ORPHAN MEDICAL INC
Form 10-Q
May 15, 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 March 31, 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 ___ No _X_

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	10,519,509
(Class)	(Outstanding at May 1, 2003)

INDEX

ORPHAN MEDICAL, INC.(R)

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

Balance Sheets - March 31, 2003 and December 31, 2002.

Statements of Operations - Three months ended March 31, 2003 and March 31, 2002.

Statements of Cash Flows - Three months ended March 31, 2003 and March 31, 2002.

Notes to Financial Statements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Item 4. Controls and Procedures

PART II. OTHER INFORMATION

Items 1 through 5 have been omitted since all items are inapplicable or answers negative.

Item 6. Exhibits and Reports on Form 8-K

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

ORPHAN MEDICAL, INC.
BALANCE SHEETS

	MARCH 31 2003 (Unaudited)	DECEMBER 3 2002
Assets		
Current assets:		
Cash and cash equivalents	$ 2,250,434	$ 6,920,6
Restricted cash	251,744	251,1

Accounts receivable, less allowance for doubtful accounts of $40,300 and $25,000, respectively	2,961,103	2,215,4
Inventories	2,028,739	2,019,7
Prepaid expenses and other	574,882	576,1
Total current assets	8,066,902	11,983,2
Property and equipment:		
Property and equipment	2,121,126	2,096,6
Accumulated depreciation	(1,052,520)	(940,9
	1,068,606	1,155,7
Total assets	$ 9,135,508	$ 13,138,9
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 1,400,479	$ 1,379,7
Accrued royalties	197,311	234,6
Accrued compensation	1,314,782	1,795,4
Accrued expenses	2,077,438	1,901,2
Total current liabilities	4,990,010	5,311,1
Capital lease obligation-less current maturities	74,084	78,0
Commitments		
Shareholders' equity:		
Senior Convertible Preferred Stock, $.01 par value; 14,400 shares authorized; 8,706 shares issued and outstanding	87	
Series B Convertible Preferred Stock, $.01 par value; 5,000 shares authorized; 3,816 and 3,677 shares issued and outstanding	38	
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; 10,519,509 and 10,460,283 issued and outstanding	105,195	104,6
Additional paid-in capital	74,676,311	74,033,4
Accumulated deficit	(70,710,217)	(66,388,3
Total shareholders' equity	4,071,414	7,749,7
Total liabilities and shareholders' equity	$ 9,135,508	$ 13,138,9

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.

STATEMENTS OF OPERATIONS
ORPHAN MEDICAL, INC.
(Unaudited)

	For the Three Months Ended	
	March 31, 2003	March 31, 2002
Revenues	$ 4,568,267	$ 3,681,638
Cost of sales	746,720	533,276
Gross Profit	3,821,547	3,148,362
Operating expenses:		
Research and development	1,696,883	1,077,031
Sales and marketing	4,160,430	2,019,916
General and administrative	1,825,777	1,068,454
Total operating expenses	7,683,090	4,165,401
Loss from operations	(3,861,543)	(1,017,039)
Other income:		
Interest, net	7,841	84,332
Net loss	(3,853,702)	(932,707)
Less: Preferred stock dividends	234,090	225,730
Net loss attributable to common shareholders	$ (4,087,792)	$ (1,158,437)
Basic and diluted loss per common share	$ (0.39)	$ (0.11)
Weighted average number of shares outstanding	10,472,263	10,282,223

SEE ACCOMPANYING NOTES.

STATEMENTS OF CASH FLOWS
ORPHAN MEDICAL, INC.

(Unaudited)

	For the Three Months Ended	
	March 31,	March 31,

	2003	2002
OPERATING ACTIVITIES		
Net loss	$ (3,853,702)	$ (932,707)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	111,619	41,269
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	(744,367)	(271,682)
Inventories	(8,981)	(22,233)
Accounts payable and accrued expenses	(321,105)	(1,278,489)
Net cash used in operating activities	(4,816,536)	(2,463,842)
INVESTING ACTIVITIES		
Purchase of property and equipment	(24,508)	(52,101)
Net cash provided by (used in) investing activities	(24,508)	(52,101)
FINANCING ACTIVITIES:		
Employee stock purchase plan	9,090	10,650
Stock option exercise proceeds	166,261	23,162
Private common stock placement	--	(8,101)
Cash dividends	(30)	(197)
Principal payments on capital lease	(4,528)	--
Net cash provided by financing activities	170,793	25,514
Increase (decrease) in cash and cash equivalents	(4,670,521)	(2,490,429)
Cash and cash equivalents at beginning of period	6,920,685	19,011,245
Cash and cash equivalents at end of period	$ 2,250,434	$ 16,520,816

SEE ACCOMPANYING NOTES

ORPHAN MEDICAL, INC.

