ORPHAN MEDICAL INC
Form 10-Q
November 14, 2003

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

[X] Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended September 30, 2003

[ ] Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission File Number 0-24760

Orphan Medical, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**41-1784594**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
13911 Ridgedale Drive, Suite 250, Minnetonka, MN 55305	**(952) 513-6900**
(Address of principal executive office and zip code)	(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months, and (2) has been subject to such filing requirements for the past 90 days.

Yes _X_ No __

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes _X_ No __

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practical date.

Common Stock, $.01 par value	10,744,703
(Class)	(Outstanding at November 1, 2003)

INDEX

ORPHAN MEDICAL, INC.®

Page No.

Antizol®, Antizol-Vet®, Cystadane®, Xyrem®, MedExpand , The Orphan Drug Company , Orphan Medical, Inc. and Dedicated to Patients with Uncommon Diseases® are trademarks of the Company.

PART I FINANCIAL INFORMATION

ITEM 1. Financial Statements

ORPHAN MEDICAL, INC.
BALANCE SHEETS
(In thousands except share data)

	September 30, 2003	December 31, 2002
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 26,680	$ 6,921
Restricted cash	127	251
Accounts receivable, less allowance for doubtful accounts of $56 and $25, respectively	1,480	2,215
Inventories	1,232	2,020
Prepaid expenses and other	715	576
Total current assets	30,234	11,983
Property and equipment, net	855	1,156
Total assets	$ 31,089	$ 13,139
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 763	$ 1,380
Accrued royalties	133	235
Accrued compensation	1,080	1,795
Accrued expenses	2,348	1,901

	September 30, 2003	December 31, 2002
Total current liabilities	4,324	5,311
Capital lease obligation-less current maturities	66	78
Commitments		
Shareholders equity:		
Senior Convertible Preferred Stock, $.01 par value; 14,400 shares authorized; 8,706 shares issued and outstanding		
Series B Convertible Preferred Stock, $.01 par value; 5,000 shares authorized; 3,957 and 3,677 shares issued and outstanding		
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; 25,000,000 shares authorized; 10,744,703 and 10,460,283 issued and outstanding	108	105
Additional paid-in capital	76,665	74,033
Accumulated deficit	(50,074)	(66,388)
Total shareholders equity	26,699	7,750
Total liabilities and shareholders equity	$ 31,089	$ 13,139

Note: The Balance Sheet at December 31, 2002 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

See Accompanying Notes.

Orphan Medical, Inc.
Statements of Operations
(In thousands except per share data)

(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues, net	$ 2,982	$ 4,155	$ 11,898	$ 11,337
Cost of sales	501	609	1,965	1,661
Gross Profit	2,481	3,546	9,933	9,676
Operating expenses:				
Research and development	2,540	2,254	6,135	4,668

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
Sales and marketing	3,316	3,539	11,103	7,262
General and administrative	1,542	1,922	5,247	4,484
Total operating expenses	7,398	7,715	22,485	16,414
Loss from operations	(4,917)	(4,169)	(12,552)	(6,738)
Interest income, net	40	64	27	215
Other income			30,267	
Net (loss) income before taxes	(4,877)	(4,105)	17,742	(6,523)
Income tax expense	(251)		(509)	
Net (loss) income	(5,128)	(4,105)	17,233	(6,523)
Less: Preferred stock dividends	238	235	704	688
Net (loss) income attributable to common shareholders	$ (5,366)	$ (4,340)	$ 16,529	($ 7,211)
(Loss) earnings per common share				
Basic	$ (0.50)	$ (0.42)	$ 1.56	$ (0.70)
Diluted	$ (0.50)	(0.42)	1.33	(0.70)
Weighted average number of shares outstanding				
Basic	10,682	10,373	10,573	10,331
Diluted	10,682	10,373	12,912	10,331

See Accompanying Notes.

