payment obligations by the issuance of unregistered common shares of stock for the Senior Convertible Preferred Stock and additional preferred stock for the Series B Convertible Preferred Stock, which will cause preferred stock dividends to increase in subsequent quarters.

Net loss applicable to common shareholders was $14.0 million for the year ended December 31, 2004 compared to net income applicable to common shareholders of $10.1 million for the twelve months ended December 31, 2003. This change is the result of a net gain of $30.3 million on the divestment of three products in 2003. Basic and diluted loss per common share for the year ended December 31, 2004 was $1.26. Basic and diluted income per share for the year ended December 31, 2003 were $0.95 and $0.85, respectively. The loss for 2003 excluding the gain on the divestment of products was $19.7 million and a net loss per share of $1.86.

Twelve Months Ended December 31, 2003 vs. Twelve Months Ended December 31, 2002

In June 2003, we announced the disposition of Busulfex to ESP Pharma, Inc. for $29.3 million plus the book value of inventory, approximately $0.2 million. We announced the sale of the product Sucraid to a specialty pharmaceutical company on May 6, 2003 for $1.5 million. We also divested a third product, Elliotts B Solution to the same specialty company for proceeds that were not material. Proceeds from these dispositions will be used for further development and marketing of Xyrem and for the creation of a stronger presence in the sleep and CNS markets. Total gain from the divestment of these products of $30.3 million is recorded as Gain on divestment of products in the Statement of Operations.

Product Revenue Summary

The following is a summary of product revenue for the year ended December 31, 2003 compared to product revenue for the year ended December 31, 2002:

	Year ended December 31,		Variance	
	2003	2002	$	%
Antizol	$ 6,622	$ 6,103	$ 519	9%
Antizol-Vet	274	288	(14)	(5)%
Cystadane	1,186	994	192	19%
Xyrem	3,931	250	3,681	1472%
Busulfex(1)	3,321	7,748	(4,427)	(57)%
Elliotts B(1)	15	35	(20)	(57)%
Sucraid(1)	177	712	(535)	(75)%
Total	$ 15,526	$ 16,130	$ (604)	(4)%

(1) These products were divested during the second quarter of 2003.

Product revenue decreased $0.6 million or 4% to $15.5 million for the year ended December 31, 2003 compared to $16.1 million the prior year. The decrease is the result of the product divestments completed in June 2003, offset by increases in Xyrem, Antizol and Cystadane revenues. The divested products contributed $3.5 million of revenue through the divestment date in 2003 compared to $8.5 million of revenue in fiscal 2002. Revenue from Xyrem was $3.9 million for the year ended December 31, 2003 compared to $0.3 million in fiscal 2002. This increase is the result of increased prescription volume for the product. The product was commercially launched in early October 2002. Antizol revenue increased $0.5 million or 9% as hospital stocking of the product rose slightly, along with an increase in the number of uses resulting from poisonings during the year.

Cost of product revenues increased $0.2 million or 10% to $2.4 million for the twelve months ended December 31, 2003 from $2.2 million for the twelve months ended December 31, 2002. The increase is primarily attributable to the change in product sales mix in 2003 as a result of the product divestments discussed earlier. The gross margin for 2003 was 84% compared to 86% the prior year. The margins on all products decreased slightly in 2003 as a result of increases in the costs of product liability insurance, a component of cost of sales. The products that were divested during the year had a lower combined margin, 81% than the combined margin on the remaining products, 86%. Cost of sales as a percentage of revenues will fluctuate from quarter to quarter and from year to year depending on, among other factors, demand for the Company s products, new product introductions and the mix of approved products shipped.

Product development expense increased $2.1 million or 24% to $10.8 million for the year ended December 31, 2003 compared to $8.7 million for the prior year. This increase is attributable to increased clinical trial activity in 2003 compared to the prior year. At December 31, 2003, we had two Phase III(b) trials underway to evaluate Xyrem as a treatment for excessive daytime sleepiness associated with narcolepsy. We had only one Phase III(b) trial underway in 2002.

Sales and marketing expense increased $3.6 million or 28% to $16.4 million from the $12.8 expense recorded in 2002. The primary reason for the increase is a full-year of expense associated with the commercialization of Xyrem. These costs included $7.4 million for the sales force for Xyrem, hired late in the third quarter of 2002, and the sales administration functions compared to $1.8 million the prior year; $5.1 million of expenses for marketing programs for Xyrem compared to $4.2 million in 2002; and other smaller increases. These increases were offset by certain expense savings associated with the divestment of products in 2003, $2.5 million. Sales and marketing expense include the costs of the field sales force, marketing programs and marketing and sales administration costs.

General and administrative expense increased $0.7 million or 16% to $4.8 million for the year ended December 31, 2003 compared to $4.1 million the prior year. This increase is the result of increased staffing and other infrastructure expenses to support the Company s growth.

Interest income declined from the prior year as the rate of investment return on the Company s excess cash declined from 2002.

We recorded minimum interest expense associated with our line of credit facility, capital lease and the amortization of warrants issued in connection with the line of credit facility

entered into in March 2003. The amortization of warrants is over the term of the credit facility or one year.

We have a history of pre-tax losses and had not generated taxable income since inception until 2003. While the Company had pre-tax income in 2003, the Company utilized a portion of its net operating loss carryforward and therefore, only recorded income tax expense for the alternative minimum taxes that were owed.

As of December 31, 2003, we had $35.9 million of net operating loss carryforwards available to offset future taxable income which begin to expire in 2010. In addition, under the Tax Reform Act of 1986, the amounts of and benefits from net operating loss carryforwards may be impaired or limited in certain circumstances, including significant changes in ownership interests. Future use of the Company s net operating loss carryforwards may be restricted due to changes in ownership or from future tax legislation.

The Company has established a valuation allowance against the entire amount of its deferred tax asset because it has not been able to conclude that it is more likely than not that it will be able to realize the deferred tax asset, due primarily to its history of operating losses.

Preferred stock dividends relate to the Senior Convertible Preferred Stock that was issued on July 23, 1998 and Series B Convertible Preferred Stock issued on August 2, 1999. Both have dividend rates of 7.5%. Preferred stock dividends were $0.9 million for the twelve months ended December 31, 2003 and 2002. Preferred stock dividends, which commenced on February 1, 1999, are payable in arrears on August 1 and February 1 of each year. Prior to February 2001, the Company satisfied its dividend payment obligation by issuing additional preferred stock, as permitted by the terms of the Senior Convertible Stock. Subsequent to February 2001, the Company intends to continue to satisfy its future dividend payment obligations by the issuance of unregistered common shares of stock for the Senior Convertible Preferred Stock and additional preferred stock for the Series B Convertible Preferred Stock, which will cause preferred stock dividends to increase in subsequent quarters.

Net income applicable to common shareholders was $10.1 million for the twelve months ended December 31, 2003 compared to a net loss applicable to common shareholders of $12.3 million for the twelve months ended December 31, 2002. Basic and diluted income per share for the year ended December 31, 2003 were $0.95 and $0.85, respectively. Basic and diluted loss per common share for the year ended December 31, 2002 was $1.19. The loss for 2003 excluding the gain on the divested products was $19.7 million and a net loss per share of $1.86.

Liquidity and Capital Resources

Since July 2, 1994, the effective date the Company was spun-off from Chronimed Inc., it has financed its operations principally from net proceeds from several public and private financings, interest income and product sales. The various public and private placement transactions since inception resulted in aggregate net proceeds, after commissions and expenses, of $60.5 million. In addition, the Company raised approximately $30.9 million net proceeds from the divestment of three products in June 2003.

Net working capital (current assets less current liabilities) decreased to $10.4 million at December 31, 2004 from $19.8 million at December 31, 2003. Cash and cash equivalents decreased to $12.7 million at December 31, 2004 from $23.3 million at December 31, 2003. The Company invests excess cash in short-term, interest-bearing, investment grade securities.

The primary sources of capital for the year ended December 31, 2004 were product revenues, licensing and royalty revenues and proceeds from the exercise of stock options. The Company expects the primary sources in 2005 to be product revenues and licensing and royalty revenues. The Company does not expect the stock option activity to continue because the Company had over 400,000 options that would have expired in 2004 had they not been exercised.

In October 2003, the Company announced that it had licensed European sales and marketing rights for Xyrem (sodium oxybate) oral solution to UCB Pharma (formerly Celltech Pharmaceuticals). Under the terms of the agreement, UCB Pharma will be responsible for the registration, sales and marketing of Xyrem in Europe. UCB Pharma has made an initial payment of $2.5 million to Orphan Medical. The Company received a $1.0 million milestone payment in 2004 as a result of the submission of the marketing application in Europe. In 2005, the Company has received an additional $1.0 million milestone payment as a result of the submission of the sNDA on January 15, 2005. UCB Pharma will make further payments of up to $5 million tied to product development and registration milestones and up to $6 million tied to sales-related milestones. UCB Pharma will also pay Orphan Medical a royalty on sales of the product which is expected to begin at the earliest in late 2005. The ten-year licensing agreement includes the use of Xyrem in narcolepsy and provides UCB Pharma with rights to negotiate in regard to other potential future indications including fibromyalgia syndrome. The term of this agreement is for 10 years from the date of approval in Europe with automatic extension until UCB Pharma provides 12 month notice to Orphan Medical. The agreement may be terminated under certain conditions including material breach of contract provisions prior to the ten year initial term.

Our continued viability depends on our ability to generate sufficient cash from operations or seek others sources of working capital. We incurred a net loss applicable to common shareholders of $14.0 million for the year ended December 31, 2004. We expect a loss applicable to common shareholders in fiscal 2005 as well. Management continues to control operations of the business to ensure that sufficient capital is available to execute its operating plans. Management believes it will meet its 2005 operating plan; however there can be no assurance that the goals of the operating plan will be met. Management believes that revenue generated from operations, including milestone payments from UCB Pharma, and funds available from its credit facility will be sufficient to fund the working capital requirements of the Company.

The Company continues to invest its capital in product development activities that may provide opportunities to enhance the commercial opportunities for Xyrem. The Company has outstanding commitments of $12.0 million for future product development and sales and marketing activities. In addition, the Company also continues to use capital to develop and enhance the commercial programs for Xyrem. The Company expects that these efforts may result in increased Xyrem revenues. In the longer term, the Company expects that its current cash balances, cash flow from product revenues and any milestone payments received in accordance with the terms of the UCB Pharma agreement will be sufficient to fund operations well into 2006. The Company may consider additional sources of capital should it decide to expand its product development programs or acquire additional products.

On April 14, 2004, the Company filed a shelf registration statement with the Securities and Exchange Commission (SEC) for the registration of 4,000,000 shares of common stock. Although we believe we have sufficient cash available for currently anticipated clinical trials and our sales and marketing activities, proceeds might be used for trials or sales and marketing activities related to products that we may acquire or develop in the future or for trials or sales and marketing activities related to new indications of existing products. This statement was declared effective by SEC on September 7, 2004, however there can be no assurance of a successful offering.

The Company entered into a credit facility with a commercial bank on March 28, 2003. The facility has been amended in June 2003 as part of the product divestments; in March 2004; in September 2004 and again in February 2005. The September 2004 amendment included the addition of a term loan to the Company s credit facility. As of February 2005, the line of credit facility, which expires January 1, 2006, includes a borrowing base equal to 80% of eligible accounts receivable up to a maximum amount of $4.5 million. Certain other assets have also been pledged as collateral for this facility. In addition to the line of credit facility, the Company has a term loan facility with a term of one-year, which can be used specifically for equipment purchases not to exceed $1.0 million. However the term loan is not available until the Company receives net proceeds of at least $7.5 million in an equity financing transaction. The interest rate for both facilities is equal to two points over the bank s prime rate, with a minimum rate of 6.75%. The Company will be subject to certain other requirements during the term of the facility, including minimum monthly net equity amounts and maximum monthly operating losses. The minimum net equity amount for January 2005 through May 31, 2005 is $5.0 million plus 50% of any additional equity securities or subordinated debt offering. The minimum net equity amount from June 2005 to January 1, 2006 is $4.5 million plus 50% of additional equity securities or subordinated debt offering. The maximum net operating loss for each month of the facility is as follows: January 2005 $1.25 million; for February and March 2005 $1.75 million; April 2005 to

June 2005 $1.25 million and July to the end of term of the facility $1.0 million. At December 31, 2004, there was $1.3 million available under this facility.