NOTES TO FINANCIAL STATEMENTS
(Unaudited)

1. BASIS OF PRESENTATION

Orphan Medical, Inc. (the "Company") acquires, develops, and markets products of high medical value intended to address inadequately treated or uncommon diseases within selected strategic therapeutic areas. 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 six products that have been approved for marketing by the Food and Drug Administration (the "FDA") and is currently developing one potential product. The Company expects to seek additional products for development.

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 period ended March 31, 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. 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.

3. STOCK-BASED COMPENSATION

At December 31, 2002 the Company has a stock-based employee compensation plan, which is described more fully in Note 8. 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 for the periods ended March 31, 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.

4. 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 18 months 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.

Deferred revenue represents prepayment from customers for products not yet shipped.

5. 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.

	MARCH 31, 2003	DECEMBER 31, 2002
Raw materials and packaging	$ 500,528	$ 1,023,256
Finished goods	1,528,210	996,502
	$ 2,028,738	$ 2,019,758

6. 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 March 31, 2003, the Company estimates that it could incur approximately $7.1 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.

7. 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, which has a term of one-year, includes a borrowing base equal to 75% of eligible accounts receivable up to a maximum amount of $3.5 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 has not borrowed under this facility at March 31, 2003.

The following table illustrates the effect on net loss and net 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.

	QUARTER ENDED MARCH 31, 2003	2002
Net loss as reported	$(4,087,792)	$(1,158,437)
Add stock-based employee compensation included in net loss	--	
Deduct total stock-based employee compensation expense determined under fair value-based method for all awards	(574,335)	(329,055)
Pro forma net loss	(4,662,127)	(1,487,492)
Loss per share		
Basic and diluted - as reported	$ (0.39)	$ (0.11)
Basic and diluted - as pro forma	$ (0.45)	$ (0.14)

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" within 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 March 31, 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 March 31, 2003 of $70.7 million. In addition, the Company expects to incur additional losses from operations in fiscal years at least for the next 6 fiscal quarters.

RECENT DEVELOPMENTS

The Company completed the sale of the product Sucraid to a specialty pharmaceutical company on May 6, 2003 with the receipt of $1.5 million of proceeds. The Company will also receive royalties based on future revenues. The Company has also indicated that it has committed to sell the product Elliotts B Solution later in the second quarter. Proceeds from that transaction will not be significant. The sale of these products will provide operating capital to the Company and allow the Company to begin to focus its commitment to build an expanded presence in the sleep and central nervous system (CNS) therapeutic areas.

On April 30, 2003 the Company announced a revised forecast for total revenue for the current fiscal year in the range of $20.0 to $23.0 million, including $4.5 to $6.0 million of revenue from sales of Xyrem. The Company's market research indicates that most physicians are prescribing Xyrem first for patients suffering from severe cataplexy and intend to treat patients with mild and moderate cataplexy once they have greater experience with Xyrem. Prescribers also indicate that they evaluate patients for Xyrem treatment when they come in for regularly scheduled appointments rather than asking patients to come in for a separate visit. These factors have slowed the anticipated uptake of Xyrem. The Company remains confident that Xyrem will become the first line treatment for cataplexy. The Company anticipates a higher level of marketing and sales activities in the second quarter to drive increased prescribing breadth and depth in the second half of 2003 and into 2004. Three major medical meetings, supported by expanded local medical education programs, will occur in the second quarter. The Associated Professional Sleep Societies (APSS) meeting, attended by most sleep specialists in the United States, occurs in June.

The Company continues to estimate that the total cataplexy market is in excess of $125 million annually. Cataplexy is a debilitating symptom of narcolepsy, affecting sixty to ninety percent of the 140,000 Americans with narcolepsy. It involves the sudden partial or total loss of muscle tone, usually triggered by strong emotions such as laughter, anger, or surprise.

