ORPHAN MEDICAL INC
Form 10-Q
May 10, 2001

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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, 2001

[ ] 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 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	8,482,943
(Class)	(Outstanding at April 30, 2001)

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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), "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, 2001 (Unaudited)	DECEMBER 31, 2000
Assets		
Current assets:		
Cash and cash equivalents	$ 5,785,883	$ 1,115,319
Available-for-sale securities	3,026,401	10,301,935
Accounts receivable, less allowance for doubtful accounts of $142,000 and $116,200 for 2001 and 2000, respectively	1,088,090	1,578,544
Inventories	1,605,329	1,602,949
Prepaid expenses	459,031	221,240
Total current assets	11,964,733	14,819,987
Property and equipment:		
Property and equipment	1,003,189	968,118
Accumulated depreciation	(546,338)	(504,187)
	456,851	463,931
Other assets	8,202	12,967
Total assets	$12,429,787	$15,296,885
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	247,765	1,298,047
Accrued outdated product return allowance	143,174	181,483
Accrued compensation	540,199	806,839
Deferred revenues	438,480	500,850
Accrued expenses	1,592,865	1,766,739
Total current liabilities	2,962,483	4,553,958
Commitments		
Shareholders' equity:		
Senior Convertible Preferred Stock, $.01 par value; 14,400 shares authorized; 8,706 and 8,706 shares issued and outstanding	87	87
Series B Convertible Preferred Stock, $.01 par value; 5,000 shares authorized; 3,294 and 3,174 shares issued and outstanding	33	32
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; 8,482,943 and 8,442,759 issued and		

outstanding	84,829	84,427
Additional paid-in capital	58,401,581	57,849,390
Accumulated deficit	(49,015,680)	(47,178,667)
Unrealized gain (loss) on available-for-sale securities	(3,546)	(12,342)
Total shareholders' equity	9,467,304	10,742,927
Total liabilities and shareholders' equity	12,429,787	$15,296,885

Note: The balance sheet at December 31, 2000 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, 2001	March 31, 2000
Revenues	$ 2,341,510	$ 2,742,456
Cost of sales	289,666	459,353
Gross Profit	2,051,844	2,283,103
Operating expenses:		
Research and development	906,193	1,766,403
Sales and marketing	1,566,707	804,590
General and administrative	1,116,392	735,429
Total operating expenses	3,589,292	3,306,422
Loss from operations	(1,537,448)	(1,023,319)
Other income:		
Interest, net	146,974	125,474
Net loss	(1,390,474)	(897,845)
Less: Preferred stock dividends	221,129	211,426

Net loss attributable to common shareholders	(1,611,603)	$(1,109,271)
Basic and diluted loss per common share	$ (0.19)	$ (0.15)
Weighted average number of shares outstanding	8,463,610	7,288,125

See accompanying notes.

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STATEMENTS OF CASH FLOWS
ORPHAN MEDICAL, INC.
(Unaudited)

	For the Three Months Ended	
	March 31, 2001	March 31, 2000
OPERATING ACTIVITIES		
Net loss	(1,390,474)	$ (897,845)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	42,151	32,474
Compensatory options	--	16,991
Changes in operating assets and liabilities:		
Accounts payable and accrued expenses	(1,603,557)	75,378
Inventories	(2,380)	71,184
Accounts receivable and current assets	257,426	(202,444)
Net cash used in operating activities	(2,696,834)	(904,262)
INVESTING ACTIVITIES		
Purchase of office equipment	(35,070)	(45,072)
Purchases of short-term investments	--	(12,639,256)
Maturities of short-term investments	7,284,331	3,782,159
Net cash provided by (used in) investing activities	7,249,261	(8,902,169)
FINANCING ACTIVITIES:		
Employee stock purchase plan	33,033	366,756

Stock option exercise proceeds	85,113	1,506,348
Private common stock placement	--	10,719,963
Cash dividends	(9)	(1,721)
Net cash provided by financing activities	118,137	12,591,346)
Increase (decrease) in cash and cash equivalents	4,670,564	2,784,915
Cash and cash equivalents at beginning of period	1,115,319	205,678
Cash and cash equivalents at end of period	5,785,883	$ 2,990,593
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash interest received	228,728	$ 138,427

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 market segments. 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, 2001 are not necessarily indicative of the results that may be expected for the year ended December 31, 2001. 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, 2000.