Orphan Medical, Inc.
Statements of Cash Flows
(In thousands)

(Unaudited)

	For the Nine Months Ended September 30, 2003	September 30, 2002
Operating activities		
Net income (loss)	$ 17,233	$ (6,523)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	394	165
Gain on disposition of products	(30,267)	
Changes in operating assets and liabilities:		
Accounts receivable and current assets	596	(649)
Inventories	787	(634)
Accounts payable and accrued expenses	(871)	2,041
Net cash used in operating activities	(12,128)	(5,600)
Investing activities		

	For the Nine Months Ended	
Purchase of office equipment	(33)	(668)
Decrease in restricted cash	124	
Net proceeds on disposition of products	30,267	
Net cash provided (used in) by investing activities	30,358	(668)
Financing activities		
Employee stock purchase plan	35	31
Stock option exercise proceeds	1,507	335
Payments on capital lease	(12)	
Private common stock placement		(8)
Cash dividends	(1)	(1)
Net cash provided by financing activities	1,529	357
Increase (decrease) in cash and cash equivalents	19,759	(5,911)
Cash and cash equivalents at beginning of period	6,921	19,011
Cash and cash equivalents at end of period	$ 26,680	$ 13,100

See Accompanying Notes.

ORPHAN MEDICAL, INC.

NOTES TO FINANCIAL STATEMENTS
(Unaudited)

1. Basis of Presentation

Business

Orphan Medical acquires, develops, and markets products of high medical value intended to treat sleep disorders, pain and other central nervous 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). While three have been divested, the Company is focusing its resources on Xyrem®(sodium oxybate) oral solution, a medication approved for cataplexy, a significant and debilitating symptom of narcolepsy. The Company is conducting clinical trials to assess Xyrem in treating excessive daytime sleepiness and fragmented nighttime sleep, the other prominent symptoms of narcolepsy. 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 areas it serves.

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal, recurring accruals) considered necessary for fair presentation have been included. Operating results for the three-month and nine-month period ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ended December 31, 2003. For further information, refer to the audited financial statements and accompanying notes contained in the Company s Annual Report filed on Form 10-K for the year ended December 31, 2002.

2. Disposition of Products

On June 10, 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 on May 6, 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 central nervous system (CNS) markets.

3. 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.

4. Stock-Based Compensation

At September 30, 2003 the Company has a stock-based employee compensation plan. The Company accounts for its 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 for the three or nine month periods ended September 30, 2003 or 2002, 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 income (loss) and net income (loss) 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.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
(in thousands except per share data)				
Net income (loss) as reported	$ (5,366)	$ (4,340)	$ 16,529	$ (7,211)
Deduct total stock-based employee compensation expense determined under fair value-based method for all awards	(791)	(489)	(2,049)	(1,457)
Pro forma net income (loss)	$ (6,157)	$ (4,829)	$ 14,480	$ (8,668)
Earnings (loss) per share				
Basic as reported	$ (0.50)	$ (0.42)	$ 1.56	$ (0.70)
Basic as pro forma	$ (0.58)	$ (0.47)	$ 1.37	$ (0.84)
Diluted as reported	$ (0.50)	$ (0.42)	$ 1.33	$ (0.70)
Diluted as pro forma	$ (0.58)	$ (0.47)	$ 1.24	$ (0.84)

5. 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, from all domestic customers products that have reached their expiration date, which range from two to four 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. The Company monitors the exchange of product and modifies its reserve as necessary. Management bases these reserves on historical experience and these estimates are subject to change.

6. 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.

