ORPHAN MEDICAL INC
Form 10-Q
May 09, 2002

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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X Quarterly Report pursuant to Section 13 or 15(d) of the Securities
--- Exchange Act of 1934 for the quarterly period ended March 31, 2002

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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 Numb |
| 13911 Ridgedale Drive, Suite 250, Minnetonka, MN 55305 | (952) 513-6900 |
| (Address of principal executive offices 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 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 | 10,344,457 |
|---|---|
| (Class) | (Outstanding at April 30, 2002) |

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ORPHAN MEDICAL, INC.(R)

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Antizol(R), Antizol-Vet(R), Caprogel(TM), Busulfex(R), Intrachol(TM), Cystadane(R), Elliotts B(R) Solution, Sucraid(R), Xyrem(R), MedExpand(TM), "The" Orphan Drug Company(TM), Orphan Medical(R), Inc. and Dedicated to Patients with Uncommon Diseases(R) are trademarks of the Company.



PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

ORPHAN MEDICAL, INC.
BALANCE SHEETS

| | MARCH 31 2002 |
|---|---|

| | | |
|---|---|---|
| | (Unaudited) | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 16,520,816 | $ |
| Accounts receivable, less allowance for doubtful accounts of $34,700 and $25,000 for 2002 and 2001, respectively | 1,653,846 | |
| Inventories | 1,264,353 | |
| Prepaid expenses | 327,246 | |
| Total current assets | 19,766,261 | |
| Property and equipment: | | |
| Property and equipment | 1,108,743 | |
| Accumulated depreciation | (714,412) | |
| | 394,331 | |
| Total assets | $ 20,160,592 | $ |
| Liabilities and shareholders' equity | | |
| Current liabilities: | | |
| Accounts payable | $ 434,385 | $ |
| Accrued royalties | 193,811 | |
| Accrued compensation | 494,162 | |
| Deferred revenues | - | |
| Accrued expenses | 1,551,220 | |
| Total current liabilities | 2,673,578 | |
| 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; 3,546 and 3,417 shares issued and outstanding | 35 | |
| 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; 10,291,357 and 10,263,961 issued and outstanding | 102,914 | |
| Additional paid-in capital | 72,848,201 | |
| Accumulated deficit | (55,464,223) | |
| Total shareholders' equity | 17,487,014 | |
| Total liabilities and shareholders' equity | $ 20,160,592 | $ |

Note: The balance sheet at December 31, 2001 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, 2002 | March 31, 2001 |
| Revenues | $ 3,681,638 | $ 2,341,510 |
| Cost of sales | 533,276 | 289,666 |
| Gross Profit | 3,148,362 | 2,051,844 |
| Operating expenses: | | |
| Research and development | 1,077,031 | 906,193 |
| Sales and marketing | 2,019,916 | 1,566,707 |
| General and administrative | 1,068,454 | 1,116,392 |
| Total operating expenses | 4,165,401 | 3,589,292 |
| Loss from operations | (1,017,039) | (1,537,448) |
| Other income: | | |
| Interest, net | 84,332 | 146,974 |
| Net loss | (932,707) | (1,390,474) |
| Less: Preferred stock dividends | 225,730 | 221,129 |
| Net loss attributable to common shareholders | $ (1,158,437) | $ (1,611,603) |
| Basic and diluted loss per common share | $ (0.11) | $ (0.19) |
| Weighted average number of shares outstanding | 10,282,223 | 8,463,610 |

See accompanying notes.



STATEMENTS OF CASH FLOWS
ORPHAN MEDICAL, INC.

(Unaudited)

