ORPHAN MEDICAL INC
Form 10-Q
May 10, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

ý Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

for the quarterly period ended March 31, 2005

o 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 No.)
13911 Ridgedale Drive, Suite 250, Minnetonka, MN 55305	**(952) 513-6900**
(Address of principal executive offices, including zip code)	(Registrant s telephone number, including area code)

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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 ý No o

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

Yes ý No o

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	**11,489,399**
(Class)	(Outstanding at April 27, 2005)

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ORPHAN MEDICAL, INC. ®

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

ORPHAN MEDICAL, INC.

BALANCE SHEETS

($ in thousands, except share and per share amounts)

	March 31, 2005 (Unaudited)	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 9,542	$ 12,709
Restricted cash	125	125
Accounts receivable, less allowance for doubtful accounts of $25 and $25, respectively	3,044	2,303
Inventories	2,642	2,482
Prepaid expenses	1,842	372
Other	35	177
Total current assets	17,230	18,168
Office equipment and software, net	356	464
Total assets	$ 17,586	$ 18,632
Liabilities and shareholders equity		
Current liabilities:		
Accounts payable	$ 1,926	$ 2,014
Accrued compensation	780	1,091
Deferred revenue	833	1,250
Accrued expenses and other	4,380	3,444
Total current liabilities	7,919	7,799
Capital lease obligation-less current maturities	38	43
Commitments		
Shareholders equity:		
Senior Convertible Preferred Stock, $.01 par value; 14,000 shares authorized; 8,706 shares issued and outstanding; liquidation preference of $8,706		
Series B Convertible Preferred Stock, $.01 par value; 5,000 shares authorized; 4,420 and 4,259 shares issued and outstanding; liquidity preference of $4,420 and $4,259		
Series C Convertible Preferred Stock, $.01 par value; 4 ,000 shares authorized; 0 shares issued and outstanding		
Series D Convertible Preferred Stock, $.01 par value; 1,500,000 shares authorized; 0 shares issued and outstanding		
Common stock, $.01 par value; 23,477,000 shares authorized; 11,488,024 and 11,430,066 issued and outstanding	115	114
Additional paid-in capital	81,610	81,006
Accumulated deficit	(72,096)	(70,330)
Total shareholders equity	9,629	10,790
Total liabilities and shareholders equity	$ 17,586	$ 18,632

See Accompanying Notes.

Orphan Medical, Inc.

Statements of Operations

($ in thousands, except per share amounts)

(Unaudited)

	For the Three Months Ended March 31,	
	2005	**2004**
Product revenues, net	$ 6,692	$ 4,403
Licensing and royalty revenue	1,453	1,000
Total revenue	8,145	5,403
Operating expenses:		
Cost of product revenues	985	631
Product development	2,564	4,222
Sales and marketing	4,297	3,398
General and administrative	1,627	1,207
Total operating expenses	9,473	9,458
Loss from operations	(1,328)	(4,055)
Interest income	60	52
Interest expense	(7)	(22)
Net loss before taxes	(1,275)	(4,025)
Income tax expense		
Net loss	(1,275)	(4,025)
Less: Preferred stock dividends	242	239
Net loss applicable to common shareholders	$ (1,517)	$ (4,264)
Loss per share applicable to common shareholders		
Basic and diluted	$ (0.13)	$ (0.40)
Weighted average number of shares outstanding		
Basic and diluted	11,458	10,775

See Accompanying Notes.

Orphan Medical, Inc.

Statements of Cash Flows

($ in thousands)

(Unaudited)

	For the Three Months Ended March 31,	
	2005	**2004**
Operating activities		
Net loss	$ (1,275)	$ (4,025)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	108	111
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	(2,069)	653
Inventories	(160)	138
Accounts payable and accrued expenses	839	(2,226)
Deferred revenue	(417)	
Net cash used in operating activities	(2,974)	(5,349)
Investing activities		
Purchase of office equipment		(34)
Net cash used in investing activities		(34)
Financing activities		
Employee stock purchase plan	16	16
Stock option exercise proceeds	98	150
Principal payments on capital lease	(6)	(4)
Payments on premium finance note	(302)	
Cash dividends	1	
Net cash (used in) provided by financing activities	(193)	162
Decrease in cash and cash equivalents	(3,167)	(5,221)
Cash and cash equivalents at beginning of period	12,709	23,285
Cash and cash equivalents at end of period	$ 9,542	$ 18,064
Schedule of non-cash financing activities		
Premium finance note for corporate insurance	$ 885	$

Orphan Medical, Inc.