THREE MONTHS ENDED MARCH 31, 2003 VS. THREE MONTHS ENDED MARCH 31, 2002

Net loss applicable to common shareholders was $4.1 million for the three months

ended March 31, 2003 compared to $1.2 million for the three months ended March 31, 2002. The increase in net loss can be attributed, in part, to an increase in sales and marketing expenses associated with the product Xyrem, which was commercially launched early in the fourth quarter of 2002. Research and development expenses also increased during the quarter as a result of increased expense associated with ongoing clinical trials, post-approval trials and the initiation of the EXCEEDS trial. General and administrative expenses also increased in the quarter compared to prior year as a result of increased staffing and infrastructure to support Xyrem. These increases in expenses were partially offset by an increase in revenue for the quarter ended March 31, 2003 compared to the same period in the prior year. The preferred stock dividend increased in the first quarter of 2003 compared to the first quarter of 2002 due to issuance of additional preferred shares in August 2002 and February 2003 to pay dividends on outstanding Preferred Stock. This preferred stock dividend increased the net loss applicable to common shareholders in the current quarter.

Net sales increased 24% to $4.6 million for the three months ended March 31, 2003 compared to $3.7 million for the same period in the prior year. Sales for Xyrem were approximately $600,000 for the quarter ended March 31, 2003. More than 500 physicians had written 1,250 prescriptions for Xyrem. The Company's market research indicates that overall satisfaction by both patients and physicians continues to be strong and third party reimbursement has been high.

As of March 31, 2003, over one-third of all hospitals with emergency departments in the United States had purchased Antizol, an antidote for suspected or confirmed ethylene glycol or methanol poisoning. Revenue for Antizol increased 22% above the comparable period last year. Use of Busulfex in preparative regimens for bone marrow transplantation continued to grow resulting in an increase in first quarter revenue of 32% compared to prior year in the United States and Canada. The increase was largely due to the conversion of additional protocols in key institutions to regimens that include Busulfex. The market share for Busulfex increased to 55% in transplants where busulfan-based regimens are used. International revenue declined approximately 32% from the prior year. The prior year amount included sales to the distribution partner for the completion of clinical trails in Asia. Sales from these sources will vary from quarter to quarter based on the needs of the distribution partners.

Gross profit margins decreased to 84% for the quarter ended March 31, 2003 compared to 85% for the same period the prior year due to product mix. Cost of sales was $0.7 million for the three months ended March 31, 2003 compared to $0.5 million for the same period the prior year. 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 57% to 1.7 million in the three months ended March 31, 2003 compared to $1.1 million for three months ended March 31, 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 106% to $4.2 million for the three months ended March 31, 2003 from $2.0 million for the three months ended March 31, 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. Sales and marketing expenses will likely continue at For the Three Months Ended this level or increase slightly as the Company continues to broaden the awareness of Xyrem.

General and administrative expense increased 70% to $1.8 million for the period ended March 31, 2003 compared to $1.1 million for the three months ended March 31, 2002. The increase results from increased staffing and other infrastructure supporting the growth of the Company. General and administrative expenses will increase during the next few quarters as the Company expands its infrastructure to support Xyrem.

Other income is the sum of interest income from investment activities less interest expense from financing activities. Other income decreased as a result of lower invested balances and lower interest rates on any excess cash invested.

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 $0.2 million for both the 2003 and 2002 first quarters. 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 Senior Preferred Stock dividend, the Company elected to issue 33,167 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, which will cause preferred stock dividends to increase in subsequent quarters. The Company also intends to satisfy the Series B Convertible Preferred Stock obligation by issuing additional preferred shares.

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 of $60.5 million from several public and private financings, interest income and product sales.

Net working capital (current assets less current liabilities) decreased from $6.8 million at December 31, 2002 to $3.1 million at March 31, 2003. Cash and cash equivalents decreased from $6.9 million at December 31, 2002 to $2.3 million at March 31, 2003. The decrease is a result of cash used to fund operations.

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 new line of credit facility, which has a term of one-year, includes a borrowing base equal to 75% of eligible accounts receivable up to a maximum amount of $3.5 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 has not borrowed under this facility at March 31, 2003.

The Company's commitments for outside development spending were $7.1 million at

March 31, 2003 and $5.6 million at December 31, 2002. This increase is the result of the initiation of the EXCEEDS clinical trial. 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, proceeds from the sale of the Company's rights to Sucraid and Elliotts B, and license fees earned at the execution of an agreement with a European partner for the registration and marketing of Xyrem will be sufficient to fund its operations at least through March 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) minimum net equity assets in excess of $10.0 million or (2) a market capitalization of at least $50.0 million. The Company met the market capitalization threshold at March 31, 2003. The Company's market capitalization was approximately $88.4 million (based on the last sale price of $8.40 and 10,519,509 shares outstanding as of March 31, 2003). Although the Company does not expect to be profitable in 2003, 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 have adequate capital to meet the net tangible asset requirement through the year 2003 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. 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 quarters ended March 31, 2002 and 2001, respectively.