| | For the Three Months Ended | |
|---|---|---|
| | March 31, 2002 | March 31, 2001 |
| OPERATING ACTIVITIES | | |
| Net loss | $ (932,707) | $ (1,390,474) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 41,269 | 42,151 |
| Compensatory options | - | - |
| Changes in operating assets and liabilities: | | |
| Accounts payable and accrued expenses | (1,278,489) | (1,603,557) |
| Inventories | (22,233) | (2,380) |
| Accounts receivable and other current assets | (271,682) | 257,426 |
| Net cash used in operating activities | (2,463,842) | (2,696,834) |
| INVESTING ACTIVITIES | | |
| Purchase of office equipment | (52,101) | (35,070) |
| Maturities of short-term investments | - | 7,284,331 |
| Net cash provided by (used in) investing activities | (52,101) | 7,249,261 |
| FINANCING ACTIVITIES: | | |
| Employee stock purchase plan | 10,650 | 33,033 |
| Stock option exercise proceeds | 23,162 | 85,113 |
| Private common stock placement | (8,101) | - |
| Cash dividends | (197) | (9) |
| Net cash provided by financing activities | 25,514 | 118,137 |
| Increase (decrease) in cash and cash equivalents | (2,490,429) | 4,670,564 |
| Cash and cash equivalents at beginning of period | 19,011,245 | 1,115,319 |
| Cash and cash equivalents at end of period | $ 16,520,816 | $ 5,785,883 |

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, 2002 are not necessarily indicative of the results that may be expected for the year ended December 31, 2002. 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, 2001.

2. USE OF ESTIMATES

The preparation of financial statements in conformity with generally accepted accounting principles 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. REVENUE RECOGNITION

Sales are recognized at the time a product is shipped to the Company's customers and are recorded net of reserves for estimated returns of outdated product and discounts. The Company is obligated to accept from all domestic customers the return of products that have reached their expiration date. The Company is not obligated to accept returns of outdated product from its international distribution partners. The Company monitors the return of product and modifies its accrual for outdated product returns as necessary. Management bases the reserve on historical experience and these estimates are subject to change.

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

4. 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, 2002 | DECEMBER 31, 2001 |
|---|---|---|
| Raw materials and packaging | $ 866,756 | $ 981,583 |
| Finished goods | 397,597 | 260,537 |
| | $ 1,264,353 | $ 1,242,120 |

5. COMPREHENSIVE LOSS

The following summarizes the comprehensive loss for the periods ended:

| | MARCH 31, 2002 | 2001 |
|---|---|---|
| Net Income | $ (932,707) | $ (1,390,474) |
| Unrealized gain on securities | - | 8,796 |
| Total net comprehensive income | $ (932,707) | $ (1,381,678) |

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, 2002, the Company estimates that it could incur approximately $4.7 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 has a commercial revolving line of credit with a bank, which expires in June 2002. The maximum amount available to the Company under this arrangement is $1.0 million, subject to certain limitations. The Company's indebtedness to the bank may not exceed the lesser of (1) 75 percent of the Company's trade accounts receivable that have been outstanding for 90 days or less or (2) $1.0 million. Advances are charged a variable rate of interest equal to the prime rate plus one half of a percent. Through March 31, 2002, the Company has not borrowed under this arrangement. The Company expects to renew this line of credit under substantially the same terms.

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, 2002 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 30, 2002 of $55.5 million. In addition, the Company expects to incur additional losses from operations in fiscal years 2002 and 2003.

RECENT DEVELOPMENTS

On April 10, 2002 the Company announced that the FDA issued an Approvable Letter for Xyrem(R) (sodium oxybate) oral solution as a treatment for cataplexy, a sudden loss of muscle tone associated with narcolepsy. The letter requires, as a condition of final approval of Xyrem, that Orphan Medical clarify certain respiratory data and submit satisfactory final labeling and promotional materials. It also requires the FDA to conduct additional clinical trial site review.

The Company is currently preparing its formal response and believes it can provide a complete response to the respiratory and labeling issues presented in the Approvable Letter within approximately 30 days of the date of the letter. Under the Prescription Drug User Fee Act, the FDA is then required to complete its review within sixty days of receiving the Company's response.

With regard to the clinical site inspection, Xyrem, as an orphan drug, is supported by a relatively small safety database. In the letter, the FDA raised a question about the supporting documentation at one of the 28 sites at which clinical data was generated. As a consequence, the FDA said it would require additional clinical site review, which will begin within the next month.

Regarding the respiratory issues, the FDA questioned data related to the variability in

sleep disordered breathing events, particularly in two patients with pre-existing moderate to severe sleep apnea. The Company believes it can adequately respond with existing clinical trial data, since the observed variability was not associated with oxygen desaturation and showed no dose relationship between drug and effect.