	September 30, 2003	December 31, 2002
Raw materials and packaging	$ 311	$ 1,023
Finished goods	921	997
	$ 1,232	$ 2,020

7. Earnings Per Share

Earnings per share is computed in accordance with SFAS No. 128, Earnings Per Share . Basic earnings (loss) per share is computed based on the weighted average number of common shares outstanding during the period. Diluted earnings (loss) 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 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. The following is a reconciliation of net income (loss) and weighted average common shares outstanding for purposes of calculating basic and diluted earnings (loss) per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
(in thousands except per share data)				
Numerator				
Numerator for basic earnings per share income available to common shareholders	$ (5,366)	$ (4,340)	$ 16,529	$ (7,211)
Add back to effect assumed conversions:				
Preferred stock dividends			704	
Numerator for diluted earnings per share	$ (5,366)	$ (4,340)	$ 17,233	$ (7,211)
Denominator				
Denominator for basic earnings per share weighted average shares	10,682	10,373	10,573	10,331
Effect of dilutive securities:				

	Three Months Ended September 30,		Nine Months Ended September 30,	
Preferred shares			1,659	
Stock options			423	
Warrants			257	
Denominator for diluted earnings per share weighted average shares and assumed conversions	10,682	10,373	12,912	10,331
Basic earnings per share	$ (0.50)	$ (0.42)	$ 1.56	$ (0.70)
Diluted earnings per share	$ (0.50)	$ (0.42)	$ 1.33	$ (0.70)

8. Commitments

The Company has various commitments under agreements with outside consultants and contractors to provide services relating to drug development, drug acquisition, manufacturing and marketing. At September 30, 2003, the Company estimates that it could incur approximately $13.5 million of additional expenditures in subsequent periods under existing commitments. Commitments for research and development expenditures will likely fluctuate from quarter to quarter and from year to year depending on, among other factors, the timing of product development and the progress of clinical development programs.

9. Borrowings

The Company entered into a new line of credit facility with a commercial bank on March 27, 2003. The new line of credit facility has a term of one-year and includes a borrowing base equal to 75 percent of eligible accounts receivable up to a maximum amount of $2.5 million. Certain other assets have also been pledged as collateral for this facility. The interest rate is equal to two points over the bank s prime rate. The Company is also subject to certain other requirements during the term of the facility, including (a) minimum quarterly net tangible equity of $6.0 million plus 50 percent of the proceeds of any equity securities or subordinated debt offering and (b) maximum monthly operating loss of $2.7 million. The Company had not borrowed under this facility at September 30, 2003.

10. Income taxes

In 2003 the Company disposed of three products resulting in a net gain of $30.3 million. As a result of the gain from product dispositions, the Company estimates that it will have alternative minimum tax expense of $0.5 million in fiscal 2003.

11. Subsequent Event

On October 30, 2003 Orphan Medical, Inc. announced that it had licensed European sales and marketing rights for Xyrem to Celltech Pharmaceuticals, a division of Celltech Group Plc. Celltech has indicated that it expects to file a Xyrem marketing authorization application for the cataplexy indication in Europe in early 2004 and, upon approval, will use its specialist sales forces to market the product to the target audience of neurologists and sleep specialists.

Under the terms of the agreement, Celltech will be responsible for the registration, sales and marketing of Xyrem in Europe. Celltech made an upfront 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 $7 million tied to sales-related milestones. Celltech will also pay Orphan Medical a royalty on sales of the product which will begin no earlier than 2005. The licensing agreement includes the use of Xyrem in narcolepsy and provides Celltech with rights to negotiate in regard to

other potential future indications including fibromyalgia syndrome.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Cautionary Statement

This Quarterly Report on Form 10-Q contains statements that are not descriptions of historical facts. The words or phrases will likely result , look for , may result , will continue , is anticipated , expect , project , or similar expressions are intended to identify forward-looking statements w the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be forward-looking statements that are subject to risks and uncertainties. Actual results could differ materially from those currently anticipated due to a number of factors, including those identified in the section of this Quarterly Report filed on Form 10-Q for the quarterly period ended September 30, 2003 titled Risk Factors.

General

Since its inception, the activities of the Company have consisted primarily of obtaining the rights for developing and marketing proposed pharmaceutical products, managing the development of these products and preparing for and initiating the commercial introduction of six products. The Company operates in a single business segment: pharmaceutical products. The Company has experienced recurring losses from operations and has generated an accumulated deficit through September 30, 2003 of $50.1 million. In addition, the Company expects to incur additional losses from operations in fiscal years at least for the next six fiscal quarters.