The Company s commitments for outside operating expenses decreased to approximately $12.0 million at December 31, 2004 from $14.7 million at December 31, 2003. These commitments are generally for less than one year. The change is principally attributable to the decline in commitments for clinical trials for Xyrem and other development activities. The Company expects development spending to increase approximately 15% in 2005 as compared to 2004 as a result of the spending related to the fibromyalgia trial and other development activities. The Company also continues to look at new product opportunities and any new initiatives will increase development spending. Due to the dependence of this estimate on the results of the studies and other variable components, the actual result of this estimate may be different.

The Company has future contractual commitments for the following cash obligations (in thousands):

	Total	Less than 1 year	1-3 Years	3-5 Years	More than 5 Years
Capital lease obligations	$ 71	$ 24	$ 47	$	$
Operating lease obligations (1)	1,257	558	699		
Outside operating commitments	12,023	12,023			
Total contractual cash obligations	$ 13,351	$ 12,605	$ 746	$	$

(1) These amounts include facilities, office equipment, and automobiles for the Company s field sales force.

The Company expects that sales and marketing spending will increase approximately 10% compared to 2004 spending levels. Management believes that existing cash, expected milestone payments from the UCB Pharma agreement and operating cash flows from product sales will be sufficient to fund its operations at least through December 31, 2005.

For continued listing on the NASDAQ National Market, a company must satisfy a number of requirements, which in the Company s case include either: (1) minimum net equity in excess of $10.0 million or (2) a market capitalization of at least $50.0 million. The Company met both requirements at December 31, 2004. Although the Company does not expect to be profitable in 2005, the Company nevertheless expects to continue to meet the requirements for listing on the NASDAQ National Market. However there can be no assurance that the Company will continue to have adequate capital to meet the requirements through the year 2005 and thereafter.

In connection with the 1998 and 1999 private placements of convertible preferred stock, the Company agreed to certain restrictions and covenants, which could limit its ability to obtain additional financing. The most important of the restrictions are: (1) the Company cannot incur additional indebtedness, except for indebtedness secured solely by the Company s trade receivables, until it has profitable operations, subject to certain limitations and (2) the Company cannot, without the approval of a majority of the preferred stockholders, issue additional equity securities unless the selling price per share exceeds the then conversion price of the outstanding convertible preferred stock or the sale of equity is accomplished in a public offering. The present conversion price is $8.14 for the Senior Convertible Preferred Stock and $6.50 for the Series B Convertible Preferred Stock. Even without these restrictions, the Company can make no assurances that additional financing opportunities will be available or, if available, on acceptable terms.

Off-Balance Sheet Arrangements

We do not participate in transactions or have relationships or other arrangements with an unconsolidated entity, which include special purpose and similar entities or other off-balance sheet arrangements.

Recent Accounting Pronouncements

In January 2003, the FASB issued Financial Interpretation No. 46, or FIN 46, *Consolidation of Variable Interest Entities*, and in December 2003, issued a revision to FIN 46 (FIN 46R). FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity should be included in the consolidated financial statements of the entity. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period ending after December 15, 2003. The adoption of FIN 46 did not have a material effect on our results of operations, cash flows or financial position.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity.* SFAS No. 150 establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances) because that financial instrument embodies an obligation of the issuer. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The Company adopted SFAS No. 150 as of July 1, 2003. The adoption of SFAS No. 150 did not have a material effect on our results of operations, cash flows or financial position.

In December 2004, the FASB issued SFAS No. 123(R), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation and supersedes APB 25 Accounting for Stock Issued to Employees . SFAS 123(R) requires companies to recognize the cost of employee services received in exchange for awards of equity instruments, based on the grant date fair value of those awards, in the financial statements. The effective date of SFAS No. 123(R) is the first reporting period beginning after June 15, 2005, although early adoption is allowed. SFAS No. 123(R) permits companies to adopt its requirements using either a modified prospective method, or a modified retrospective method. Under the modified prospective method, compensation cost is recognized in the financial statements beginning with the effective date, based on the requirements of SFAS No. 123(R) for all share-based payments granted after that date, and based on the requirements of SFAS No. 123 for all unvested awards granted prior to the effective date of SFAS 123(R). Under the modified retrospective method, the requirements are the same as under the modified prospective method, but also permits entities to restate financial statements of previous periods based on proforma disclosures made in accordance with SFAS No. 123. The Company expects to adopt the modified prospective method under SFAS No. 123(R) effective January 1, 2005. Based on the balance of unvested stock options outstanding at December 31, 2004, the adoption of SFAS No. 123(R) will result in approximately $2.2 million of expense in 2005.

RISK FACTORS

An investment in our common stock involves a number of risks, including among others, risks associated with companies that operate in the pharmaceutical industry. These risks are substantial and inherent in our operations and industry. Any investor or potential investor should carefully consider the following information about these risks before buying shares of common stock.

We have a history of losses, which we expect to continue.

We have been unprofitable since our inception in January 1993, with the exception of 2003 due to the divestment of three products. We expect operating losses at least through 2005 because anticipated gross profits from product revenues and anticipated licensing and royalty revenues will not offset our operating expenses. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter. Our actual losses will depend on, among other factors, the timing of product development, regulatory approval, and market demand for our Food and Drug Administration approved products. We cannot assure you that we will ever generate sufficient product revenues to achieve profitability.

We cannot be sure that future capital will be available to meet our expected capital requirements.

Although we believe that we have sufficient capital to meet our current business objectives at December 31, 2004, we may need additional capital if we expand our business, if business conditions change or results of operations are not as expected. Adequate funds for our operations, continued development, and expansion of our business plans, whether from financial markets or from other sources, may not be available when needed on acceptable terms, or at all. If we issue additional securities your ownership may be diluted.

In addition there are restrictions on our ability to raise additional capital that are part of the terms of the sales of our preferred stock. On July 23, 1998, we completed the private sale to UBS Capital of $7.5 million of Senior Convertible Preferred Stock. On August 2, 1999, we completed another private sale to UBS Capital of $2.95 million of Series B Convertible Preferred Stock. In conjunction with the issuance of the preferred shares, we agreed to several restrictions and covenants, and granted certain voting and other rights to the holders of the preferred shares. One of the most important of these restrictions is that we cannot incur additional indebtedness, except for indebtedness secured solely by our trade receivables, until we have profitable operations, subject to certain limitations. Another important restriction is that, without the approval of a majority of the preferred stockholders, we cannot issue additional equity securities unless the selling price per share exceeds the then conversion price of the outstanding convertible preferred stock or the sale of equity is accomplished in a public offering. The present conversion price is $8.14 per share for the Senior Convertible Preferred Stock and $6.50 for the Series B Convertible Preferred Stock. These restrictions could make it more difficult and more costly for us to obtain additional capital. We cannot assure you that additional sources of capital will be available to us or, if available, on terms acceptable to us.

Possible Price Volatility and Limited Liquidity of Common Stock.

There is generally significant volatility in the market prices and limited liquidity of securities of early stage companies, and particularly of early stage pharmaceutical companies. Contributing to this volatility are various factors and events that can affect our stock price in a positive or negative manner. These factors and events include, but are not limited to:

- general national and international economic and political developments;
- governmental approvals, refusals to approve, regulations or actions;
- developments or disputes relating to patents or proprietary rights;
- public concern over the safety of therapies;
- financial performance;

fluctuations in financial performance from period to period; and

small float or number of shares of our stock available for sale and trade.

There is also a risk that the market value and the liquidity of the public float for our common stock could be adversely affected in the event we no longer meet the Nasdaq s requirements for continued listing on the National Market. For continued listing on the Nasdaq National Market, a company must satisfy a number of requirements, which in our case includes either: (1) minimum net equity in excess of $10.0 million as reported on Form 10-Q or Form 10-K or (2) a market capitalization of at least $50.0 million. Market capitalization is defined as total outstanding shares multiplied by the last sales price quoted by Nasdaq. We met both criteria as of December 31, 2004, however, we cannot assure you that the market capitalization threshold will continue to be met or that we will be able to generate adequate capital to meet the net tangible asset requirement.

These and other factors and events may have a significant impact on our business and on the market price of the common stock.

There is a limited market for our products.

Most orphan drugs have a potential United States market of less than $25 million annually and many address annual markets of less than $1 million. The combined revenue from the sales of Antizol, Cystadane, and Antizol-Vet in 2004 was approximately $10.7 million. We believe that the total market opportunity for these three products is not likely to exceed the $10.0 - $11.0 million range in the foreseeable future.

Revenue from Xyrem in 2004 was approximately $10.6 million. Xyrem is indicated for the treatment of cataplexy in narcolepsy, and, if our clinical trials in our product development programs that are underway produce positive data, this data may result in increased market opportunity for Xyrem. We cannot assure you, however, that sales of our products will be adequate to make us profitable even if the products are accepted by medical specialists and used by patients.

We currently rely on the limited protection of the Orphan Drug Act for certain products.

Since our inception, all of our products, with the exception of Antizol-Vet, have been granted orphan drug status by the FDA. Medicines developed or acquired in the future may hold orphan drug status, although we may develop or acquire products that do not hold such status if we can obtain appropriate proprietary protection through patents or otherwise. Currently two of our products have orphan drug status: Xyrem with an expiration date of July 17, 2009 and Antizol, with an expiration date of December 8, 2007 for the methanol indication.

We are not aware of any company intending to market a competitive product when the orphan drug protection for these products expires.

United States

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition. The Orphan Drug Act generally defines rare disease or condition as one that affects populations of fewer than 200,000 people in the United States. The Orphan Drug Act provides us with certain limited protections for our products.

The first step in obtaining the limited protection under the Orphan Drug Act is acquiring the FDA s approval of orphan drug designation, which must be requested before submitting a New Drug Application (NDA). After the FDA grants orphan drug designation, it publishes the generic identity of the therapeutic agent and the potential orphan use specified in the request. Orphan drug designation does not constitute FDA approval. In addition, orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory approval process.

The second step in obtaining the limited protection under the Orphan Drug Act is acquiring the FDA s recognition of orphan drug status. The Orphan Drug Act confers orphan drug status upon the first company to receive FDA approval to market a drug with orphan drug designation for a specific designated indication. Orphan drug status does not protect against another formulation or drug of materially different composition from being approved, with or without orphan drug status, for the same indication. FDA approval also results in United States marketing exclusivity for a period of seven years, subject to certain limitations. Although obtaining FDA approval to market a product with orphan drug status can be advantageous, we cannot assure you that the scope of protection or the level of marketing exclusivity will remain in effect in the future. In addition, United States orphan drug status does not provide any marketing exclusivity in foreign markets. Although certain foreign countries provide development and marketing benefits to orphan drugs, we cannot assure you that such benefits can be obtained or, if obtained, will be of material value to us. The FDA has granted us orphan drug status for Xyrem, Antizol, and

Cystadane. Upon expiration of orphan drug status, our products might be subject to competition from other pharmaceutical companies, with the exception of Xyrem which has patent protection.

Even if the FDA approves an NDA for a drug with orphan drug designation, the FDA may still approve the same drug for a different indication, or a molecular variation of the same drug for the same indication. In addition, the FDA does not restrict doctors from prescribing an approved drug for uses not approved by the FDA for that drug. Thus, a doctor could prescribe another company s drug for indications for which our product has received FDA approval and orphan drug status. Significant off label use, that is, prescribing approved drugs for unapproved uses, could adversely affect the marketing potential of any of our products that have received orphan drug status and NDA approval by the FDA.

The possible amendment of the Orphan Drug Act by Congress has been the subject of congressional discussion from time to time over the last ten years. Although Congress has made no significant changes to the Orphan Drug Act for a number of years, members of Congress have from time to time proposed legislation that would limit the application of the Orphan Drug Act. We cannot assure you that the Orphan Drug Act will remain in effect or that it will remain in effect in its current form. The precise scope of protection that orphan drug designation and marketing approval may afford in the future is unknown. We cannot assure you that the current level of exclusivity will remain in effect.

Europe

An orphan drug act was enacted in the European Union that provides up to ten years of market exclusivity for a drug that meets the requirements of the act. For a pharmaceutical product to qualify for the benefits of the act, the prevalence or incidence (whichever is greater) must not exceed five patients per 10,000 in the population. Our European partners have obtained orphan drug designation for Cystadane in Europe. The Company has obtained orphan drug designation for Xyrem and Antizol, for use in methanol poisonings, in Europe. European orphan drug designation of Antizol was withdrawn by the Company in 2003. We cannot provide assurance that any of our pharmaceutical products will qualify for orphan drug protection in the European Union or that another company will not obtain an approval that would block us from marketing our product in the European Union.