	For the Three Months Ended	
	March 31, 2003	March 31, 2002
Domestic	$ 3,572,714	$ 2,543,925
International	995,553	1,137,713
Total	$ 4,568,267	$ 3,681,638

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 2003 because anticipated gross profits from

product revenues will not offset our operating expenses and additional spending to continue 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 out 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 the market capitalization criteria as of March 31, 2003, 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.

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 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, Elliotts B Solution, Cystadane , and Busulfex.

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 aware that the FDA granted to Sparta Pharmaceutical, which has been acquired by SuperGen Inc., orphan drug designation for an intravenous busulfan for a closely related indication. If the FDA approves an NDA for SuperGen drug for a different

indication, SuperGen could seek orphan drug status. 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 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 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 partners have obtained orphan drug designation for both Busulfex and Cystadane Europe. The Company has obtained orphan drug designation for Xyrem and Antizol, for use in methanol poisonings, 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 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 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. 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. This would result in additional cost and delay for further studies to provide additional data on safety or effectiveness.

FDA APPROVAL DOES NOT GUARANTEE FINANCIAL SUCCESS.

Six of our 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.

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 a single supplier for the supply of bulk drug substance used in Busulfex, 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 used in products that provided approximately 88% of our total revenues in 2002, 2001 and 2000, and which are expected to account for approximately 70% of our revenues in 2003. We depend substantially on a different supplier for the supply of bulk drug substance used in Xyrem, which is expected to account for approximately 20% of our revenue in 2003. If we were to lose this company as a supplier, we would be required to identify a new supplier. 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 Busulfex, Antizol, Antizol-Vet, Xyrem, 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 a single supplier for drug product manufacturing of Busulfex, Antizol, and 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 for drug products that provided approximately 88% of our total revenues in 2002, 2001 and 2000, and which are expected to account for approximately 70% of our revenues in 2003. We depend substantially on

a different supplier for the supply of Xyrem, which is expected to account for approximately 20% of our revenue in 2003. If we were to lose this company as a supplier, 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 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 Busulfex, Antizol, Antizol-Vet or Xyrem, 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, 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.

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 will be the only source through which Xyrem can be obtained. Distribution will be governed by the FDA's Subpart H regulations and will fully comply with the risk-management controls jointly developed by Orphan Medical, the FDA, the Drug Enforcement Agency and law enforcement agencies. Every shipment of Xyrem will be 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 and specialty distribution and marketing services to physician practices with respect to our products. The contractor currently distributes Busulfex, Elliotts B Solution, 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 Busulfex, Elliotts B Solution,

Antizol, and Antizol-Vet, and other potential products.

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 Busulfex, 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. 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, Busulfex, and Cystadane in Israel. Full regulatory approval for all products except Antizol 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.

- ASIA. We have licensed marketing and distribution rights for Busulfex in Japan, the Peoples Republic of China, Taiwan and South Korea. Distribution is limited to clinical trial usage until full regulatory approval is achieved. We have also licensed marketing and

distribution rights for Busulfex in Turkey.

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 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, Elliotts B Solution, 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 a patent with respect to our formulation of Xyrem. United States patents issued to the licensor covers our formulation and use of Busulfex. 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.

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

The Company's Chief Executive Officer and Chief Financial Officer have concluded, based on

their evaluation within 90 days of the filing date of this report, that the Company's disclosure controls and procedures are adequately designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Securities and Exchange Act of 1934, as amended, is recorded, processed, summarized and reported, within the time periods specified in applicable rules and forms. There have not been any significant changes in the Company's internal controls or in other factors that could significantly affect those controls, subsequent to the date of such evaluation, including any corrective actions taken with regard to significant deficiencies and material weaknesses.

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
99.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.2	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(b) Reports on Form 8-K:

None.

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 May 15, 2003 By /s/ Timothy G. McGrath

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

CERTIFICATIONS

I, John H. Bullion, President and Chief Executive Officer of Orphan Medical, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Orphan Medical, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by

this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

/S/ John H. Bullion

President and Chief Executive Officer

28

I, Timothy G. McGrath, Vice President and Chief Financial Officer of Orphan Medical, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Orphan Medical, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether

29

or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 15, 2003

/S/ Timothy G. McGrath

Vice President and Chief Financial Officer

INDEX TO EXHIBITS