Recent Developments

On October 30, 2003 Orphan Medical, Inc. announced that it had licensed European sales and marketing rights for Xyrem to Celltech Pharmaceuticals, a division of Celltech Group plc. Celltech has indicated that it expects to file a Xyrem marketing authorization application for the cataplexy indication in Europe in early 2004 and, upon approval, will use its specialist sales forces to market the product to the target audience of neurologists and sleep specialists.

Under the terms of the agreement, Celltech will be responsible for the registration, sales and marketing of Xyrem in Europe. Celltech made an upfront 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 $7 million tied to sales-related milestones. Celltech will also pay Orphan Medical a royalty on sales of the product which will begin no earlier than 2005. The licensing agreement includes the use of Xyrem in narcolepsy and provides Celltech with rights to negotiate in regard to other potential future indications including fibromyalgia syndrome.

On June 10, 2003, the Company announced the disposition of the rights to Busulfex to ESP Pharma, Inc. for $29.3 million plus the book value of inventory, approximately $0.2 million. The Company announced the disposition of the product Sucraid to a specialty pharmaceutical company on May 6, 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 central nervous system (CNS) markets.

Three Months Ended September 30, 2003 vs. Three Months Ended September 30, 2002

Net loss applicable to common shareholders was $5.4 million for the three months ended September 30, 2003 compared to a net loss applicable to common shareholders of $4.3 million for the three months ended September 30, 2002. This change is attributable to a decrease in total revenues for the current quarter as compared to the prior year resulting from the product dispositions that occurred during the quarter ended June 30, 2003. The revenue decrease from product dispositions was partially offset by a full quarter of revenue from Xyrem which was approved in July 2002. Operating expenses decreased from the prior year primarily due to the additional expense of commercial launch preparation incurred during the third quarter of 2002.

Net sales decreased 28 percent to $3.0 million for the three months ended September 30, 2003 compared to $4.2 million for the same period in the prior year largely due to the aforementioned product dispositions. Net sales for the quarter ended September 30, 2002 included $2.1 million

from the divested products, which did not recur in the current period. Sales of Xyrem were approximately $1.1 million for the quarter ended September 30, 2003. As of September 30, 2003, more than 900 physicians had written 2,934 prescriptions for Xyrem of which 2,017 had been filled, with over 400 prescriptions in process. Approximately 16 percent of patients do not fill their initial prescription. After initiating therapy, there has been an 12 percent discontinuation rate following use of Xyrem of which only 4 percent is due to side effects and 2 percent due to lack of efficacy. The Company experienced prescription growth of 32 percent during the quarter as compared to the quarter ended June 30, 2003.

Sales of Antizol® (fomepizole) Injection were comparable to the prior year.

Gross profit margins decreased to 83 percent for the quarter ended September 30, 2003 compared to 85 percent for the same period the prior year due to product mix. Cost of sales as a percentage of net sales 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.

Research and development expense increased 13 percent to $2.5 million in the three months ended September 30, 2003 compared to $2.3 million for the three months ended September 30, 2002. The increase results from increased spending for the ongoing Phase III(b) trials for Xyrem. Both of these trials for Xyrem are now underway and will increase research and development spending in subsequent quarters. Clinical spending for trials is dependent on a number of factors, including among others, the number of human subjects screened and enrolled in the trial, and the number of active clinical sites. Development expenses will increase in the fourth quarter of 2003 to approximately $3.0 million.

Sales and marketing expense decreased 6 percent to $3.3 million for the three months ended September 30, 2003 from $3.5 million for the three months ended September 30, 2002. This decrease is attributable to timing of spending for the support of the commercial activities of Xyrem, approved by the FDA in July 2002 and launched in October 2002. Expenses in the prior year included spending for the preparation of the commercial launch of Xyrem. Sales and marketing expenses will be in the $4.0 million range the fourth quarter of 2003.