In its letter, the FDA stated that it is prepared to approve Xyrem under Subpart H of the Food, Drug & Cosmetic Act once acceptable final labeling is submitted and the clinical site and respiratory matters are adequately addressed. Subpart H provides for restrictions on the marketing, distribution and risk management of pharmaceuticals. Orphan Medical has supplied the FDA with a risk management program under which distribution of Xyrem will be controlled through one central pharmacy.

On April 25, 2002 the Company announced that it has both licensed patent rights and acquired certain data relating to butamben (butyl-p-aminobenzoate) suspension. The Company will investigate butamben as a supplement to opiate analgesia treatment for intractable cancer pain. Initiation of a full development program will depend on the outcome of the Company's continuing market research and development assessment of the product. The Company expects to complete its assessment in the fourth quarter of 2002. If the assessment is positive, the Company will initiate a development program. Costs associated with the acquisition and the completion of the assessment will not be material to the financial results in fiscal 2002.

In addition to licensing worldwide rights under two patents, the Company has acquired pre-clinical and early clinical data. In these studies, a series of epidurally delivered butamben appeared to be highly selective in blocking pain transmission with no residual sensory or motor effects. It also appeared to have long lasting effects, averaging about six months.

THREE MONTHS ENDED MARCH 31, 2002 VS. THREE MONTHS ENDED MARCH 31, 2001

Net loss applicable to common shareholders was $1.2 million for the three months ended March 31, 2002 compared to $1.6 million for the three months ended March 31, 2001. The decrease in net loss can be attributed, in part, to an increase in revenue for the quarter ended March 31, 2002 compared to the same period in the prior year. In addition, the Company had higher expenses for the three months ended March 31, 2002 in both sales and marketing and research and development compared to the same period in the prior year. These increases were offset by lower general and administrative expenses for the first three months of 2002 as compared to the same period in the prior year. The preferred stock dividend increased in the first quarter of 2002 over the first quarter of 2001 due to issuance of additional preferred shares in August 2001 and February 2002 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 57% to $3.7 million for the three months ended March 31, 2002 compared to $2.3 million for the same period in the prior year. The number of institutions using Antizol(R) (fomepizole) Injection continued to grow. Revenue was 29% above the comparable period last year with 59 new hospitals ordering for the first time.

Use of Busulfex(R) (busulfan) Injection in preparative regimens for bone marrow transplantation continued to grow resulting in an increase in first quarter revenue of 36% compared to prior year. The increase was largely due to the conversion of additional protocols in key institutions to regimens that include Busulfex, as the top 25 centers using Busulfex have increased their use by 50% compared to the prior year. International revenue for Busulfex was 547% above the comparable period in the prior year. A substantial portion of the increase was due to the shipment of clinical supplies of drug product to two of our international distribution partners. In addition, shipments of Busulfex for both named patient usage and to countries where Busulfex has not been approved increased over the comparable period in the prior year. Sales from these sources will vary from quarter to quarter based on the needs of the distribution partners.

Gross profit margins decreased to 86% for the 2002 quarter compared to 88% for the 2001 quarter due to product mix. Cost of sales was $0.5 million for the three months ended March 31, 2002 compared to $0.3 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 19% from $0.9 million for the three months ended March 31, 2001 to $1.1 million for three months ended March 31, 2002. The increase results from reduced research and development spending on Xyrem during the first quarter of 2001 pending the outcome of the NDA submission and the increased spending for ongoing Phase III(b) trials for Xyrem during the first quarter of 2002. The Phase III(b) trial for Xyrem now underway will increase research and development spending in subsequent quarters. Clinical spending for this trial will be 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 29% from $1.6 million for the three months ended March 31, 2001 to $2.0 million for the three months ended March 31, 2002. This increase is attributable to spending related to pre-approval market planning for Xyrem. Sales and marketing expenses will likely continue to increase in subsequent quarters, however, at reduced rates of increase

General and administrative expense decreased 4% from $1.2 million for the three months ended March 31, 2001 to $1.1 million for the three months ended March 31, 2002. The decrease in general and administrative expenses is due to a reduction in general consulting expenses for the quarter. 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 43% from $146,974 in the first quarter of 2001 to $84,332 in the first quarter of 2002. Although the average invested balance in the first quarter of 2002 is much larger than the invested balances in the prior

year, the average rate of return has decreased from approximately 6.25% during the first quarter of 2001 to approximately 2.9% during the first quarter of 2002. Other income is expected to decline in subsequent quarters as currently invested funds are used to fund Xyrem marketing and development activities, and for working capital requirements.