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 for discounts for prompt payment. 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, 2001	DECEMBER 31, 2000
Raw materials and packaging	$ 1,129,519	$ 1,213,464
Finished goods	475,810	389,485
	$ 1,605,329	$ 1,602,949

5. COMPREHENSIVE INCOME

The following summarizes the comprehensive income for the periods ended:

	MARCH 31,	
	2001	2000
Net Income	$(1,390,474)	$(1,109,271)
Unrealized gain on securities	8,796	--

Total net comprehensive income	$(1,381,678)	(1,109,271)

6. COMMITMENTS

The Company has various commitments under agreements with outside consultants and contractors to provide services relating to drug development, drug acqusition, manufacturing and marketing. At March 31, 2001, the Company estimates that it could incur approximately $3.9 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 on May 15, 2001. The maximum amount available to the Company under this arrangement is $500,000, 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) $500,000. In addition, the Company must maintain a minimum balance of at least $250,000 in accounts which the bank controls. Advances are charged a variable rate of interest equal to the prime rate plus one half of a percent. Through March 31, 2001, 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

THREE MONTHS ENDED MARCH 31, 2001 VS. THREE MONTHS ENDED MARCH 31, 2000

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, 2001 titled Risk Factors.

GENERAL

The Company incorporated in Minnesota in June 1994 to carry on the business previously conducted by the Orphan Medical Division of Chronimed, Inc. In September 2000, the Company reincorporated in Delaware. Since its inception in January 1993, the activities of the Orphan Medical Division and 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, 2001 of $49.0 million. In addition, the Company expects to incur additional losses from operations in 2001 and 2002.

Net loss applicable to common shareholders was $1.6 million for the three months ended March 31, 2001 compared to $1.1 million for the three months ended March 31, 2000. The increase in net loss can be attributed, in part, to a decrease in revenue for the quarter ended March 31, 2001 compared to the same period in the prior year. In addition, the Company had higher expenses for the three months ended March 31, 2001 in both sales and marketing and general and administrative compared to the same period in the prior year. These increases were offset by lower research and development expenses for the first three months of 2001 as compared to the same period in the prior year. The preferred stock dividend increased in the first quarter of 2001 over the first quarter of 2000 due to issuance of additional preferred shares in August 2000 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 decreased 15% to $2.3 million for the three months ended March 31, 2001 compared to $2.7 million for the same period in the prior year. Sales of Antizol(R) (fomepizole) Injection were lower for the three months ended March 31, 2001 as compared to the same period in the prior year. During 2000 several pharmaceutical wholesale supply chain management customers started to stock Antizol in inventory in addition to shipping directly to end users. This

stocking activity increased the sales during that time period. The Company believes that these pharmaceutical wholesale supply chain management customers are now fully stocked and that the sales predominantly reflect actual hospital purchasing in the current quarter. Domestic sales for Busulfex(R) (busulfan) Injection continue to grow. Busulfex is increasingly being considered for use in many bone marrow and stem cell transplant preparatory regimens. The Company has been successful in obtaining protocol status for Busulfex in a growing number of oncology protocols at leading bone marrow transplant centers. International sales for Busulfex for the three months ended March 31, 2001 were less than during the same period in the prior year. During the first quarter of 2000 one of our international distribution partners purchased an initial supply of Busulfex. While the distribution partner continues to purchase the product, the quantities are less than the initial stocking quantity.