Patents and other proprietary rights are important factors in our business.

The pharmaceutical industry and the investment community place considerable importance and value on obtaining patent, proprietary, and trade secret protection for new technologies, products and processes. The patent position of pharmaceutical firms is often highly uncertain and generally involves complex legal, technical and factual questions. Our success depends on several issues, including, but not limited to our ability:

to obtain, and enforce proprietary protection for our products under United States and foreign patent laws and other intellectual property laws;

to preserve the confidentiality of our trade secrets; and

to operate without infringing the proprietary rights of third parties.

We evaluate the desirability of seeking patent or other forms of protection for our products in foreign markets based on the expected costs and relative benefits of attaining such protection. We cannot assure you that any patents will be issued from any applications or that any issued patents will afford us adequate protection or competitive advantage. Also, we cannot assure you that any issued patents will not be challenged,

invalidated, infringed or circumvented. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to our products. We cannot assure you that patents now in existence or later issued to others will not adversely affect the development or commercialization of our products.

We believe that the active ingredients or compounds in our FDA-approved products, Cystadane, Antizol, Antizol-Vet, and Xyrem, are in the public domain and presently are not subject to composition of matter patent protection in the United States. We have a patent with respect to our formulation of Xyrem oral solution and other patents pending or issued.

We have orphan drug protection for Antizol and Xyrem, which provides proprietary protection against potential competition. We could, however, incur substantial costs asserting any infringement claims that we may have against others. Upon expiration of orphan drug status our products might be subject to competition from other pharmaceutical companies.

We seek to protect our proprietary information and technology, in part, through confidentiality agreements and inventors rights agreements with our employees. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise be disclosed to or discovered by our competitors. We also cannot assure you that our planned activities will not infringe patents owned by others. We could incur substantial costs in defending infringement suits brought against us. We also could incur substantial costs in connection with any suits relating to matters for which we have agreed to indemnify our licensors or distributors. An adverse outcome in any such litigation could have a material adverse effect on our business and prospects. In addition, we often must obtain licenses under patents or other proprietary rights of third parties. We cannot assure you that we can obtain any such licenses on acceptable terms, if at all. If we cannot obtain required licenses on acceptable terms, we could encounter substantial difficulties in developing, manufacturing or marketing one or more of our products.

The FDA must agree with investigational new drug applications, including any such applications with respect to butamben, prior to the initiation of clinical development programs.

Prior to the initiation of a clinical development program, companies submit an investigational new drug application (IND) to the FDA. If the FDA notifies the submitting sponsor that the IND requires additional information or is not approvable, the potential development program may be significantly delayed or terminated. We cannot assure you that IND applications submitted by us to the FDA, including with respect to butamben if we decide to initiate a development program for this product, will proceed in a timely manner. Further, it is possible that FDA action may result in the termination of the potential development program. Although we do not expect to derive any revenues from butamben prior to 2009, we cannot assure you that a termination of any potential development program will not adversely affect the prospects of our business.

The Company is in the process of determining a production and manufacturing process for preclinical and clinical trial activities that can be validated and then support commercial activities post approval. This manufacturing process is different from the process used to manufacture butamben injection which was on file with FDA for the previous IND. Because the manufacturing process for the product in Orphan Medical s development program is different from the original manufacturing process in the IND, the Company will file this data in an IND application with the FDA prior to the initiation of the clinical development program.

Approval from the FDA and foreign regulatory authorities must occur before any new products or a new indication for an existing product we may develop can be commercially sold, including butamben.

Government regulation in the United States and abroad is a significant factor in the testing, production and marketing of our current and future products. Each product must undergo an extensive regulatory review process conducted by the United States Food and Drug Administration and by comparable agencies in other countries. Appropriate approvals must be obtained before we are able to market or promote a product. We must also receive regulatory approval for each new indication for a product prior to marketing for that indication. We cannot market any medicine we may develop or license as a prescription product in any jurisdiction, including foreign countries, in which the product does not receive regulatory approval. The approval process can take many years and requires the expenditure of additional resources.

We depend on external laboratories and medical institutions to conduct our pre-clinical and clinical analytical testing in compliance with good clinical and laboratory practices established by the FDA. The data obtained from pre-clinical and clinical testing is subject to varying interpretations that could delay, limit or prevent regulatory approval. In addition, changes in FDA policy for drug approval during the period of development and in the requirements for regulatory review of each submitted NDA could result in additional delays or outright rejection.

In January 2005, we submitted an sNDA to expand the Xyrem label to encompass improvement in the other primary symptoms of narcolepsy, specifically the reduction of excessive daytime sleepiness (EDS) and the improvement in fragmented nighttime sleep, in addition to the established efficacy of Xyrem in treating cataplexy. We expect that the FDA will take action on this sNDA in late 2005. If approved, this sNDA may provide an expanded indication which could increase the market opportunity for the product in excess of $250 million, however, there can be no assurance that such application will be approved by the FDA.

We cannot assure you that the FDA or any foreign regulatory authority will approve a regulatory marketing application in a timely manner, if at all, with respect to any products we develop. Generally, the FDA and foreign regulatory authorities approve only a very small percentage of newly discovered pharmaceutical compounds that enter pre-clinical development. Moreover, even if the FDA approves a product, it may place commercially unacceptable limitations on the uses, or indications, for which a product may be marketed. This would result in additional cost and delay to the extent that further studies are required to provide additional data on safety or effectiveness.

FDA approval does not guarantee financial success.

Four of our currently marketed products have been approved for marketing by regulatory authorities in the United States and elsewhere. We cannot assure you that any of our products will be commercially successful or achieve the expected financial results as a result of limited markets for our products as discussed in the risk factor entitled, There is a limited market for our products . We may encounter unanticipated problems relating to the development, manufacturing, distribution and marketing of our products. Some of these problems may be beyond our financial and technical capacity to solve. The failure to adequately address any such problems could have a material adverse effect on our business and our prospects. In addition, the efforts of government entities and third party payors to contain or reduce the costs of health care may adversely affect our sales and limit the commercial success of our products.

We cannot completely insulate our drug development portfolio from the possibility of clinical or commercial failures or generic competition. Some products that we have selected for development may not produce the results expected during clinical trials or receive FDA approval. Drugs approved by the FDA may not generate product sales of an acceptable level. We have discontinued the development of eleven products from our portfolio since inception.

In addition we continue to invest in the development of additional indications for Xyrem. This spending, along with costs associated with the on-going marketing and selling of Xyrem, resulted in a loss from operations in fiscal 2004. We expect that we will incur a loss from operations in 2005.

Significant government regulation continues once a product is approved for sale.

After a reviewing division of the FDA approves a drug, the FDA s Division of Drug Marketing, Advertising and Communication must accept such drug s marketing claims, which are the basis for the drug s labeling, advertising and promotion. We cannot be sure that the Division of Drug Marketing, Advertising and Communication will accept marketing claims we propose to the agency. The failure of the Division of Drug Marketing, Advertising and Communication to accept our proposed marketing claims could have a material adverse effect on our business and prospects.

The FDA can require that a company conduct post-marketing adverse event surveillance programs to monitor any side effects that occur after the company s drug is approved for marketing. If the surveillance program indicates unsafe side effects, the FDA may recall the product, and suspend or terminate a company s authorization to market the product. The FDA also regulates the manufacturing process for an approved drug. The FDA may impose restrictions or sanctions upon the subsequent discovery of previously unknown problems with a product or manufacturer. One possible sanction is requiring the recall of such product from the market. The FDA must approve any change in manufacturer as well as most changes in the manufacturing process prior to implementation. Obtaining the FDA s approval for a change in manufacturing procedures or change in manufacturers is a lengthy process and could cause production delays and loss of sales, which would have a material adverse effect on our business and our prospects.

In addition we have additional regulatory requirements with respect to certain DEA regulations and amendments. While we believe that we are compliant with appropriate regulations and amendments, there can be no assurance that we will maintain compliance with such regulations.

Certain foreign countries regulate the sales price of a product after marketing approval is granted. We cannot be sure that we can sell our products at satisfactory prices in foreign markets even if foreign regulatory authorities grant marketing approval.

We rely on others for product development opportunities.

We engage only in limited research to identify new pharmaceutical compounds. To build our product portfolio, we have adopted a license and acquisition strategy. This strategy for growth requires us to identify and acquire pharmaceutical products targeted at niche markets within our selected therapeutic markets. These products usually require further development and approval by regulatory bodies before they can be marketed. We cannot assure you that any such products can be successfully acquired, developed, approved or marketed. We must rely upon the willingness of others to sell or license pharmaceutical product opportunities to us. Other companies, including those with substantially greater resources, compete with us to acquire such products. We cannot assure you that we will be able to acquire rights to additional products on acceptable terms, if at all. Our failure to acquire or license any new pharmaceutical products, or our failure to promote and market any products successfully within an existing therapeutic area, could have a material adverse effect on our business and our prospects.

We have contractual development rights to certain compounds through various license agreements. Generally, the licensor can unilaterally terminate these agreements for several reasons, including, but not limited to the following reasons:

for cause if we breach the contract;

if we become insolvent or bankrupt;

if we do not apply specified minimum resources and efforts to develop the compound under license; or

if we do not achieve certain minimum royalty payments, or in some cases, minimum sales levels.

We cannot assure you that we can meet all specified requirements and avoid termination of any license agreements. We cannot assure you that if any agreement is terminated, we will be able to enter into similar agreements on terms as favorable as those contained in our existing license agreements.

We have invested most of our capital in the development of products already licensed to or under the control of the Company, therefore this risk has not had a material impact on our business in the past. As we look for additional opportunities to expand our product portfolio, this risk factor may have an adverse effect on our business.

A failure by our manufacturers or suppliers to deliver product timely could adversely affect sales revenue.

We do not have and do not currently intend to establish any manufacturing capability for drug products. Instead, we engage third parties to manufacture our products. Failure by parties with whom we contract to adequately perform their responsibilities may delay the submission of products for regulatory approval, impair our ability to deliver our products on a timely basis or otherwise adversely affect our business and our prospects.

The loss of either a bulk drug supplier or drug product manufacturer would require us to obtain regulatory clearance in the form of a pre-approval submission and incur validation and other costs associated with the transfer of the bulk drug or drug product manufacturing process. We believe that it could take as long as two years for the FDA to

approve such a submission. Because our products are targeted to relatively small markets and our manufacturing production runs are small by industry standards, we have not incurred the added costs to certify and maintain secondary sources of supply for bulk drug substance or backup drug product manufacturers for some products. Should we lose either a bulk drug supplier or a drug product manufacturer, we could run out of marketable product to meet market demands or investigational product for use in clinical trials, while we wait for the FDA approval of a new bulk drug supplier or drug product manufacturer.

During the course of negotiations in the ordinary course of business to renew or extend an agreement with a manufacturing vendor, on occasion, the Company s vendors have indicated that if price increases cannot be successfully negotiated, their agreement may need to be terminated. If this were to occur, we believe that there are alternate manufacturing and supply sources that would be available both on acceptable terms and on a timely basis for our products. In addition, our agreements generally require the manufacturer or supplier to continue to perform their obligations under these agreements for at least one year, and in some cases, two years, following formal notice of termination, during which period we would seek to implement new manufacturing and supply relationships. However, we cannot assure you that the change of a bulk drug supplier or drug product manufacturer and the transfer of the processes to another third party will be approved by the FDA, and if approved, in a timely manner. Therefore, we may experience additional costs and delay with switching providers, which in turn could adversely affect sales revenue.

Bulk Drug Supply

Bulk drug substance is the active chemical compound used in the manufacture of our drug products. We currently have a single supplier for the supply of bulk drug substance used in Cystadane, Antizol and Antizol-Vet. If we were to lose this company as a supplier, we would be required to identify a new supplier for the bulk drug substance. We also currently use a single supplier for the supply of bulk drug substance used in Xyrem, which is expected to exceed 60% of our revenue in 2005. If we were to lose this company as a supplier, we would be required to identify a new supplier. We decided to terminate the relationship with the manufacturer of the bulk drug substance for Antizol and Antizol-Vet. The agreement with the terminated bulk drug substance manufacturer expires in May 2006. We have contracted with a new manufacturing source for this product and have begun the transfer of the manufacturing process. While we believe that this transfer will be completed in a timely manner and that there will be no interruption in the supply of our Antizol and Antizol-Vet, there can be no assurance that this process will be completed in the appropriate time period to ensure supply of inventory.