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 2002 and 2001 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, 2002 Senior Preferred Stock dividend, the Company elected to issue 23,914 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, it has financed its operations principally from net proceeds from several public and private financings, interest income and product sales. In December 2001, the Company completed a private placement of 1.707 million shares of newly issued common stock, resulting in net proceeds of $13.0 million. The various public and private placement transactions since inception resulted in aggregate net proceeds, after commissions and expenses, of $60.5 million.

Net working capital (current assets less current liabilities) decreased from $18.0 million at December 31, 2001 to $17.1 million at March 31, 2002. Cash and cash equivalents decreased from $19.0 million at December 31, 2001 to $16.5 million at March 31, 2002. The decrease is a result of a $1.3 million decrease in current liabilities as a result of payments in the first quarter offset by an increase in prepaid expenses. The Company continues to invest its excess cash in interest bearing, investment grade securities. The Company has a $1.0 million commercial revolving line of credit with a bank, expiring in June, 2002. The Company expects to renew this facility on substantially similar terms. To date, the Company has not borrowed under this arrangement.

The Company's commitments for outside development spending were $4.7 million at March 31, 2002 and $4.0 million at December 31, 2001. If additional products are licensed for development, these expenditures and commitments could increase significantly.

Management believes the Company's current cash availability and anticipated operating



cash flows from product sales will be sufficient to fund its operations at least

through March 31, 2003.

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 tangible assets in excess of $4.0 million or (2) a market capitalization of at least $50.0 million. Net tangible assets are defined as total assets less the sum of total liabilities and intangible assets. The Company met both of the thresholds at March 31, 2002. The Company's net tangible assets at March 31, 2002 equaled approximately $17.5 million and the Company's market capitalization was approximately $133.8 million (based on the last sale price of $13.00 and 10,291,357 shares outstanding as of March 31, 2002). Although the Company does not expect to be profitable in 2002, the Company nevertheless expects to continue to meet the net tangible asset requirement 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 2002 and thereafter. The NASDAQ National Market issued new listing qualifications, which will become effective November 2002, and which will replace the net asset requirement with a minimum net equity requirement of $10.0 million. At March 31, 2002, the Company meets the new listing requirements with respect to market capitalization. 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 2002 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, 2002 | March 31, 2001 |
| Domestic | $ 2,543,925 | $ 1,920,905 |
| International | 1,137,713 | 420,605 |
| Total | $ 3,681,638 | $ 2,341,510 |

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 investors should carefully consider the following information about these risks before buying shares of common stock.

WE HAVE A HISTORY OF LOSSES.

We have been unprofitable since our inception in 1994. We expect operating losses in 2002 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.

THERE ARE RESTRICTIONS ON OUR ABILITY TO RAISE ADDITIONAL CAPITAL. IF WE ARE UNABLE TO OBTAIN ADDITIONAL FINANCING, WE MAY NOT BE ABLE TO SUPPORT OUR CURRENT OR FUTURE BUSINESS OPERATIONS.

On July 23, 1998, we completed the private sale to UBS Capital II, LLC of $7.5 million of Senior Convertible Preferred Stock. On August 2, 1999, we completed another private sale to UBS Capital II of $3.0 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. On December 7, 2001, we completed the private sale of 1.7 million shares of common stock to a group of investors led by Alta BioPharma Partners II, L.P. In connection with this sale, UBS Capital II agreed to forfeit its right as a preferred stockholder to enforce the restrictions and covenants relating to our ability to incur additional indebtedness and issue additional equity securities. However, we are still subject to other restrictions and covenants relating to the preferred stock, and these restrictions could make it more difficult and more costly for us to obtain additional capital.

We expect our spending for research and development and sales and marketing to increase significantly in fiscal 2002. Although we believe that we have sufficient capital to meet our business objectives in fiscal 2002, if we expand our business plan, or unanticipated events occur, we may need additional capital. We cannot assure you that additional sources of capital will be available to us, or if available, on terms acceptable to us. If we issue additional equity securities, your ownership interest may be diluted.