General and administrative expense decreased 20 percent to $1.5 million for the period ended September 30, 2003 compared to $1.9 million for the three months ended September 30, 2002. General and administrative expenses will be in the $1.5 million range in the fourth quarter of 2003.

Interest (expense) income is the sum of interest income from investment activities less interest expense from financing activities. The Company pays a minimum interest expense related to the Company s credit facility.

During the quarter ended September 30, 2003, the Company recorded $0.3 million of income tax expense as an increase in the estimated tax expense related to the gain on product dispositions. Since the Company expects to be unprofitable for at least the next six quarters, the Company continues to provide a valuation allowance for the entire amount of deferred tax assets.

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 percent. Preferred stock dividends were $0.2 million for both the three-months ended September 30, 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. The Company has chosen to satisfy its dividend payment obligation by issuing additional common or preferred stock, as permitted by the terms of the Senior Convertible Preferred Stock and the Series B Convertible Preferred Stock respectively. For the February 1, 2003 and August 1, 2003 Senior Preferred Stock dividend, the Company elected to issue 33,167 and 32,646, respectively, shares of common stock to satisfy its obligation. The Company also intends to continue to satisfy this obligation in the future by issuing common stock. The Company is obligated to pay the dividend for the Series B Convertible Preferred Stock in cash or through the issuance of additional preferred shares. The Company also intends to satisfy the Series B Convertible Preferred Stock obligation by issuing additional preferred shares, which will cause preferred stock dividends to increase in subsequent quarters.

Nine Months Ended September 30, 2003 vs. Nine Months Ended September 30, 2002

Net income applicable to common shareholders was $16.5 million for the nine months ended September 30, 2003 compared to a net loss applicable to common shareholders of $7.2 million for the nine months ended September 30, 2002. The aforementioned product dispositions resulted in gross proceeds of $30.8 million and approximately $0.5 million of expenses associated with the transactions. Operating expenses increased over the prior year primarily due to the commercialization of Xyrem and the ongoing development activities for Xyrem. These increases in expenses were offset by the disposition of products during the nine months ended September 30, 2003 and an increase in net sales for the nine months ended September 30, 2003 compared to the same period in the prior year.

Net sales increased 5 percent to $11.9 million for the nine months ended September 30, 2003 compared to $11.3 million for the same period in the prior year. Sales for the nine months ended September 30, 2002 included $6.2 million from the divested products. Net sales for the current year included $3.5 million up to the dates of divestment. Sales for Xyrem were approximately $2.5 million for the nine months ended September 30, 2003.

Sales of Antizol increased 15 percent over the same period the prior year as more hospitals with emergency rooms are stocking the product.

Net sales for the nine months ended September 30, 2003 included approximately $3.6 million from divested products prior to the divestiture of these products.

Gross profit margins decreased to 83 percent for the nine months ended September 30, 2003 compared to 85 percent for the same period the prior year due to product mix. Cost of sales as a percentage of net sales 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.

Research and development expense increased 31 percent to $6.1 million in the nine months ended September 30, 2003 compared to $4.7 million for nine months ended September 30, 2002. The increase results from increased spending for the ongoing Phase III(b) trial for Xyrem and the initiation of the EXCEEDS trial during the first quarter of 2003. Both of theses trials for Xyrem now underway will increase research and development spending in subsequent quarters. Clinical spending for trials is dependent on a number of factors, including among others, the number of human subjects screened and enrolled in the trial, and the number of active clinical sites.

Sales and marketing expense increased 53 percent to $11.1 million for the nine months ended September 30, 2003 from $7.3 million for the nine months ended September 30, 2002. This increase is attributable to spending supporting the commercial launch of Xyrem, approved in July 2002 and launched in October 2002. These expenses included the addition of staff, including a dedicated sales force and other staff supporting the selling and marketing efforts for Xyrem, along with extensive marketing and medical education efforts.