Drug Product Manufacture

From bulk drug substance, drug product manufacturers formulate a finished drug product and package the product for sale or for use in clinical trials. We also use a single supplier for drug product manufacturing of Antizol, Antizol-Vet and a different supplier has been authorized to manufacture Xyrem. If we were to lose either of these companies as a manufacturer, we would be required to identify a new manufacturer. We cannot assure you that our drug product manufacturing arrangements with either or both of these suppliers will not change. We have also decided to change the relationship with the manufacturer of finished drug product for Xyrem. The supply agreement with the terminated Xyrem finished drug product manufacturer expires in July 2005. The current manufacturer will continue to manufacturer the product; however, final packaging will be completed by an additional vendor. We have identified a new source for this packaging and are in the process of negotiating a final agreement and, once the agreement is signed, we will begin the transfer of this process. While we believe that this process will be completed in a timely manner and that there will be no interruption in the supply of Xyrem, there can be no assurance that this process will be completed in the appropriate time period to ensure supply of inventory.

We cannot control our contractors compliance with applicable regulations.

The FDA defines and regulates good manufacturing practices to which bulk drug suppliers and drug product manufacturers are subject. The Drug Enforcement Agency (DEA) defines and regulates the handling and reporting requirements for certain drugs which have abuse potential, known as scheduled drugs. Foreign regulatory authorities prescribe similar rules and regulations. Our supply and manufacturing contractors must comply with these regulatory requirements. Failure by our contractors to comply with FDA or DEA requirements or applicable foreign requirements could result in significant time delays or in our inability to commercialize or continue to market a product. Either result could have a material adverse effect on our business and prospects. Failure to comply with good manufacturing practices or other applicable legal requirements can lead to federal seizure of violative products, injunctive actions brought by the federal government, or potential criminal and civil liability for Orphan Medical, our officers, or our employees. This risk has not impacted us in the past and we are not aware of any instances of noncompliance with applicable regulations that may materially impact our business. We cannot assure you that we will be able to maintain relationships either domestically or abroad with contractors whose facilities and procedures comply or will continue to comply with FDA or DEA requirements or applicable foreign requirements.

We have a single distributor for three of our products: Antizol, Antizol-Vet and Cystadane.

We have an agreement with a single distribution contractor to provide integrated distribution and operations services to support transactions between us and our wholesalers, specialty distributors, and direct customers. The contractor currently distributes Antizol, Antizol-Vet and Cystadane. The contractor may also distribute future products should those products receive marketing clearance from the FDA. A failure by this distributor to fulfill its responsibilities might have an adverse affect on our ability to meet customer demand in a timely manner.

We cannot assure you that our distribution arrangements with this entity or other third parties would be available, or continue to be available to us on commercially acceptable terms. The loss of a distributor or failure to renew agreements with an existing distributor could have a material adverse effect on our business and prospects.

Xyrem is classified as a Schedule III controlled substance.

We have an agreement with a specialty pharmacy to distribute Xyrem. Xyrem is classified as a Schedule III controlled substance and approved under Subpart H of the FDA s review process, and distribution is strictly controlled. The specialty pharmacy is the only source through which Xyrem can be obtained. Distribution is governed by the FDA s Subpart H regulations and complies with the risk-management controls jointly developed by Orphan Medical, the FDA, the Drug Enforcement Agency and law enforcement agencies. Every shipment of Xyrem is subject to stringent safeguards to ensure it reaches only individuals for whom it has been legitimately prescribed. Our contractor for this product also provides reimbursement management, patient assistance and information hotline services and specialty distribution and marketing services to physician practices with respect to Xyrem. The Company is in the process of extending this distribution agreement to July 31, 2007. We cannot assure you that the agreement will be extended on terms acceptable to the Company.

Our purchases of sodium oxybate, the active ingredient in Xyrem, for use in the production of Xyrem are subject to quotas that are published and approved by the U.S. Drug Enforcement Administration. Supply disruption could result from delays in obtaining DEA approvals or the receipt of approvals for quantities of sodium oxybate that are insufficient to meet current or projected product demand. The quota system also limits our ability to build inventories as a method of insuring against possible supply disruptions.

We rely on foreign marketing alliances and have no assurance of foreign licensees.

Our strategy to sell our products in foreign markets is to license foreign marketing and distribution rights to a foreign company after a new drug application is submitted or approved in the United States. We consider Europe, Asia, and Canada our most attractive foreign markets. Our current foreign arrangements are:

Europe. We have licensed the marketing and distribution rights for Xyrem and Cystadane in Europe. If our licensees are unsuccessful in their registration and distribution efforts, we may find it difficult to contract with other distributors for these products within Europe. Distribution of all products except Antizol is limited to named patient or emergency use basis until full regulatory approval is obtained. Antizol has been approved for use in the United Kingdom but is limited to named patient basis in other parts of

Europe. This distribution of the Company s products is expected to result in a limited contribution to the Company s revenues.

Australia and New Zealand. We have licensed marketing and distribution rights for Cystadane in Australia and New Zealand, but sales of these products have not been material. We do not expect sales to increase in the near future to the point that they become material.

Israel. We have licensed marketing and distribution rights for Antizol and Cystadane in Israel. Full regulatory approval for Cystadane was obtained in Israel in February 2000. We do not expect such distribution to result in material revenues.

Canada. We have licensed marketing and distribution rights for Antizol in Canada. For Cystadane we have only licensed the distribution rights in Canada. We do not expect such distribution to result in material revenues.

We depend on our foreign licensees for the regulatory registration of our products in foreign countries. We cannot be sure that our licensees can obtain such registration. In addition, we cannot be sure that we will be able to negotiate commercially acceptable license agreements for our other products or in additional foreign countries. Furthermore, we cannot assure you that these companies will be successful in negotiating acceptable pricing or in marketing and selling our products in their respective territories.

Our products might be recalled.

A product can be recalled at our discretion or at the discretion of the FDA, the U.S. Federal Trade Commission, or other government agencies having regulatory authority for marketed products. A recall may occur due to disputed labeling claims, manufacturing issues, quality defects, safety issues, or other reasons. We cannot assure you that a product recall will not occur. We do not carry any insurance to cover the risk of a potential product recall. Any product recall could have a material adverse effect on our business and prospects. To date, no recall of products marketed by the Company has occurred.

We face limits on price flexibility and third-party reimbursement.

The flexibility of prices that we can charge for our products depends on government regulation, both in the United States and abroad, and on other third parties. One important factor is the extent to which reimbursement for our products will be available to patients from government health administration authorities, private health insurers and other third-party payors. Government officials and private health insurers are increasingly challenging the price of medical products and services. We are uncertain as to the pricing flexibility we will have with respect to, and if we will be reimbursed for, newly approved health care products.

In the United States, we expect continuing federal and state proposals to implement greater government control of the pricing and profitability of prescription pharmaceuticals. Cost controls, if mandated by a government agency, could decrease, or limit, the price we receive for our products or products we may develop in the future. We may not be able to recover our development costs, which could be substantial. We may not be able to realize an appropriate profit margin. This could have a material adverse effect on our business. Furthermore, federal and state regulations govern or influence reimbursement of health care providers for medical treatment of certain patients. We cannot assure you that action taken by federal and/or state governments, if any, with regard to health care reform will not have a material adverse effect on our business and prospects.

Certain private health insurers and third-party payors may attempt to control costs further by selecting exclusive providers of pharmaceuticals. If such arrangements are made with our competitors, these insurers and third-party payors would not reimburse patients who purchase our competing products. This would diminish the market for our products and could have a material adverse effect on our business and prospects.

We face intense competition in our industry.

Competition in the pharmaceutical industry is intense. Potential competitors in the United States are numerous and include pharmaceutical, chemical and biotechnology companies. Many of these companies have substantially greater capital resources, marketing experience, research and development staffs and facilities than we do. We seek to limit potential sources of competition by developing products that are eligible for orphan drug status upon NDA approval or other forms of protection. We cannot assure you, however, that our competitors will not succeed in developing similar technologies and products more rapidly than we can. Similarly, we cannot assure you that these competing technologies and products will not be more effective than any of those that we have developed or are currently developing.

We expect rapid technological and other change to be constant in our industry.

The pharmaceutical industry has experienced rapid and significant technological change as well as structural changes, such as those brought about by changes in heath care delivery or in product distribution. We expect that pharmaceutical technology will continue to develop and change rapidly, and our future success will depend, in large part, on our ability to develop and maintain a competitive position. Technological development by others may result in our products becoming obsolete before they are marketed or before we recover a significant portion of the development and commercialization expenses incurred with respect to such products. In addition, alternative therapies, new medical treatments, or changes in the manner in which health care is delivered or products provided could alter existing treatment regimes or health care practices, and thereby reduce the need for one or more of our products, which would adversely affect our business and our prospects.

We face substantial product liability and insurance risks.

Testing and selling health care products entails the inherent risk of product liability claims. The cost of product liability insurance coverage has increased and is likely to continue to increase in the future. Substantial increases in insurance premium costs in many cases have rendered coverage economically impractical. We currently carry product liability coverage in the aggregate amount of $30 million for all claims made in any policy year. Although to date we have not been the subject of any product liability or other claims, we cannot assure you that we will be able to maintain product liability insurance on acceptable terms or that our insurance will provide adequate coverage against potential claims. A successful uninsured product liability or other claim against us could have a material adverse effect on our business and prospects.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Exposure

We manage our investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain a high degree of liquidity to meet operating needs, and obtain competitive returns subject to prevailing market conditions. Investments are made with average maturities matching the liquidity needs of the Company. These types of investments are subject to risk of default, changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market interest rates increase. Due to the conservative nature of our investments and relatively short effective maturities of the debt instruments, we believe interest rate risk is mitigated. Our investment policy specifies the credit quality standards for our investments and limits the amount of exposure from any single issue, issuer or type of investment.

Foreign Currency Exposure

Most of our revenue, expenses and capital spending are transacted in U.S. dollars. Our foreign currency transactions are translated into U.S. dollars at prevailing rates. Gains or losses resulting from foreign currency transactions are included in current period income or loss as incurred. Currently, all material transactions are denominated in U.S. dollars, and we have not entered into any material transactions that are denominated in foreign currencies.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements of the Company as of December 31, 2004 and 2003 and for the three years ended December 31, 2004 begin on page F-1 of this Annual Report. Quarterly financial information about the Company for the years ended December 31, 2004 and 2003 is provided in Note 15 to the Company s financial statements included with this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Under the supervision and with the participation of the Company s management, including its principal executive officer and principal financial officer, the Company has evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the Exchange Act)). Based upon this evaluation, the principal executive officer and principal financial officer have concluded that, as of the end of the period covered by this report, the Company s disclosure controls and procedures were effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

During the most recently completed fiscal quarter, there was no change made in the Company s internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

The annual report of the Company s management on internal control over financial reporting is provided on page F-2. The attestation report of Ernst & Young LLP, the Company s independent accountants, regarding the Company s internal control over financial reporting is provided on page F-3.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Directors of the Registrant.

The information required by this item is incorporated by reference from the information under the caption Election of Directors contained in the Company s Proxy Statement to be filed with the Securities and Exchange Commission in connection with the solicitation of proxies for the Company s Annual Meeting of Shareholders to be held on or about June 15, 2005 (the Proxy Statement). The Company has made no changes to the procedures by which shareholders can recommend nominees.

Executive Officers of the Registrant.

Information concerning Executive Officers of the Company is included in this Annual Report in Item 4A under the caption Executive Officers of the Registrant .

Identification of the Audit Committee; Audit Committee Financial Expert.

The information required in this item is incorporated by reference from the information under the caption Board of Directors Meetings and Committees in the Company s Proxy Statement.

Compliance with 16(a) of the Securities Exchange Act of 1934.

The information required by this item is incorporated by reference from the information under the caption Section 16(a) Beneficial Ownership Reporting Compliance contained in the Proxy Statement.

Code of Ethics.