THE MARKET PRICE OF OUR COMMON STOCK COULD FLUCTUATE IN RESPONSE TO QUARTERLY OPERATING RESULTS AND OTHER FACTORS.

The market price of our common stock could fluctuate significantly in response to a number of factors, including:

- our quarterly financial performance;
- 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; and
- small float or number of shares of our common stock available for sale and trade.

The market value and 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) net tangible assets in excess of $4.0 million as reported on Form 10-Q or Form 10-K or (2) a market capitalization of at least $50.0 million. Net tangible assets are defined as total assets less the sum of total liabilities and intangible assets. Market capitalization is defined as total outstanding shares multiplied by the last sales price quoted by Nasdaq. Although we currently meet the requirements for listing on the Nasdaq National Market, we cannot assure you that we will continue to meet these requirements. The Nasdaq National Market has issued new listing qualifications which will become effective November 2002, and which will replace the net tangible asset requirement with a minimum net equity requirements of $10.0 million. At March 31, 2002, we met the new listing qualifications with respect to market capitalization. We cannot assure you that we will continue to meet the new listing qualification requirements.

The market price of our common stock may also fluctuate significantly in response to other factors over which we have no control and that may not be directly related to us. Fluctuations or decreases in the trading price of our common stock may adversely affect your ability to trade your shares and you may lose all or a part of your investment. In addition, fluctuations and decreases in our stock price could adversely impact our business and our ability to raise capital through additional equity financings.

THERE IS A LIMITED MARKET FOR OUR PRODUCTS.

While we will seek to obtain and market products that address diseases that affect patient populations larger than those affected by orphan diseases (200,000 or fewer patients in the United States), many of our opportunities will address orphan diseases. 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 a "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 obtaining "orphan drug designation" for a product from the FDA. 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, nor does it provide any advantage in, or shorten the duration of, the regulatory approval process.

The second step in obtaining limited protection under the Orphan Drug Act for a specific product is acquiring the FDA's recognition of "orphan drug status." This step involves submission of a New Drug Application ("NDA") to the FDA containing all clinical study results, safety and manufacturing information and requesting approval to market a drug for the designated indication. The FDA will grant orphan drug status to the first company to receive approval of an NDA for the designated indication. Orphan drug status gives a company the exclusive right to market the approved product in the United States for a period of seven years, subject to certain limitations. Obtaining orphan drug status for a particular product may not, however, prevent another company from developing or marketing the same drug having a different formation or composition for the same or different indication. In addition, orphan drug status does not provide any marketing exclusivity in foreign markets. While 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 or will have meaningful or material value to us. Although certain foreign countries provide exclusivity, development and marketing benefits for orphan drugs, we cannot assure you that such benefits can be obtained or, if obtained, will be of material value to us.

We have obtained orphan drug status for Antizol, Elliotts B Solution, Cystadane, Sucraid, and Busulfex. We have obtained orphan drug designation for Xyrem, our narcolepsy drug and our NDA requesting orphan drug status for Xyrem is currently under review by the FDA. If the FDA approves another company's NDA for sodium oxybate (the generic identity of the therapeutic agent for Xyrem) for the same indication as Xyrem prior to approving our NDA for Xyrem, that company will be entitled to exclusive marketing rights for sodium oxybate, and the FDA would not approve our application to market



Xyrem for seven years, if at all. We are aware that the FDA has granted Teva (formerly Biocraft) orphan drug designation for the use of sodium oxybate to treat the symptoms of narcolepsy, however, we have obtained the exclusive right to use Teva's data for one controlled study included in our NDA submission.

While we are not aware of any activities to develop sodium oxybate by any other U.S. company, we cannot assure you that such activities are not being conducted, or that the FDA will approve our NDA for Xyrem first for the designated indication. We also cannot assure you that the FDA will not grant orphan drug designation and orphan drug status to other competing products before or after approving our NDA for Xyrem.