Gross profit margins increased to 88% for the 2001 quarter compared to 83% for the 2000 quarter due to product mix. Cost of sales was $0.3 million for the three months ended March 31, 2001 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 decreased 49% from $1.8 million for the three months ended March 31, 2000 to $0.9 million for three months ended March 31, 2001. The decrease results from reduced research and development spending on Xyrem during the current quarter pending the outcome of the NDA submission. The first quarter 2001 spending includes ongoing trials for Xyrem and other development activities for Busulfex. 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 95% from $0.8 million for the three months ended March 31, 2000 to $1.6 million for the three months ended March 31, 2001. This increase is largely attributable to spending related to significantly higher spending in pre-approval market planning for Xyrem. Sales and marketing expenses will likely continue to increase in subsequent quarters, however, at substantially reduced rates of increase

General and administrative expense increased 52% from $0.7 million for the three months ended March 31, 2000 to $1.1 million for the three months ended March 31, 2001. The increase in general and administrative expenses is related to building infrastructure including the addition of staff to prepare for the anticipated Xyrem launch. General and administrative expenses are not expected to rise significantly above current levels in the next few quarters.

Other income is the sum of interest income from investment activities less interest expense from financing activities. Other income increased 17% from $125,474 in the 2000 first quarter to $146,974 in the 2000 first quarter. This increase is the result of additional invested funds from the sale of common stock in the first quarter of 2000.

Other income is expected to decline in subsequent quarters as currently invested funds are used to fund Xyrem development activities, and other company operations 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 2001 and 2000 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 preferred stock and common stock, as permitted by the terms of the Senior Convertible Preferred Stock and the Series B Convertible Preferred Stock. For the February 1, 2001 Senior Preferred Stock dividend, the Company elected to issue 20,572 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. The 1999 private placement of convertible preferred stock resulted in net proceeds of $2.9 million. In February 2000, the Company completed a private placement of 1.365 million shares of newly issued common stock, resulting in net proceeds of $10.7 million. The various public and private placement transactions since inception

resulted in aggregate net proceeds, after commissions and expenses, of $47.5 million.

Net working capital (current assets less current liabilities) decreased from $10.3 million at December 31, 2000 to $9.0 million at March 31, 2001. Cash and cash equivalents, and available-for-sale securities decreased from $11.4 million at December 31, 2000 to $8.8 million at March 31, 2001. The Company continues to invest its excess cash in interest bearing, investment grade securities. The Company has a $500,000 commercial revolving line of credit with a bank, expiring on May 15, 2001. The Company expects to renew this facility on substantially similar terms. In connection with the financing transaction in August 1999, the Company received a $2.05 million commitment in the form of a line of credit from UBS Capital. Amounts outstanding under this line of credit bear an interest rate of 7.5% and mature on August 2, 2002. To date, the Company has not borrowed under either of these arrangements.

The Company's commitments for outside development spending was at $3.9 million at both December 31, 2000 and March 31, 2001. The Company expects development spending to not increase significantly over current levels unless additional products are licensed for development.

The Company expects spending during 2001 for research and development, along with sales and marketing to increase over 2000 levels. Management believes the Company's current working capital and anticipated operating cash flows from product sales will be sufficient to fund its operations at least through March 31, 2002.

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, 2001. The Company's net tangible assets at March 31, 2001 equaled approximately $9.5 million and the Company's market capitalization was approximately $92.8 million (based on the last sale price of $10.938 and 8,482,943 shares outstanding as of March 31, 2001). Although the Company does not expect to be profitable in 2001 and 2002, the Company nevertheless expects 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 2001 and thereafter.

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

if available, on acceptable terms.

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, 2001 and 2000, respectively.

	For the Three Months Ended	
	March 31, 2001	March 31, 2000
Domestic	$1,920,905	$2,197,650
International	420,605	544,806
Total	$2,341,510	$2,742,456

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 in 2001 and 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.

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) 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. We met both of these criteria as of March 31, 2001, however, we cannot assure you that the market capitalization threshold will continue to be met or that we will continue to have 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 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 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 Antizol, Elliotts B Solution, Cystadane, Sucraid, and Busulfex.