The information required by this item is incorporated by reference from the information under the caption Ethics Policy contained in the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the information under the caption Executive Compensation (except for the information under Report of the Compensation Committee and Comparative Stock Performance), Compensation of Directors , and Compensation Committee Interlocks and Insider Participation contained in the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the information under the caption Security Ownership of Certain Beneficial Owners and Management contained in the Proxy Statement.

Equity Compensation Plan Information

The following table summarizes information as of December 31, 2004 relating to equity compensation plans of the Company pursuant to which grants of options, restricted stock, or other rights to acquire shares may be granted from time to time. As of December 31, 2004, the Company had no equity compensation plans that were not approved by security holders.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)	Weighted-average exercise price of outstanding options, warrants and rights (2)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (1)) (3)
Equity compensation plans approved by security holders	1,744,040	$ 9.37	1,999,930

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference from the information contained under the caption Certain Relationships and Related Transactions contained in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required in this item is incorporated by reference from the information under the caption Audit Fees , Audit-Related Fees , Tax Fees , All Other Fees and Pre-Approval Policy in the Company s Proxy Statement.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Financial Statements

Description

Audited Financial Statements:
Report of Independent Auditors
Management Annual Report on Internal Control over Financial Reporting
Attestation Report of Independent Registered Accounting Firm on Internal Control over Financial Reporting
Balance Sheets
Statements of Operations
Statements of Cash Flows
Statement of Changes in Shareholders Equity
Notes to Financial Statements

Financial Statement Schedules

The following financial statement schedule should be read in conjunction with the Audited Financial Statements referred to above. Financial statement schedules not included in the Form 10-K have been omitted because they are not applicable or the required information is shown in the Audited Financial Statements or Notes thereto.

Description

Schedule II Valuation and Qualifying Accounts: Years Ended December 31, 2004, 2003 and 2002

Listing of Exhibits

Exhibit Number	**Description**	**Method of Filing**
3.1	Certificate of Incorporation	(2)
3.2	Bylaws of OMI, as amended	(1)
10.01	Distribution and Spin-off Agreement between OMI and Chronimed effective July 2, 1994	(3)
10.02	Sublicense Agreement regarding 4-Methylpyrazole between Chronimed and Mericon Investment Group, Inc. dated December 17, 1993	(4)
10.03	Employment Agreement between OMI and John Howell Bullion dated October 29, 1999	(7)
10.04	Assumption Agreement and Consent to Assignment regarding 4-Methylpyrazole between OMI and Mericon Investment Group, Inc. dated October 5, 1994	(5)
10.05	License Agreement regarding 4-Methylpyrazole between Kenneth McMartin and Mericon Investment Group, Inc. dated July 6, 1993	(6)

10.06	IRS tax qualification letter dated January 10, 1996 regarding the favorable determination of the tax status of the OMI 401(k) Savings Plan	(8)

Exhibit Number	Description	Method of Filing
10.07	Stock Purchase Agreement between OMI and UBS Capital II LLC dated July 23, 1998.	(9)
10.08	Common Stock Purchase Warrant between OMI and R.J. Steichen dated January 1, 1999.	(10)
10.09	Purchase Agreement and Letter of Intent between OMI and Caduceus Capital Trust, Caduceus Capital II L.P., PaineWebber Eucalyptus Fund LLC, and PaineWebber Eucalyptus Fund Ltd.	(11)
10.10	Purchase Agreement and Letter of Intent between DG LUX LACUNA APO BIOTECH FUND	(12)
10.11	Stock Purchase Agreement between OMI and UBS Capital II LLC dated August 2, 1999	(13)
10.12	Warrant to purchase shares of Series C Convertible Preferred Stock or Series D Non-Voting Preferred Stock	(14)
10.13	Warrant to purchase shares Series D Non-Voting Preferred Stock	(15)
10.14	Form of Change in Control Agreement to be entered into between the OMI and Certain Executives	(16)
10.15	License agreement for Xyrem between OMI and Celltech Pharmaceuticals plc dated October 30, 2003	(17)
10.16	Distribution and Services Agreement between OMI and Express Script Specialty Distribution Services, Inc. date July 29, 2002	(18)
10.17	OMI 1994 Stock Option Plan	(1)
10.18	OMI Employee Incentive Stock Option Agreement 1994 Stock Option Plan	(1)
10.19	OMI Non-Incentive Stock Option Agreement 1994 Stock Option Plan	(1)
10.20	OMI Non-Incentive Stock Option Agreement 1994 Stock Option Plan	(1)
10.21	OMI 2004 Stock Incentive Plan	(19)
10.22	OMI Non-Incentive Stock Option Agreement 2004 Stock Incentive Plan	Filed herewith
23.1	Consent of Ernst & Young LLP	Filed herewith
24	Power of Attorney	(17)
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith

(1) Incorporated by reference to the corresponding exhibit numbers in OMI s Registration Statement on Form 10 filed on August 31, 1994, Commission File No. 0-24760.

(2) Incorporated by reference to the corresponding exhibit number in OMI s Registration Statement on Form S-3 filed on February 5, 2002, Commission File No. 333-82222.

(3) Incorporated by reference to Exhibit 10.3 to OMI s Registration Statement on Form 10 filed on August 31, 1994, Commission File No. 0-24760.

(4) Incorporated by reference to Exhibit 10.9 to OMI s Registration Statement on Form 10 filed on August 31, 1994, Commission File No. 0-24760.

(5) Incorporated by reference to Exhibit 10.14 to OMI s Registration Statement on Form S-1 filed on March 3, 1995, Commission File No. 033-89916.

(6) Incorporated by reference to Exhibit 10.15 to OMI s Registration Statement on Form S-1 filed on March 3, 1995, Commission File No. 033-89916.

(7) Incorporated by reference to Exhibit 10.11.1 to OMI s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-24760.

(8) Incorporated by reference to Exhibit 10.36 to OMI s Registration Statement on Form S-1 filed on March 11, 1996, Commission File No. 333-02200.

(9) Incorporated by reference to Exhibit 10.48 to OMI s Quarterly Report on Form 10-Q for the quarter ended June 30, 1998, Commission File No. 0-24760.

(10) Incorporated by reference to Exhibit 10.52 to OMI s Annual Report on Form 10-K for the year ended December 31, 1998, Commission File No. 0-24760.

(11) Incorporated by reference to Exhibit 10.53 to OMI s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-24760.

(12) Incorporated by reference to Exhibit 10.54 to OMI s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-24760.
(13) Incorporated by reference to Exhibit 10.55 to OMI s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, Commission File No. 0-24760.
(14) Incorporated by reference to Exhibit 10.57 to OMI s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, Commission File No. 0-24760.
(15) Incorporated by reference to Exhibit 10.58 to OMI s Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, Commission File No. 0-24760.
(16) Incorporated by reference to Exhibit 10.59 to OMI s Annual Report on Form 10-K for the year ended December 31, 1999, Commission File No. 0-24760.
(17) Incorporated by reference to Exhibit 10.15 to OMI s Amendment No.4 to Annual Report on Form 10-K for the year ended December 31, 2003, Commission File No. 0-24760.
(18) Incorporated by reference to Exhibit 10.16 to OMI s Amendment No.4 to Annual Report on Form 10-K for the year ended December 31, 2003, Commission File No. 0-24760.
(19) Incorporated by reference to Appendix B to OMI s Definitive Proxy Statement as filed on April 29, 2004, Commission File No. 0-24760.

* Confidential treatment has been requested for portions of this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934 as amended. The confidential portions have been deleted and filed separately with the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, on the 15th day of March, 2005.

ORPHAN MEDICAL, INC.

By: /s/ John Howell Bullion

John Howell Bullion
Chief Executive Officer

/s/ Timothy G. McGrath

Timothy G. McGrath
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 15, 2005.

SIGNATURE	TITLE
/s/ John Howell Bullion John Howell Bullion	Chief Executive Officer (Principal Executive Officer) and a Director
* Michael Greene	Director
* Julius A. Vida	Director
* Farah Champsi	Director
* William M. Wardell Ph.D., M.D.	Director
* Thomas King	Director
/s/ Timothy G. McGrath Timothy G. McGrath	Chief Financial Officer (Principal Financial Officer and Accounting Officer)

By: /s/ John Howell Bullion
John Howell Bullion, Attorney-In-Fact

* John Howell Bullion, pursuant to the Powers of Attorney executed by each of the directors above whose name is marked by a * , by signing his name hereto, does hereby sign and execute this Annual Report on behalf of each of the directors in the capacities in which the name of each appears above.

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders

Orphan Medical, Inc.

We have audited the accompanying balance sheets of Orphan Medical, Inc. as of December 31, 2004 and 2003, and the related statements of operations, changes in shareholders equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in Item 15(a)(2). These financial statements and schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements and 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Orphan Medical, Inc. at December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the financial statement schedule referred to above, when considered in relation to the basic financial statements taken as a whole, presents 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 Orphan Medical, 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 and our report dated March 14, 2005 expressed an unqualified opinion thereon.

Minneapolis, Minnesota
March 14, 2005

/s/ Ernst & Young LLP

REPORT OF MANAGEMENT

Management's Report on the Financial Statements

Responsibility for the financial statements and other information presented throughout the Annual Report on Form 10-K rests with the management of Orphan Medical, Inc. The Company believes that the financial statements have been prepared in conformity with accounting principles generally accepted in the United States and present the substance of transactions based on the circumstances and management's best estimates and judgment.

The Board of Directors of the Company has an Audit Committee composed of directors who are independent of Orphan Medical, Inc. The commitee meets periodically with management, the internal auditors and the independent accountants to consider audit results and to discuss internal accounting control, auditing and financial reporting matters.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining an adequate system of internal control over financial reporting as defined by Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. The Company's system of internal controls is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of publicly filed financial statements in accordance with accounting principles generally accepted in the United States.

To test compliance, the Company carries out an extensive audit program. This program includes a review for compliance with written policies and procedures and a comprehensive review of the adequacy and effectiveness of the internal control system. Although control procedures are designed and tested, it must be recognized that there are limits inherent in all systems of internal control and, therefore, errors and irregularities may nevertheless occur. Also, estimates and judgments are required to assess and balance the relative cost and expected benefits of the controls. Projection 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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in its Internal Control-Integrated Framework. Based on our assessment and those criteria, management believes that the Company designed and maintained effective internal control over financial reporting as of December 31, 2004.

The Company's independent accountants, Ernst & Young LLP, have been engaged to render an independent professional opinion on the financial statements and issue an attestation report on management's assessment of the Company's system of internal control over financial reporting. Their opinion on the financial statements appears on page F-1 and their attestation on the system of internal controls over financial reporting appears on page F-3.

Minneapolis, Minnesota

March 14, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders

Orphan Medical, Inc.

We have audited management s assessment, included in the accompanying Management's Report on Internal Controls Over Financial Reporting, that Orphan Medical, 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 (the COSO criteria). Orphan Medical, 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 Orphan Medical, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Orphan Medical, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Orphan Medical, Inc. as of December 31, 2004 and 2003, and the related statements of operations, changes in shareholders equity, and cash flows for each of the three years in the period ended December 31, 2004 of Orphan Medical, Inc., and our report dated March 14, 2005 expressed an unqualified opinion thereon.

Minneapolis, Minnesota
March 14, 2005

/s/ Ernst & Young LLP

Orphan Medical, Inc.

Balance Sheets

(In thousands except share and per share data)

	December 31, 2004	December 31, 2003
Assets		
Current assets:		
Cash and cash equivalents	$ 12,709	$ 23,285
Restricted cash	125	128
Accounts receivable, less allowance for doubtful accounts of $25 and $112, respectively	2,303	2,552
Inventories	2,482	1,696
Prepaid expenses and other	549	907
Total current assets	18,168	28,568
Office equipment and software	2,301	2,136
Accumulated depreciation	(1,837)	(1,382)
	464	754
Total assets	$ 18,632	$ 29,322
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 2,014	$ 2,923
Accrued royalties	97	141
Accrued compensation	1,091	881
Deferred revenue	1,250	2,500
Accrued expenses	3,347	2,319
Total current liabilities	7,799	8,764
Capital lease obligation-less current maturities	43	62
Commitments		
Shareholders equity:		
Senior Convertible Preferred Stock, $.01 par value; 14,000 shares authorized; 8,706 shares issued and outstanding; liquidation preference of $8,706		
Series B Convertible Preferred Stock, $.01 par value; 5,000 shares authorized; 4,259 and 3,957 shares issued and outstanding; liquidation preference of $4,259 and $3,957		
Series C Convertible Preferred Stock, $.01 par value; 4,000 shares authorized; 0 shares issued and outstanding		
Series D Convertible Preferred Stock, $.01 par value; 1,500,000 shares authorized; 0 shares issued and outstanding		
Common stock, $.01 par value; 23,477,000 shares authorized; 11,430,066 and 10,747,656 issued and outstanding	114	107
Additional paid-in capital	81,006	76,714
Accumulated deficit	(70,330)	(56,325)
Total shareholders equity	10,790	20,496
Total liabilities and shareholders equity	$ 18,632	$ 29,322

See accompanying notes.