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 has granted Sparta Pharmaceutical, which was acquired by SuperGen Inc., orphan drug designation for an intravenous busulfan with an indication closely related to the indication for our product Busulfex. If the FDA approves an NDA for SuperGen's product for a different indication, SuperGen could seek orphan drug status for that product, which competes with Busulfex. In addition, the FDA does not restrict doctors from prescribing an approved drug for uses not approved by the FDA. Thus, a doctor could prescribe another company's drug for indications for which our product has received FDA approval and orphan drug status. Significant "off label" use, that is, prescribing approved drugs for unapproved uses, could adversely affect the marketing potential of any of our products that have received orphan drug status and NDA approval by the FDA.

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

EUROPE

The European orphan drug act provides for up to ten years of market exclusivity for a pharmaceutical product that meets the requirement of the European orphan drug act. For a pharmaceutical product to qualify under the act, the prevalence (or incidence), of the condition being treated must not exceed five patients per 10,000 population. Our European partners submitted and obtained orphan drug designation under the act for Busulfex and Cystadane, and in May 2001 we were granted orphan drug designation under the act for Antizol for use in methanol poisonings. We submitted a request for orphan drug status for Xyrem in the European Union in 2001. At this time we have not received a formal response to this request. While these products are currently designated as orphan drugs, we cannot assure you that these products will continue to qualify for orphan drug protection in Europe or that we will be able to obtain orphan drug protection in Europe for other or future products. We also cannot provide you any assurance that



another company will not obtain an approval which would block us from marketing our products in Europe.

THE SALE OF OUR PRODUCTS IS DEPENDENT UPON GOVERNMENTAL APPROVAL.

Government regulation in the United States and abroad is a significant factor in

the testing, production and marketing of our products. Each product must undergo an extensive regulatory review process conducted by FDA and by comparable agencies in other countries. We cannot market any pharmaceutical product we develop or license as a prescription product in any jurisdiction, including foreign countries, without 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 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 or any foreign regulatory authority 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.

GOVERNMENTAL APPROVAL OF OUR PRODUCTS DOES NOT GUARANTEE FINANCIAL SUCCESS.

Six of our products have been approved for marketing by regulatory authorities in the United States or elsewhere. Even if we obtain FDA approval to market Xyrem, we cannot assure you that Xyrem or our other 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,



primarily to focus our development efforts and resources on our products that fit within our three therapeutic areas: Antidote; Oncology Support; and Sleep Disorders or for which we believe there is an opportunity for growth or profitability. We evaluate new opportunities in these and other therapeutic areas which we believe have opportunities for growth. We cannot assure you that any of these discontinued products currently, or may in the future, have any value. Depending on available financing, we may develop one or more of these discontinued products in the future. We cannot assure you that we will continue development of our current or any proposed products, or that we will continue

marketing all of our FDA approved products.

SIGNIFICANT GOVERNMENT REGULATION CONTINUES ONCE A PRODUCT IS APPROVED FOR SALE.

After the FDA approves a drug, the FDA's Advertising and Communication division must accept the drug's marketing claims, which are the basis for the drug's labeling, advertising and promotion. We cannot assure you that the FDA will approve our proposed marketing claims. Failure to obtain approval of our proposed marketing claims could have a material adverse effect on our business and prospects.

The FDA requires that we conduct "post-marketing adverse event surveillance programs" to monitor any side effects that occur after any of our drug products are approved for marketing. If the surveillance program indicates unsafe side effects, the FDA may recall the product, and suspend or terminate our 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. To date, none of our products have been subject to an FDA recall. We cannot assure you that our products will not be subject to an FDA recall in the future.

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

If the FDA approves an NDA, the new product may be marketed for the applications or treatments that have been approved by the FDA. The claims with which a product can be marketed are also subject to review and approval by the Division of Drug Marketing, Advertising and Communications ("DDMAC"), the FDA's marketing surveillance department within the Center for Drugs. The FDA often clears a product for marketing with a modification, or restriction to the proposed label claims or requires that post-marketing surveillance, or Phase IV testing, to be conducted. The method and system of a drug's distribution can also be controlled by the FDA if approved under Subpart H regulations.



WE DEPEND ON OTHERS FOR PRODUCT DEVELOPMENT OPPORTUNITIES.