We have obtained orphan drug designation for Xyrem and, on October 2, 2000, we submitted an NDA for approval. Sodium oxybate is the generic identity of the therapeutic agent for Xyrem. Despite orphan drug designation for Xyrem, another pharmaceutical company could attempt to develop sodium oxybate for the same designated indication as Xyrem or may seek approval of an NDA for their drug prior to the approval of an NDA for Xyrem. If the FDA first approves another sponsor's NDA for sodium oxybate and for the same indication as Xyrem, that sponsor will be entitled to

exclusive marketing rights. In that case, 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 in our NDA submission. While we are not aware of activities to develop sodium oxybate by any other US Company, we cannot assure you that the FDA will approve Xyrem first for the designated indication. We also cannot assure you that the FDA will not grant orphan drug designation and marketing approval to other competing products prior to 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 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's product for a different indication, SuperGen could seek orphan drug status. In addition, the FDA does not restrict doctors from prescribing an approved product for uses not approved by the FDA for that product. 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 population. Our European partners have submitted both Busulfex and Cystadane for designation as orphan drugs in Europe. The Company has also submitted Antizol, for use in methanol poisonings, for designation as an orphan drug 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 which 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 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 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. Moreover, even if the FDA approves a product, it may place commercially unacceptable limitations on the uses, "indications," or conditions for which a product may be marketed or on the way it is marketed. This could result in additional cost and delay for further studies to provide additional data on safety or effectiveness. It could also result in the development of costly distribution systems. Any one of, or a combination of, these factors could lead to the decision not to market the drug.

FDA APPROVAL 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 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 requires 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 in only 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 preferably 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 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 products that fit within one of our strategic therapeutic market segments, or our failure to promote and market any products successfully or products within an existing strategic therapeutic market segment, 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 services 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 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 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 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 2000 and 90% of 1999 revenues and are expected to generate approximately 85% of 2001 total revenues. 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 approved 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. 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 2000 and 90% of 1999 and are expected to generate approximately 85% of 2001 total revenues. We have identified an affiliate of DSM, N.V as drug product manufacturer for Xyrem and have contracted with them for its manufacture. We cannot assure you that our drug product manufacturing arrangements with Boehringer and DSM will not change in the future. We cannot assure you that any change would not adversely affect production of Busulfex, Antizol, Antizol-Vet, or Xyrem, or any other drug that we might attempt to develop or market.

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 subsidiary of Cardinal Health, Inc.("Cardinal") to provide a variety of services to support the effective distribution of our currently approved products. Cardinal will provide integrated distribution and

operations services to process and support transactions between us and our wholesalers, specialty distributors, and direct customers. Cardinal will also provide patient assistance and information hotline services,

and specialty distribution and marketing services to physician practices. Cardinal currently distributes Busulfex, Elliotts B Solution, Antizol, Antizol-Vet, and Sucraid. Cardinal may also distribute our proposed products should those products receive marketing approval from the FDA. We will substantially depend upon Cardinal's ability to successfully distribute Busulfex, Elliotts B Solution, Antizol, Antizol-Vet, and Sucraid and potentially any other of our products that may receive marketing clearance from the FDA in the future.

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 substantially depend upon Chronimed's ability to successfully distribute Cystadane directly to patients in the United States.

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

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 developments are:

- Europe. We have licensed the marketing and distribution rights for Busulfex, Antizol, Cystadane and Sucraid 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 "emergency use" 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 and Sucraid in Australia and New Zealand. We do not expect revenues to be material from such distribution.

- Israel. We have licensed marketing and distribution rights for Antizol, Busulfex, Cystadane, Elliotts B Solution and Sucraid in Israel. Full regulatory approval for all products except Antizol was obtained in Israel in February 2000. Antizol has been submitted for approval, however, approval has not yet been received. 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.

- Central America. We have licensed marketing and distribution rights for Elliotts B Solution in Central America, but sales have not been material. We do not expect domestic or foreign revenues of Elliotts B Solution to become material.

- 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, emergent unexpected 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 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 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 and proposed products, Cystadane, Elliotts B Solution, Antizol, Antizol-Vet, Xyrem and Sucraid, are in the public domain and presently are not 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 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 at 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 $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.
Registrant

Date May 10, 2001

By /s/ Timothy G. McGrath

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