Orphan Medical, Inc.

Statements of Operations

(In thousands except share and per share data)

	For the Year Ended December 31,		
	2004	**2003**	**2002**
Product revenues, net	$ 21,337	$ 15,526	$ 16,130
Licensing and royalty revenue	2,431		
Total revenue	23,768	15,526	16,130
Operating expenses:			
Cost of product revenues	2,952	2,415	2,191
Product development	13,221	10,805	8,713
Sales and marketing	16,583	16,361	12,776
General and administrative	4,245	4,773	4,106
Total operating expenses	37,001	34,354	27,786
Loss from operations	(13,233)	(18,828)	(11,656)
Interest income	208	135	263
Interest expense	(22)	(119)	(8)
Other income, net		51	
Gain on divestment of products		30,267	
Net (loss) income before taxes	(13,047)	11,506	(11,401)
Income tax expense		509	
Net (loss) income	(13,047)	10,997	(11,401)
Less: Preferred stock dividends	967	945	922
Net (loss) income applicable to common shareholders	$ (14,014)	$ 10,052	$ (12,323)
(Loss) income per common share applicable to common shareholders			
Basic	$ (1.26)	$ 0.95	$ (1.19)
Diluted	$ (1.26)	$ 0.85	$ (1.19)
Weighted average number of shares outstanding			
Basic	11,087,324	10,612,965	10,349,679
Diluted	11,087,324	12,966,954	10,349,679

See accompanying notes.

Orphan Medical, Inc.

Statements of Cash Flows

(In thousands)

	For the Year Ended December 31,		
	2004	**2003**	**2002**
Operating activities			
Net (loss) income	$ (13,047)	$ 10,997	$ (11,401)
Adjustments to reconcile net (loss) income to net cash used in operating activities:			
Gain on divestment of products		(30,267)	
Depreciation	455	441	268
Amortization of warrants	21	65	
Issuance of common stock for charitable contribution		115	
Changes in operating assets and liabilities:			
Accounts receivable and other current assets	607	(668)	(1,082)
Inventories	(786)	324	(778)
Accounts payable and accrued expenses	284	952	228
Deferred revenue	(1,250)	2,500	1,117
Net cash used in operating activities	(13,716)	(15,541)	(11,648)
Investing activities			
Purchase of office equipment and software	(165)	(39)	(947)
Decrease (increase) in restricted cash	3	123	(251)
Net proceeds from divestment of products		30,267	
Net cash (used in) provided by investing activities	(162)	30,351	(1,198)
Financing activities			
Offering costs from December 2001 private offering			(8)
Proceeds from Employee Stock Purchase Plan	59	48	61
Proceeds from stock options and warrants	3,262	1,522	704
Principal payments on capital lease	(18)	(15)	
Preferred stock dividend	(1)	(1)	(1)
Net cash provided by financing activities	3,302	1,554	756
Net (decrease) increase in cash and cash equivalents	(10,576)	16,364	(12,090)
Cash and cash equivalents at beginning of year	23,285	6,921	19,011
Cash and cash equivalents at end of year	$ 12,709	$ 23,285	$ 6,921
Schedule of non-cash investing and financing activities			
Issuance of preferred stock dividends	$ 956	$ 933	$ 912
Capital lease for equipment			93
Supplemental disclosures of cash flow information			
Income taxes paid	262	410	
Interest paid	8	53	8

See accompanying notes.

Orphan Medical, Inc.

Statement of Changes in Shareholders Equity

(In thousands except share data)

	Preferred Stock		Common Stock		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2001	12,123	$	10,263,961	$ 103	$ 72,364	$ (54,073)	$ 18,394
Offering costs from December 2001 private offering					(8)		(8)
Options and warrants exercised			125,950	1	703		704
Proceeds from Employee Stock Purchase Plan			8,338		62		62
Preferred stock dividends	260		62,034	1	912	(914)	(1)
Net loss						(11,401)	(11,401)
Balance at December 31, 2002	12,383		10,460,283	105	74,033	(66,388)	7,750
Options and warrants exercised			205,278	2	1,520		1,522
Proceeds from Employee Stock Purchase Plan			6,282		48		48
Preferred stock dividends	280		65,813		933	(934)	(1)
Issuance of common stock for charitable contribution			10,000		115		115
Warrants issued with line of credit					65		65
Net income						10,997	10,997
Balance at December 31, 2003	12,663		10,747,656	107	76,714	(56,325)	20,496
Options and warrants exercised			603,913	6	3,256		3,262
Proceeds from Employee Stock Purchase Plan			7,277		59		59
Preferred stock dividends	302		71,220	1	956	(958)	(1)
Amortization of discount on warrants					21		21
Net loss						(13,047)	(13,047)
Balance at December 31, 2004	12,965	$	11,430,066	$ 114	$ 81,006	$ (70,330)	$ 10,790

See accompanying notes.

Orphan Medical, Inc.

Notes to Financial Statements

December 31, 2004

(Dollars in thousands)

1. Business Activity

Orphan Medical, Inc. (the Company) acquires, develops, and markets products of high medical value intended to treat sleep disorders, pain and other central nervous system (CNS) disorders that are addressed by physician specialists. A drug has high medical value if it offers a major improvement in the safety or efficacy of patient treatment and has no substantially equivalent substitute. The Company has had six pharmaceutical products approved for marketing by the United States Food and Drug Administration (FDA). Three of these products have been divested, and the Company is now focusing its resources on Xyrem® (sodium oxybate) oral solution, a medication approved for cataplexy, a significant and debilitating symptom of narcolepsy. The Company recently submitted a Supplemental New Drug Application for the expansion of the labeled indications for Xyrem including excessive daytime sleepiness and fragmented nighttime sleep. The Company is conducting a clinical trial to assess Xyrem in treating fibromyalgia. Enrollment in the trial is complete and data is expected to be available in mid summer 2005. A new compound, Butamben (butyl-p-aminobenzoate) suspension for injection, is being evaluated for development as a treatment of pain. The Company is seeking other approved or development-stage products in the specialty CNS areas it serves. The Company also markets Antizol® (fomepizole) Injection, as a treatment for suspected or confirmed ethylene glycol or methanol poisonings and Cystadane® (betraine anhydrous for oral solution) for the treatment of homocystimuria, an inherited metabolic disease.

The Company has experienced losses from operations since inception and has an accumulated deficit of $70.3 million at December 31, 2004. Our continued viability depends on our ability to generate sufficient cash from operations or seek others sources of working capital. We incurred a net loss applicable to common shareholders of $14.0 million for the year ended December 31, 2004. We expect a loss applicable to common shareholders in fiscal 2005 as well. The Company anticipates our current cash balance and expected cash inflows from revenue and milestone payments, along with cash available from the Company s credit facility, will be adequate to fund operations through the next year. In the event that revenue is lower than anticipated, management believes it can reduce operating expenses, including product development projects and selling and marketing programs, to manage its cash flow.

2. Summary of Significant Accounting Policies

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 amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Revenue Recognition

Sales for all products, except Xyrem® (sodium oxybate) oral solution, are recognized at the time a product is shipped to the Company s customers and are recorded net of reserves for discounts for prompt payment. Sales of Xyrem are recognized at the time product is shipped from

the specialty pharmacy to the patient and are recorded net of discounts for prompt payment. Except for Xyrem, the Company is obligated to accept, for exchange only, all domestic customers products that have reached their expiration date, which range from three to five years depending on the product. The Company is not obligated to accept exchange of outdated product from its international distribution partners. The Company establishes a reserve for the estimated cost of the exchanges. Management bases this reserve on historical experience and these estimates are subject to change.

Deferred revenue represents the initial payment received by the Company per the terms of the Company s license agreement for Xyrem with Celltech Pharmaceuticals, a division of Celltech Group plc, which has subsequently been acquired by UCB Pharma. The Company is recognizing this payment ratably over the expected regulatory approval period, which is 18 months. Future milestone payments are expected to be recognized as earned based on the achievement of the milestone as indicated in the license agreement. See Note 5 for additional details regarding the UCB Pharma transaction.

Cost of Sales

Cost of sales includes primarily third-party manufacturing and distribution costs and royalties due to third parties on sales. The Company makes royalty payments of 7% on one of its products and 1% on a second product, which ended during the third quarter of 2004. Royalty expense for prior years included royalty expenses for two products that were divested in 2003. Royalty expense was $744, $663, and $854, for the years ended December 31, 2004, 2003 and 2002, respectively.

Product Development Costs

All product development costs are charged to operations as incurred. Product development costs consist principally of preclinical and clinical testing costs, certain salary and related expenses, bulk drug and drug product costs incurred in support of clinical testing and for validation lots required by the FDA, toxicology studies and various technical consulting costs.

Cash Equivalents

The Company considers all highly liquid investments with remaining maturities of 90 days or less when purchased to be cash equivalents. Cash equivalents are carried at cost plus accrued interest, which approximates market value.

Concentration of Credit Risk

The Company invests its excess cash in U.S. government agency securities, investment grade commercial paper, and other money market instruments and has established guidelines relative to diversification and maturities in an effort to maintain safety and liquidity. These guidelines are periodically reviewed to take advantage of trends in yields and interest rates. The Company has not experienced any significant losses on its cash equivalents.

There is a concentration of sales to larger medical wholesalers and distributors. The Company performs periodic credit evaluations of its customers financial condition. Domestic receivables are due within 30 days of the invoice date. International receivables are generally due within 60 to 90 days of invoice date. Credit losses relating to customers have not been material since the Company s inception.

Significant Customers

The following is a summary of sales to significant customers that individually account for more than 10% of net sales.

	Year ended December 31,		
	2004	2003	2002
Cardinal Health, Inc.	15%	23%	24%
AmerisourceBergen Corporation	12	23	20
McKesson Corporation	10	15	16
Specialty Distribution Services (1)	48		

(1) Specialty Distribution Services is the Company s sole distributor for Xyrem domestically.

Inventories

Inventories are valued at the lower of cost or market determined using the first-in, first-out (FIFO) method. The Company s policy is to establish an excess and obsolete reserve for its products in excess of the expected demand for such products. Inventory used in clinical trials is expensed at the time of production and included in the reserve until used. The reserve at December 31, 2004 and 2003 was $251 and $290, respectively.

	December 31,	
	2004	2003
Raw materials and packaging	$ 795	$ 690
Finished goods	1,687	1,006
	$ 2,482	$ 1,696

Office Equipment and Software

The Company has contractual arrangements with third parties for the manufacture of its products and does not currently have a material investment in manufacturing or packaging equipment. Office equipment and software are stated at cost. Maintenance and repairs are expensed as incurred. Depreciation is computed using the straight-line method over the assets estimated useful lives of three to seven years.

Long-Lived Assets

The Company performs reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss would be recognized when the estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount.

Recent Accounting Pronouncements

In December 2004, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 123(R), Share-Based Payment, which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation and supersedes APB 25 Accounting for Stock Issued to Employees . SFAS 123(R) requires companies to recognize the cost of employee services received in exchange for awards of equity instruments, based on the grant date fair value of those awards, in the financial statements. The effective date of SFAS No. 123(R) is the first reporting period beginning after June 15, 2005, although early adoption is allowed. SFAS No. 123(R) permits companies to adopt its requirements using either a modified prospective method or a modified retrospective method. Under the modified prospective method, compensation cost is recognized in the financial statements beginning with the effective date, based on the requirements of SFAS No. 123(R) for all share-based payments granted after that date, and based on the requirements of SFAS No. 123 for all unvested awards granted prior to the effective date of SFAS 123(R). Under the modified retrospective method, the requirements are the same as under the modified prospective method, but also permits entities to restate financial statements of previous periods based on proforma disclosures made in accordance with SFAS No. 123. The Company expects to adopt the modified prospective method under SFAS No. 123(R) effective January 1, 2005. Based on the balance of unvested stock options outstanding at December 31, 2004, the adoption of SFAS No. 123(R) will result in approximately $2.2 million of expense in 2005.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity . SFAS No. 150 establishes standards for how an issuer classifies and measures in its statement of financial position certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances) because that financial instrument embodies an obligation of the issuer. This statement is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The Company adopted SFAS No. 150 as of July 1, 2003. The adoption of SFAS No. 150 did not have a material effect on our results of operations, cash flows or financial position.