General and administrative expense increased 17 percent to $5.2 million for the nine months ended September 30, 2003 compared to $4.5 million for the nine months ended September 30, 2002. The increase results from increased staffing and other infrastructure supporting the growth of the Company.

Interest (expense) income is the sum of interest income from investment activities less interest expense from financing activities. In addition, the Company pays minimum interest expense related to the Company s credit facility.

During the nine months ended September 30, 2003, the Company recorded $0.5 million of income tax expense related to the gain on product dispositions. Since the Company expects to be unprofitable for at least the next six quarters, the Company continues to provide a valuation allowance for the entire amount of deferred tax assets.

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 percent. Preferred stock dividends were $0.7 million for both the ninemonths ended September 30, 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. The Company has chosen to satisfy

its dividend payment obligation by issuing additional common or preferred stock, as permitted by the terms of the Senior Convertible Preferred Stock and the Series B Convertible Preferred Stock respectively. For the February 1, 2003 and August 1, 2003 Senior Preferred Stock dividend, the Company elected to issue 33,167 and 32,646, respectively, shares of common stock to satisfy its obligation. The Company also intends to continue to satisfy this obligation in the future by issuing common stock. The Company is obligated to pay the dividend for the Series B Convertible Preferred Stock in cash or through the issuance of additional preferred shares. The Company also intends to satisfy the Series B Convertible Preferred Stock obligation by issuing additional preferred shares, which will cause preferred stock dividends to increase in subsequent quarters.

Liquidity and Capital Resources

Since July 2, 1994, the effective date it was spun-off from Chronimed, Inc., the Company has financed its operations principally from net proceeds of $90.8 million from several public and private financings, interest income and product sales, including $30.3 million of net proceeds from the divestiture of products during the quarter ended June 30, 2003.

Net working capital (current assets less current liabilities) increased from $6.7 million at December 31, 2002 to $25.9 million at September 30, 2003. Cash and cash equivalents increased from $6.9 million at December 31, 2002 to $26.7 million at September 30, 2003. The increase in these amounts is directly attributable to the product dispositions discussed previously.

The Company entered into a new line of credit facility with a commercial bank on March 27, 2003, and terminated its previous line of credit on that date. The Company s line of credit facility, which has a term of one-year, includes a borrowing base equal to 75 percent of eligible accounts receivable up to a maximum amount. In conjunction with the product dispositions, the Company amended the maximum amount of the line of credit from $3.5 million to $2.5 million. Certain other assets have also been pledged as collateral for this facility. The interest rate is equal to two points over the bank s prime rate. The Company will be subject to certain other requirements during the term of the facility, including minimum quarterly net equity amounts. The Company had not borrowed under this facility as of September 30, 2003.

The Company s commitments for outside development spending were $13.5 million at September 30, 2003 and $5.6 million at December 31, 2002. This increase is the result of the initiation of the EXCEEDS clinical trial and commitments for sales and marketing programs. If additional products are licensed for development, these expenditures and commitments could increase significantly.

Management believes the Company s current cash availability, anticipated operating cash flows from product revenues and license fees from the execution of the agreement with Celltech for the registration and marketing of Xyrem in Europe will be sufficient to fund its operations at least through December 31, 2004.

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) net equity in excess of $10.0 million or (2) a market capitalization of at least $50.0 million. The Company met both the thresholds at September 30, 2003. The Company s market capitalization was approximately $96.8 million as of September 30, 2003 (Based on Nasdaq s method of calculating market capitalization which

ingnores preferred stock using the last sale price of $9.14 and 10.6 million shares outstanding). Although the Company does not expect to be profitable in 2003 or 2004, the Company nevertheless expects to continue to meet the listing requirements for listing on the Nasdaq National Market. However, there can be no assurance that the Company will continue to meet these requirements in the future.

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. Even without these restrictions, the Company can make no assurances that additional financing opportunities will be available or, if available, on acceptable terms.