We engage only in limited research to identify new pharmaceutical compounds. To build our product portfolio, we utilize 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 areas. 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 or will be successfully developed, approved or marketed. We 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 license or acquire new pharmaceutical products, or to promote and market products successfully, would 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:

- 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 will meet, or continue to meet, the requirements specified in our current or any future license agreements. We cannot assure you that if any agreement is terminated, we will be able to enter into a similar agreement on terms as favorable as those contained in our existing license agreement.

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 products. The inability to secure contracts for these components 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 our submission of products for regulatory approval, impair our ability to deliver our products on a timely basis, or otherwise adversely affect our business and our prospects.

The loss of either a 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 drug supply or manufacturing process to a new supplier or manufacturer. We believe that it could take as long as one year 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 undertaken to certify and maintain secondary sources of supply for drug substances or backup drug manufacturers for some products. If we lose either a supplier or a product manufacturer, we could run out of salable product to meet market demands or investigational product for use in clinical trials while we locate and then wait for FDA approval of a new drug supplier or manufacturer. We cannot assure you that any change in drug supplier or manufacturer or the transfer of a drug

manufacturing processes to another third party would be approved by the FDA, or approved in a timely manner. The loss of, or change in, drug supplier or a drug 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 Ash Stevens, Inc. for the supply of bulk drug substance used in Busulfex, Antizol, and Antizol-Vet. If we were to lose Ash Stevens 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 2001 and 2000, and which are expected to account for approximately 76% of our revenues in 2002. We depend substantially on Lonza, Inc. for the supply of bulk drug substance used in Xyrem. If we were to lose Lonza as a supplier, we would be required to identify a new supplier before an NDA is submitted for Xyrem. We also cannot assure you that our bulk drug supply arrangements with Ash Stevens and Lonza, 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 an affiliate of Boehringer Ingelheim for drug product manufacturing of Busulfex, Antizol, and Antizol-Vet. Upon FDA approval of Xyrem, an affiliate of DSM, N.V. has been authorized to manufacture Xyrem. If we were to lose Boehringer as a manufacturer, we would be required to identify a new manufacturer for drug products that provided approximately 88% of our total revenues in 2001 and 2000, and which are expected to account for approximately 75% of our total revenues in 2002. We cannot assure you that our drug product manufacturing arrangements with Boehringer and DSM, N.V. will not change or that the manufacturing services will continue to be available on terms satisfactory to us. Any change in our manufacturing agreements with Boehringer and DSM, N.V 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 prescriptions. Failure by our contractors to comply with FDA or DEA requirements or applicable foreign requirements could significantly delay our ability to commercialize or continue to market our products. Either result could have a material adverse effect on our business and prospects. Our contractors failure to comply with good marketing practices or other legal requirements could also result in seizure of violative products, injunctive actions brought by the federal government or 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 with, or will continue to comply with, FDA or DEA requirements or applicable foreign requirements.

WE DEPEND UPON OTHERS FOR DISTRIBUTION OF OUR PRODUCTS.

We have an agreement with CORD Logistics, Inc.(CORD), a subsidiary of Cardinal Health, Inc., to provide integrated distribution and operations services to support transactions between us and our wholesalers, specialty distributors, and direct customers. CORD also provides reimbursement management, patient assistance and information hotline services and specialty distribution and marketing services to physician practices with respect to our products. CORD currently distributes Busulfex, Cystadane, Elliotts B Solution, Antizol, Antizol-Vet, and Sucraid. CORD may also distribute future products should those products receive marketing clearance from the FDA. We are substantially dependent on CORD's ability to successfully distribute Busulfex, Elliotts B Solution, Antizol, Antizol-Vet, and Sucraid and other potential products.

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

We cannot assure you that our distribution arrangements with CORD, Chronimed 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 DEPEND ON FOREIGN COMPANIES TO SELL OUR PRODUCTS OUTSIDE OF THE UNITED STATES AND OUR INABILITY TO ESTABLISH AND MAINTAIN MARKETING ALLIANCES WITH FOREIGN COMPANIES COULD ADVERSELY AFFECT OUR BUSINESS.