In January 2003, the FASB issued Financial Interpretation No. 46, or FIN 46, Consolidation of Variable Interest Entities, and in December 2003, issued a revision to FIN 46 (FIN 46R). FIN 46 requires that if an entity has a controlling financial interest in a variable interest entity, the assets, liabilities and results of activities of the variable interest entity should be included in the consolidated financial statements of the entity. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period ending after December 15, 2003. The adoption of FIN 46 did not have a material effect on our results of operations, cash flows or financial position.

Stock-Based Compensation

At December 31, 2004, the Company has a stock-based employee compensation plan, which is described more fully in Note 10. The Company accounts for this plan under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees , and related interpretations. No stock-based compensation cost is reflected in the net (loss) income in 2004 and 2003, as all options granted under this plan had an exercise price equal to market value of the underlying common stock on the date of grant. The following table illustrates the effect on net (loss) income and net (loss) income per share if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation , to stock-based employee compensation.

	For the year ended December 31,		
	2004	2003	2002
Net (loss) income, as reported	$ (14,014)	$ 10,052	$ (12,323)
Deduct total stock-based employee compensation expense determined under fair value-based method for all awards	(3,108)	(2,375)	(1,976)
Pro forma net (loss) income	$ (17,122)	$ 7,677	$ (14,299)
(Loss) income per share as reported			
Basic	$ (1.26)	$ 0.95	$ (1.19)
Diluted	$ (1.26)	$ 0.85	$ (1.19)
(Loss) income per share as proforma			
Basic	$ (1.54)	$ 0.72	$ (1.38)
Diluted	$ (1.54)	$ 0.70	$ (1.38)

Income Taxes

The Company accounts for income taxes using the liability method. Deferred income taxes are provided for temporary differences between the financial reporting and tax bases of assets and liabilities.

3. (Loss) Income per Share

(Loss) income per share is computed in accordance with SFAS No. 128, Earnings per Share . Basic (loss) income per share is computed based on the weighted average number of common shares outstanding during the period. Diluted income per share is computed based on the weighted average shares outstanding and the dilutive impact of common stock equivalents outstanding during the period. The dilutive effect of employee stock options and warrants is measured using the treasury stock method. The dilutive effect of both series of outstanding convertible preferred stock is computed using the if-converted method. Common stock equivalents are not included in periods where there is a loss, as they are antidilutive and therefore basic and diluted loss per share are the same in the loss periods. The following is a reconciliation of net (loss) income and weighted average common shares outstanding for purposes of calculating basic and diluted (loss) income per share:

	For the year ended December 31,		
	2004	2003	2002
Numerator			
Numerator for basic (loss) income per share net (loss) income applicable to common shareholders	$ (14,014)	$ 10,052	$ (12,323)
Add back to effect assumed conversions:			
Preferred stock dividends		945	

Numerator for diluted (loss) income per share	$ (14,014)	$ 10,997	$ (12,323)
Denominator			
Denominator for basic (loss) income per share weighted average shares	11,087,324	10,612,965	10,349,679
Effect of dilutive securities:			
Convertible preferred shares		1,663,867	
Stock options		431,456	
Warrants		258,666	
Denominator for diluted (loss) income per share weighted average shares and assumed conversions	11,087,324	12,966,954	10,349,679
Basic (loss) income per share	$ (1.26)	$ 0.95	$ (1.19)
Diluted (loss) income per share	$ (1.26)	$ 0.85	$ (1.19)

Employee stock options of 1,744,040, 719,858, and 1,997,478 have been excluded from the diluted (loss) income per share calculations for 2004, 2003 and 2002, respectively, because the effect would be antidilutive. All warrants were included in the diluted income per share calculation for 2003. Warrants of 612,738 and 602,738 have been excluded from the diluted (loss) per share calculation for 2004 and 2002 because the effect would be antidilutive. All outstanding convertible preferred stock was included in the income per share calculation for 2003. All outstanding convertible preferred stock was excluded from the (loss) per share calculations for 2004 and 2002 because the effect would be antidilutive.

4. Divestment of products

On June 10, 2003, the Company announced the disposition of Busulfex(R) (busulfan) Injection to ESP Pharma, Inc. for $29.3 million plus the book value of inventory, approximately $0.2 million. The Company announced the sale of the product Sucraid(R) (sacrosidase) oral solution to a specialty pharmaceutical company on May 6, 2003 for $1.5 million. The Company also divested a third product, Elliotts B Solution(R) to another company for proceeds that were not material. Proceeds from these dispositions will be used for further development and marketing of Xyrem(R) (sodium oxybate) oral solution and for the creation of a stronger presence in the sleep and central nervous system (CNS) markets. The gain from these transactions, $30.3 million, is reflected in the Statement of Operations.

5. Product License

In October 2003, the Company announced that it had licensed European sales and marketing rights for Xyrem® (sodium oxybate) oral solution to UCB Pharma (formerly Celltech Pharmaceuticals). Under the terms of the ten-year agreement, UCB Pharma will be responsible for the registration, sales and marketing of Xyrem in Europe. UCB Pharma has made an initial payment of $2.5 million to Orphan Medical and will make further payments of up to $6 million tied to product development milestones and up to $6 million tied to sales-related milestones. UCB Pharma will also pay Orphan Medical a royalty on sales of the product which are expected to begin no earlier than 2005. The licensing agreement includes the use of Xyrem in the treatment of certain indications of narcolepsy and provides UCB Pharma with rights to negotiate in regard to other potential future indications including fibromyalgia syndrome.

6. Leases

The Company has an operating lease for office space that expires on October 31, 2007. This lease is cancelable on July 1, 2005 for a $21 cancellation fee and July 1, 2006 for an $11 cancellation fee. The Company also has operating leases for certain office equipment expiring at various times through October 2007. The Company also leases vehicles for the Company s sales force. The term of this lease runs through October 2007. The number of vehicles leased may increase as the sales force expands. The vehicle lease requires the Company to maintain $125 in an account securing a letter of credit. This cash has been disclosed as restricted in the balance sheet. In December 2002, the Company entered into a capital lease for phone equipment that expires in December 2007. The lease contains a bargain purchase option. Amortization expense for the equipment under the capital lease is included in depreciation expense.

Future minimum lease payments, including current real estate taxes and operating expenses under the facility lease, the auto lease, and the equipment leases are as follows:

	Capital Lease	Operating Leases
2005	$ 24	$ 558
2006	24	406
2007	23	293
Minimum lease payments	71	$ 1,257

Amounts representing interest		(10)
Present value of net minimum		
lease payments		61
Less current maturities		(18)
	$	43

Total rent expense was approximately $318, $345 and $476, for the years ended December 31, 2004, 2003 and 2002, respectively.

7. Borrowings

The Company extended its line of credit and term loan facility with a commercial bank on September 30, 2004. The line of credit facility had an expiration of September 29, 2005 and included a borrowing base equal to 80% of eligible accounts receivable up to a maximum amount of $4.5 million. Certain other assets had also been pledged as collateral for that facility. Each draw of the term loan has a term of one-year and can be used specifically for equipment purchases not to exceed $1.0 million. The interest rate for both loans was equal to two points over the bank s prime rate, with a minimum rate of 6.75%. The Company was also subject to certain other requirements during the term of that agreement, including (a) minimum monthly net tangible equity of $5.0 million plus 50 percent of the proceeds of any equity securities or subordinated debt offering and (b) maximum monthly operating loss of $1.75 million for October December 2004, $1.0 million for January June 2005, and $1.25 million for July - September 2005. The Company was in compliance with its covenants as of December 31, 2004. The Company had the availability to borrow $1.3 million as of December 31, 2004. The Company had not borrowed under these loans through December 31, 2004.

On February 4, 2005, the Company extended its line of credit and term loan facility to January 1, 2006. The line of credit facility includes a borrowing base equal to 80% of eligible accounts receivable up to a maximum amount of $4.5 million. Certain other assets have also been pledged as collateral for this facility. Each draw of the term loan has a term of one-year and is to be used specifically for equipment purchases not to exceed $1.0 million. The term loan is not available until the Company receives net proceeds of at least $7.5 million in an equity financing transaction. The interest rate for both loans is equal to two points over the bank s prime rate, with a minimum rate of 6.75%. The Company is also subject to certain other requirements during the term of the agreement, including (a) a minimum monthly net tangible equity requirement and (b) maximum monthly operating loss. The minimum net equity amount for January 2005 through May 31, 2005 is $5.0 million plus 50% of any additional equity securities or subordinated debt offering. The minimum net equity amount from June 2005 to January 1, 2006 is $4.5 million plus 50% of additional equity securities or subordinated debt offering. The maximum monthly operating loss is $1.25 million for January 2005, $1.75 million for February March 2005, $1.25 million for April June 2005, and $1.0 million for July January 1, 2006.

8. Income Taxes

The provision for income taxes consists of the following:

	2004	2003	2002
Current			
Federal	$	$ 335	$
State		174	
Deferred			
Federal	(6,967)	1,456	(4,107)
State	(710)	116	(357)
Change in valuation allowance	7,677	(1,572)	4,464
	$	$ 509	$

No current income taxes have been provided for the years ended December 31, 2004 and 2002 as the Company had a loss for both financial reporting and tax purposes. The Company provided tax expense of $509 in 2003. The 2003 expense is the alternative minimum tax incurred as a result of the gain on the divestment of three products in fiscal 2003.

The difference between the provision for taxes on income and the amount computed by applying the federal statutory income tax rate to income before taxes is explained below:

	2004	2003	2002
Income tax (benefit) provision at federal statutory rate	$ (4,436)	$ 3,912	$ (3,876)
State taxes, net of federal benefit	(783)	372	(368)
Change in valuation allowance	7,677	(2,019)	5,142
R&D and orphan drug credits	(2,344)	(1,782)	(920)
Other	(114)	26	22
	$	$ 509	$

As of December 31, 2004, the Company had federal net operating loss (NOL) carryforwards of approximately $48,184 and various state NOL carryforwards of approximately $58,948, contribution carryforwards of approximately $111, credit for increasing research activities (the R&D credit) carryforwards and orphan drug credit carryforwards of approximately $16,857, and an alternative minimum tax credit of approximately $402, available to reduce its future tax liabilities. The NOL, R&D and orphan drug credits expire in 2010, contribution carryforwards expire in 2009 and the alternative minimum tax credit does not expire.

Significant components of the Company s net deferred tax assets are as follows:

	December 31, 2004	December 31, 2003
Deferred tax assets:		
Net operating loss carryforwards	$ 19,920	$ 15,074
Contribution carryforwards	44	247
R&D and orphan drug credit carryforwards	17,519	13,917
Alternative minimum tax credit	402	509
Deferred revenue	500	1,000
Inventory reserves	100	116
All other reserves	407	142
Deferred tax liabilities:		
Depreciation	(79)	(119)
Valuation allowance for deferred tax assets	(38,813)	(30,886)
Net deferred tax assets	$	$

The Company has recorded a valuation allowance to reduce the carrying value of its net deferred tax asset to an amount that is more likely than not to be realized.

As a result of the 1995 public stock offering, the Company exceeded the limits allowable under Section 382 of the Internal Revenue Code related to changes in ownership percentage which governs future utilization of NOL, R&D credit, and orphan drug credit carryforwards (collectively, tax benefit carryforwards). The effect of this occurrence is to limit the annual utilization of a portion of the Company s tax benefit carryforwards attributable to the period prior to the change in ownership. Should another change in ownership occur, future utilization of the Company s tax benefit carryforwards may be subject to additional limitations under Section 382.

9. Employee Benefit Plans

The Company maintains a 401(k) Savings Plan ("the 401(k) Plan"), which is funded by elective salary deferrals by employees. The 401(k) Plan covers substantially all employees meeting minimum eligibility requirements. The 401(k) Plan does not require mandatory contributions by the Company, but discretionary contributions may be made at the election of the Company. The Company has not made any provision for discretionary contributions to the 401(k) Plan.