Geographic Sales Information

The Company tracks sales in two geographic regions, domestic and international. The Company has no assets outside of the United States. The following is a summary of net sales by geographic region for the three month and nine month periods ended September 30, 2003 and 2002, respectively. Domestic sales for the three months ended September 30, 2003 declined as a result of the product dispositions. International sales declined year over year and quarter over quarter due to the product divestments discussed earlier.

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
Domestic	$ 2,828	$ 3,260	$ 10,181	$ 8,512
International	154	895	1,717	2,825
Total	$ 2,982	$ 4,155	$ 11,898	$ 11,337

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. We expect operating losses at least through 2004 because anticipated gross profits from product revenues will not offset our operating expenses, including additional spending to support drug development activities. 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 (FDA) approved products. We cannot assure you that we will ever generate sufficient product revenues to achieve profitability.

Limitations to sources of additional capital restrictions, covenants and rights related to Senior Convertible Preferred Stock and Series B Convertible 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 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:

- announcements by us or our competitors of new product developments or clinical testing results;
- 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.

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

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, if we expand our business plans, we may need additional capital. 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 holding may be diluted.

Possible volatility of stock price and reduced liquidity of the market for the Stock possible loss of Nasdaq National Market listing and failure to qualify For Nasdaq Small Cap Market listing.

There is 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 requirements as of September 30, 2003, however, we cannot assure you that we will be able to continue to meet both requirements in future periods.

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. We cannot assure you 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 rely on the limited protection of the Orphan Drug Act.

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 indication 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 of an orphan drugalso 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® (betaine anhydrous for oral solution).

Even if the FDA approves an NDA for a drug with an 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. We are currently not aware of any orphan drug designation granted to another company for a compound similar to any of the Company s currently marketed products.

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 Europe 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 partner has obtained orphan drug designation for Cystadane in Europe. The Company has obtained orphan drug designation for Antizol, for use in methanol poisonings, and Xyrem in Europe.We cannot provide assurance that any of our pharmaceutical products will qualify for orphan drug protection in Europe or that another company will not obtain an approval that would block us from marketing our product in Europe.

The FDA and foreign regulatory authorities must approve our products for sale.

Government regulation in the United States and abroad is a significant factor in the testing, production and marketing of our current and future pharmaceutical 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. We cannot market any medicine we may develop or license as a prescription product in any jurisdiction, including most foreign countries, in which the product does not receive regulatory approval. The approval process can take many years and requires the expenditure of substantial 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 and other regulatory agencies. 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.

We cannot assure you that the FDA or any foreign regulatory authority will approve in a timely manner, if at all, any product 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. In addition addition to potentially limiting the commercial market, this could result in additional cost and delay for further studies to provide additional data on safety or effectiveness.

FDA approval does not guarantee financial success.

Three of our current 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. 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. 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 and disposed of three approved products.

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 our proposed marketing claims. 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 withdrawal 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.

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 selected strategic therapeutic market segments. 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 or products 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 depend on others to manufacture and supply the products we market.

We do not have and do not intend to establish any internal product testing, synthesis of bulk drug substance, or manufacturing capability for drug product. Accordingly, we depend on others to supply and manufacture the components incorporated into all of our finished drug products. The inability to contract for these purposes on acceptable terms could adversely affect our ability to develop and market 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 a supply or manufacturing contractor could materially 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 salable 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. 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. The loss of or the change of a bulk drug supplier or a drug product manufacturer could have a material adverse effect on our business and prospects.

Bulk Drug Supply

Bulk drug substance is the active chemical compound used in the manufacture of our drug products. We depend substantially on single suppliers for the supply of bulk drug substance used in each of our products. If we were to lose any of these companies as a supplier, we would be required to identify a new supplier for the bulk drug substance used in those products. We also cannot assure you that our bulk drug supply arrangements with our current suppliers, or any other future such supplier, might not change in the future. We cannot assure you that any change would

not adversely affect production of the Company s currently marketed products or any other drug the Company might attempt to develop or market.