Our strategy to sell our products outside of the United States is to license foreign marketing and distribution rights to a foreign company after a NDA is submitted to, or



approved by, the FDA in the United States. We consider Europe, Asia and Canada our most attractive foreign markets. Our current foreign developments are:

- Europe. We have licensed the marketing and distribution rights for Busulfex, Antizol, Cystadane and Sucraid in Europe. If our licensees' registration and distribution efforts are not successful, it may be difficult for us to contract with other distributors in Europe for these products. 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" or "emergency use." Emergency use distribution of our products is expected to result in limited revenues for us.

- Asia. We have licensed marketing and distribution rights for Busulfex in

Japan, the Peoples Republic of China, Taiwan and South Korea. Use and distribution of all products in these countries, except South Korea, is limited to clinical trials until full regulatory approval is obtained. Revenues prior to full approval are not expected to be material. Full regulatory approval for marketing of these products in South Korea was obtained in late 2001. We do not expect to generate material revenues from our South Korean marketing and distribution activities.

- Canada. We have licensed marketing and distribution rights for Antizol and Cystadane. We do not expect to generate material revenues from these marketing and distribution activities.

- Australia and New Zealand. We have licensed marketing and distribution rights for Cystadane and Sucraid in Australia and New Zealand. We do not expect to generate material revenues from these marketing and distribution activities.

- Central America. We have licensed marketing and distribution rights for Elliotts B Solution in Central America. We do not expect to generate material revenues from these marketing and distribution activities.

- Israel. We have licensed marketing and distribution rights for Antizol, Busulfex, Cystadane, and Sucraid in Israel. Full regulatory approval for all products except Antizol was obtained in February 2000. Antizol has been submitted for approval. We do not expect to generate material revenues from these marketing and distribution activities.

- Turkey. We have licensed marketing and distribution rights for Busulfex in Turkey. We do not expect to generate material revenues from these marketing and distribution activities.

We depend on our foreign licensees for the regulatory registration of our products in foreign countries. We cannot assure you that our licensees will obtain such registration. In addition, we cannot assure you 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 our foreign licensees 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, a foreign regulatory authority, or other government agencies having regulatory authority for marketed products. A recall may occur due to disputed labeling claims, manufacturing issues, quality defects, 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, none of our products have been subject to a recall. We cannot assure you that our products will not be subject to a recall in the future.

THE PRICES WE CHARGE FOR OUR PRODUCTS ARE SUBJECT TO GOVERNMENTAL REGULATION WHICH COULD ADVERSELY AFFECT OUR ABILITY TO RECOVER OUR PRODUCT DEVELOPMENT COSTS AND OUR FINANCIAL PERFORMANCE.

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 cannot predict the level of pricing flexibility we will have with respect to our products or whether we, or users of our products, will be reimbursed for newly approved health care products.

In the United States, we expect continuing federal and state proposals to implement government control of the pricing and profitability of prescription pharmaceuticals. Cost controls could decrease, or limit, the price we receive for our current and future products. 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 and prospects. 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 or state governments, if any, with regard to health care reform will not have a material adverse effect on our business and prospects.

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

WE MAY BE UNABLE TO PROTECT OUR PROPRIETARY INFORMATION, WHICH COULD NEGATIVELY AFFECT OUR ABILITY TO COMPETE IN THE PHARMACEUTICAL INDUSTRY.

The pharmaceutical industry and the investment community place considerable



importance and value on obtaining patent 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 patents issued to us 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 and proposed products, Cystadane, Elliotts B Solution, Antizol, Antizol-Vet, Xyrem and Sucraid, are in the public domain and are not currently subject to patent protection in the United States. However, we have filed a patent application with respect to our formulation of Xyrem oral solution. United States patents issued to The University of Texas System and The University of Houston-University Park, the group from whom we license the formulation for Busulfex, cover 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 THE PHARMACEUTICAL 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 designation and 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.

IF WE ARE UNABLE TO RESPOND TO RAPIDLY CHANGING TECHNOLOGIES AND OTHER

DEVELOPMENTS, WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY.

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 $20 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 Risks

Not Applicable



PART II - OTHER INFORMATION

Items 1-6 are not applicable and have been omitted.

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.
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Registrant

Date May 9, 2002 By /s/ Timothy G. McGrath
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Timothy G McGrath
Chief Financial Officer
(duly authorized officer and principal financial officer)