The Company has a stock purchase plan ("the Plan") that is funded by employee contributions, generally through payroll deductions. All employees are eligible subject to certain requirements. The purchase price is 85% of the lower of the average of the high and the low trade on the first and last trading day of each purchase period, defined as each calendar quarter. The Company reserved 200,000 shares of its common stock for future issuance at the Plan s inception. From the Plan s inception through December 31, 2004, there have been 127,913 shares issued under the Plan.

10. Stock Options

The Company has a stock option plan for employees and non-employees, the 1994 Stock Option Plan (the 1994 Plan). The 1994 Plan provides the Company may grant employee incentive stock options and non-qualified stock options at a price of not less than 100% of fair market value. Vesting terms for each option grant are established at the time of the grant. Generally, vesting terms are 20% at the date of grant and 20% on each of the following four annual anniversary dates of the option grant. Options are exercisable as prescribed by the 1994 Plan and expire up to ten years from the grant date. The 1994 Plan expired in August 2004. At December 31, 2004, the 1994 Plan has 1,493,970 shares reserved for issuance.

In June 2004, the Company s shareholders adopted the 2004 Orphan Medical, Inc. Stock Incentive Plan (the 2004 Plan). The 2004 Plan provides for the grant of options to purchase shares of Common Stock, stock appreciation rights, and restricted stock, performance awards, dividend equivalents, and other stock awards to any director, full-time or part-time employee of, any consultant or any independent contractor providing services to the Company. The 2004 Plan provides the Company may grant employee incentive stock options and non-qualified stock options at a price of not less than 100% of fair market value. Vesting terms for each option grant are established at the time of the grant. Generally, vesting terms are 20% at the date of grant and 20% on each of the following four annual anniversary dates of the option grant. Options are exercisable as prescribed by the 2004 Plan and expire up to ten years from the grant date. The 2004 Plan has 2,250,000 shares of Common Stock reserved for issuance.

Options outstanding were granted as follows:

	Plan Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2001	1,526,978	$ 6.97
Options granted	652,050	9.78
Options canceled	(55,600)	9.31
Options exercised	(125,950)	5.59
Balance at December 31, 2002	1,997,478	7.90
Options granted	555,375	9.73
Options canceled	(215,779)	10.67
Options exercised	(205,278)	7.42

Balance at December 31, 2003	2,131,796		8.14
Options granted	364,800		10.06
Options canceled	(153,643)		9.55
Options exercised	(598,913)		5.36
Balance at December 31, 2004	1,744,040	$	9.37

The following table summarizes information about the stock options outstanding at December 31, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	**Number Outstanding**	**Weighted Average Remaining Contractual Life**	**Weighted Average Exercise Price**	**Number Exercisable**	**Weighted Average Exercise Price**
$5.00 - $7.81	487,875	5.25 years	$ 6.85	442,325	$ 6.87
$7.82 - $9.75	482,525	7.86 years	9.07	326,227	9.04
$9.76 - $10.75	463,720	8.67 years	10.26	151,010	10.34
$10.76 - $14.50	309,920	7.13 years	12.48	213,280	12.55
$5.00 - $14.50	1,744,040		$ 9.37	1,132,842	$ 9.03

Fully vested and exercisable options were 1,132,842, 1,398,625, and 1,302,368, as of December 31, 2004, 2003, and 2002, respectively. The weighted average exercise prices for the fully vested and exercisable options as of December 31, 2004, 2003, and 2002, were $9.03, $7.07, and $6.86, respectively.

Pro Forma Information:

The Company applies the intrinsic-value method in accounting for stock issued to employees and directors. Accordingly, compensation expense is recognized only when options are granted with an exercise price less than fair market value of the common stock on the date of grant. Any such compensation expense is recognized ratably over the associated service period, which is generally the option vesting period.

Pro forma net (loss) income and (loss) income per share information, as required by SFAS No. 123, Accounting for Stock Based Compensation , has been determined as if the Company had accounted for employee stock options under the fair value method. The fair value of these options was estimated at grant date using a Black-Scholes option pricing model with the following assumptions for 2004, 2003 and 2002, respectively

	2004	2003	2002
Expected dividend yield	0.00%	0.00%	0.00%
Expected stock price volatility	65%	68%	70%
Risk-free interest rate	4.00%	4.00%	4.00%
Expected life of options	8 years	8 years	10 years

The weighted average fair value of the options granted in 2004, 2003, and 2002, was $7.12, $6.97 and $7.62, respectively, as computed as described above.

11. Shareholders Equity

On July 23, 1998 the Company issued $7.5 million of Senior Convertible Preferred Stock (the Preferred Shares) in a private placement. The Company realized net cash proceeds of $7.1 million from the sale of the Preferred Shares after the payment of related offering expenses. The Preferred Shares were initially convertible, at the option of the holders, into shares of the Company s Common Stock at a price equal to $8.50 per share. The August 1999 financing, as discussed in the following paragraph, triggered antidilution provisions relating to the $8.1 million of the Senior Preferred Stock held as of August 1 (after giving effect to the semi-annual in-kind dividend distributions), which resulted in a decrease in the conversion price of those shares from $8.50 to $8.14 per share. The Preferred Shares have anti-dilution protection and bear a dividend of 7.5% per annum, payable semi annually, which during the first two years may by paid either in cash or by issuing additional Common Stock valued at the then current market price. In the third year and thereafter, the dividend may be paid either in cash or by issuing Common Stock valued at the then current market price. At the Company s option upon their maturity in July 2008, the Preferred Shares must be (a) converted into Common Stock at the price specified in the original agreement as adjusted per the terms of the agreements, subject to a $3.0 million conversion fee payable in cash or by issuing additional Common Shares at the then current market price, or (b) redeemed for cash at $1,000 per share plus accrued dividends. The holders of the Preferred Shares are entitled to vote on an as-converted basis. The holders of the Preferred Shares are entitled to and have exercised their right to designate an individual to serve on the Company s Board of Directors. At this time, the Company intends to settle the conversion fee with additional shares.

On August 2, 1999, the Company completed a $5.0 million financing transaction in a private placement. The funding consisted of a purchase of 2,950 shares of the Company s Series B Convertible Preferred Stock for an aggregate purchase price of $2.95 million and a commitment of $2.05 million of debt in the form of a line of credit. The Company had not borrowed on this line of credit and it was eliminated as a part of a financing transaction in December 2001. The Series B Convertible Preferred Stock (Series B Preferred Shares) may be converted prior to August 2, 2009 into shares of the Company s Common Stock at a price of $6.50 per share. The Series B Preferred Shares have anti-dilution protection and bear a

dividend of 7.5% per annum, payable semi annually, which during the first two years may by paid either in cash or by issuing additional Series B Preferred Shares. In the third year and thereafter, the dividend may be paid either in cash or by issuing additional preferred stock. The holders of the Series B Preferred Shares do not have voting rights. At the Company s option upon their maturity in August 2009, the Series B Preferred Shares must be (a) converted into Common Stock at the prices specified in the original agreement as adjusted per the terms of the agreement, subject to a $1.2 million conversion fee payable in cash or by issuing additional Common Shares at the then current trading prices, or (b) redeemed for cash at $1,000 per share plus accrued dividends. At this time, the Company intends to settle the conversion fees with additional shares.

In conjunction with the issuance of the preferred shares, the Company agreed to several restrictions and covenants, and granted certain voting and other rights to the holders of the preferred shares. One of these restrictions is that the Company cannot incur additional indebtedness, except for indebtedness secured solely by our trade receivables, until the Company has profitable operations, subject to certain limitations. Another important restriction is that, without the approval of a majority of the preferred stockholders, the Company cannot issue additional equity securities unless the selling price per share exceeds the then conversion price of the outstanding convertible preferred stock or the sale of equity is accomplished in a public offering.

12. Stock Warrants

At December 31, 2004, the Company had 15,000 warrants outstanding to purchase common stock outstanding issued in conjunction with the line of credit facility, at $8.51 per share. These warrants are currently exercisable. The value of these warrants is $86 and was amortized to interest expense over the term of the initial line of credit facility.

In connection with the August 1999 financing, the Company issued two seven-year warrants. One of the warrants entitles the holder to receive, upon payment of the $2.05 million exercise price, either 2,050 shares of Series C Convertible Preferred Stock (which is similar to the Series B Convertible Preferred Stock and which is convertible to shares of the Company s Series D Non-Voting Preferred Stock at a conversion price of $6.50 per share) or 315,385 shares of Series D Non-Voting Preferred Stock (which is equivalent to Common Stock except that it has no voting rights) or a combination of Series C Convertible Preferred Stock and Series D Non-Voting Preferred Stock, so long as the combined purchase price for the shares does not exceed $2.05 million. The second warrant, issued in relation to the line of credit, entitled the holder to purchase 282,353 shares of Series D Non-Voting Preferred Stock at an exercise price of $4.25 per share. The value of the warrants was $82 and was amortized to interest expense over the term of the line of credit. All of these warrants are outstanding and exercisable at December 31, 2004.

13. Commitments

The Company has various commitments under agreements with outside consultants, contract drug developers and manufacturers, technical service companies, drug distributors, along with commitments for various marketing, advertising and promotional activities. In addition, the Company has commitments under license and research agreements. The Company does not have any joint venture agreements nor does it have any arrangements to perform product development or sales and marketing activities for other parties. The Company recognizes the costs associated with these commitments as incurred based on the accrual method of accounting. The Company s commitment to incur additional expenditures in subsequent periods for operating activities totaled approximately $12,023, $14,665, and $5,676, at December 31, 2004, 2003, and 2002, respectively. Commitments for these operating activities will likely fluctuate from year to year depending on, among other factors, the timing of new marketed products or new product development, if any, and other clinical trial activity. In the event that revenue is lower than anticipated, management believes it can reduce or adjust the timing of these commitments to manage its cash flow.

14. Geographic Information

The Company operates in one segment. The Company has no assets outside of the United States. The following is a summary of net sales by geographic region for the years ended December 31, 2004, 2003, and 2002, respectively.

	2004	2003	2002
Domestic	$ 20,618	$ 13,788	$ 12,553
International			
Japan		68	800
United Kingdom	59	529	915
All other	660	1,141	1,862
Total	$ 21,337	$ 15,526	$ 16,130

15. Quarterly Financial Information (unaudited)

The following are unaudited quarterly results of operations for the years ended December 31, 2004 and 2003.

	Quarter ended			
	March 31, 2004	June 30, 2004	September 30, 2004	December 31, 2004
Revenues	$ 5,403	$ 5,412	$ 7,088	$ 5,865
Gross profit	4,772	4,678	6,204	5,162
Net loss	(4,025)	(4,663)	(1,354)	(3,005)
Less: Preferred stock dividends	238	240	244	245
Net loss applicable to common shareholders	(4,263)	(4,903)	(1,598)	(3,250)
Basic and diluted loss per common share	$ (0.40)	$ (0.45)	$ (0.14)	$ (0.28)

	Quarter ended			
	March 31, 2003	June 30, 2003	September 30, 2003	December 31, 2003
Revenues	$ 4,568	$ 4,349	$ 2,982	$ 3,627
Gross profit	3,822	3,631	2,481	3,177
Net (loss) income	(3,854)	26,219(a)	(5,128)	(6,240)
Less: Preferred stock dividends	234	234	238	239
Net (loss) income applicable to common shareholders	(4,088)	25,985	(5,366)	(6,479)
(Loss) income per common share				
Basic	$ (0.39)	$ 2.47	$ (0.50)	$ (0.60)
Diluted	$ (0.39)	$ 2.06	$ (0.50)	$ (0.60)

(a) The second quarter of 2003 includes a $30.3 million gain on the divestment of certain products discussed more fully in Note 4 to these financial statements.

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS

ORPHAN MEDICAL, INC.

Description	Balance at Beginning of Period	Additions (Reductions) Charged to Costs and Expenses	Additions (Reductions) Charged to Other Accounts Describe	Deductions Describe (1)	Balance at End of Period
Year Ended December 31, 2004					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$ 112	$ (82)	$	$ 5	$ 25
Allowance for excess inventory	290	41		80	251
Year Ended December 31, 2003					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$ 25	$ 87		$	$ 112
Allowance for excess inventory	142	178		30	290
Year Ended December 31, 2002					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$ 25	$ 31	$	$ 31	$ 25
Allowance for excess inventory	493	(351)			142

(1) Amounts written off, net of recoveries.