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 depend substantially on single suppliers for drug product manufacturing of each of our products. If we were to lose any of these companies as a supplier, we would be required to identify a new manufacturer. We cannot assure you that our drug product manufacturing arrangements with these suppliers will not change or that the manufacturing services will continue to be available on terms satisfactory to us. Any change in our manufacturing agreements could adversely affect production of our currently marketed products or any other drug that we might attempt to develop or market, which could have a material adverse effect on our business and prospects.

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. 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. DEA establishes quotas for Schedule I drug substances. We cannot assure you that the DEA will always grant sufficient quotas to meet market demand for our Xyrem product line. In rare cases in the past when demand exceeded quotas there was insufficient drug substance to meet commercial drug market demand.

We depend upon others for distribution.

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 will be 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 fully 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.

We have an agreement with a distribution contractor to provide integrated distribution and operations services to support transactions between us and our wholesalers, specialty distributors, and direct customers. This contractor also provides reimbursement management, patient assistance and information hotline services along with specialty distribution and marketing services to physician practices with respect to our products.

We have a separate agreement with another distributor that distributes Antizol and Antizol-Vet. The contractor may also distribute future products should those products receive marketing clearance from the FDA. We are substantially dependent on this contractor s ability to successfully distribute Antizol and Antizol-Vet.

A mail order pharmacy is the principal distributor, on a non-exclusive basis, in the United States for Cystadane. The pharmacy distributes this product directly to patients through the mail. We are substantially dependent on this pharmacy s ability to successfully distribute Cystadane directly to patients in the United States.

We cannot assure you that our distribution arrangements with these three entities or other companies 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 would have a material adverse effect on our business and prospects.

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 (referred to in the industry as an NDA) 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, Antizol 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. A regulatory application for Xyrem has not yet been filed, but is expected to be filed in the first part of next year. Prior to complete regulatory approval, distribution of Xyrem is limited to named patient or emergency use . 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 Xyrem and Antizol is expected to result in a limited contribution to the Company s revenues. Full regulatory approval is expected for Xyrem no earlier than 2005.

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 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 report such events, should they occur, to the FDA and/or other government and regulatory agencies in accordance with applicable laws and regulations. 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 actions 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.

Patents and other proprietary rights are significant factors in the pharmaceutical industry.

The pharmaceutical industry and the investment community places 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 patent protection in the United States. However, we have an issued patent with respect to our formulation of Xyrem and for the indication of fibromyalgia and chronic fatigue. We could, however, incur substantial costs asserting any infringement claims that we may have against others.

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. To date, Orphan Medical has not been involved in any patent related litigation.

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 3. Quantitative and Qualitative Disclosures about Market Risk

Not Applicable

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and

procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of the end of the period covered by this report. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are adequately designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Securities and Exchange Act is recorded, processed, summarized and reported, within the time periods specified in applicable rules and forms.

Changes in Internal Controls. During our third fiscal quarter, there were no significant changes made in our internal control over financial reporting (as defined in Rule 13(a)-15(f) under the Exchange Act) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Items 1-5 are not applicable and have been omitted.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits:

Exhibit Number	Description
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K:

The Company recently filed the following Current Reports on Form 8-K.

Current Report on Form 8-K filed July 24, 2003 under Item 5. Other Events reporting certain financial matters.

Current Report on Form 8-K filed October 23, 2003 under Item 12, Disclosure of Results of Operations and Financial Condition reporting 2003 Third Quarter results and financial condition.

Current Report on Form 8-K filed October 31, 2003 under Item 5, Other Events reporting a licensing agreement with Celltech plc.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Orphan Medical, Inc.
Registrant

Date: November 14, 2003

By /s/ Timothy G. McGrath

Timothy G McGrath
Chief Financial Officer
(duly authorized officer and
principal financial officer)

INDEX TO EXHIBITS

Exhibit		Page
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	32
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	33
32.1	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	34
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	35