Notes to Financial Statements

($ in thousands, except per share amounts)

(Unaudited)

1. Basis of Presentation

Business

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

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, these financial statements do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal, recurring accruals) considered necessary for fair presentation have been included. Operating results for the three month period ended March 31, 2005 are not necessarily indicative of the results that may be expected for the year ended December 31, 2005. For further information, refer to the audited financial statements and accompanying notes contained in the Company s Annual Report filed on Form 10-K as amended for the year ended December 31, 2004.

2. Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

3. Stock-Based Compensation

At March 31, 2005 the Company has a stock-based employee compensation plan. The Company accounts for its plan under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees , and related interpretations. No stock-based compensation cost is reflected in the net loss for the three month periods ended March 31, 2005 or 2004, as all options granted under this plan had an exercise price equal to market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation , to stock-based employee compensation.

	Three Months Ended March 31,	
	2005	2004
Net loss applicable to common shareholders, as reported	$ (1,517)	$ (4,264)
Deduct total stock-based employee compensation expense determined under fair value-based method for all awards	(686)	(743)
Pro forma net loss	$ (2,203)	$ (5,007)
Loss per share		
Basic and diluted - as reported	$ (0.13)	$ (0.40)
Basic and diluted - as pro forma	$ (0.19)	$ (0.46)

4. Revenue Recognition

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

Deferred revenue represents the initial payment received by the Company per the terms of the Company s license agreement for Xyrem with UCB Pharma (formerly Celltech Pharmaceuticals). The Company is recognizing this payment over the expected regulatory approval period, which is 18 months.

The Company received $1.0 million during the quarter ended March 31, 2005 as payment for the achievement of a milestone per the terms of the UCB Pharma license agreement. This payment is included in Licensing and royalty revenue in the Company s Statement of Operations. Future milestone payments are expected to be recognized as earned based on the achievement of the milestone as indicated in the license agreement.

5. Inventories

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

	March 31, 2005	December 31, 2004
Raw materials and packaging	$ 733	$ 795
Finished goods	1,909	1,687
	$ 2,642	$ 2,482

6. Loss per Share

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

	Three Months Ended March 31,	
	2005	2004
Numerator		
Numerator for basic loss per share net loss applicable to common shareholders	$ (1,517)	$ (4,264)
Add back to effect assumed conversions:		
Preferred stock dividends		
Numerator for diluted loss per share	$ (1,517)	$ (4,264)
Denominator		
Denominator for basic loss per share weighted average shares	11,458	10,775
Effect of dilutive securities:		
Convertible preferred shares		
Stock options		
Warrants		
Denominator for diluted loss per share weighted average shares and assumed conversions	11,458	10,775
Basic and diluted loss per share	$ (0.13)	$ (0.40)

7. Commitments

The Company has various commitments under agreements with outside consultants, contract drug developers and manufacturers, technical service companies, drug distributors, along with commitments for various marketing, advertising and promotional activities. In addition, the Company has commitments under license and research agreements. The Company does not have any joint venture agreements nor does it have any arrangements to perform product development or sales and marketing activities for other parties. At March 31, 2005, the Company estimates that it could incur approximately $10.1 million of additional expenditures in subsequent periods for operating activities under existing commitments. Commitments for these operating activities will likely fluctuate from quarter to quarter and from year to year depending on, among other factors, the timing of new marketed products or new product development, if any, and other clinical trial activity.

8. Borrowings

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

9. Subsequent Event

The Company announced on April 19, 2005 that it has entered into an agreement and plan of merger pursuant to which Jazz Pharmaceuticals, through a wholly owned subsidiary, will acquire Orphan Medical. Under the agreement, which was unanimously approved by the Company s Board of Directors, Orphan Medical common stockholders will receive $10.75 per share in cash upon the close of the transaction. Following the merger, which will be consummated following the satisfaction or waiver of certain customary closing conditions, Orphan Medical will become a wholly owned subsidiary of Jazz Pharmaceuticals, a privately held company.

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 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 Risk Factors section of this Quarterly Report on Form 10-Q.

General

Since its inception, the activities of the Company have consisted primarily of obtaining the rights to pharmaceutical products for developing and marketing, managing the development of these products and preparing for and initiating the commercial introduction of six products. Three of these products are currently marketed and three were divested in 2003. 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, 2005 of $72.1 million. In addition, the Company expects to incur additional losses from operations for at least the next several fiscal quarters.

Recent Developments

On April 18, 2005, Orphan Medical, Inc. (the Company) entered into an Agreement and Plan of Merger with Jazz Pharmaceuticals, Inc., a Delaware corporation, and Twist Merger Sub, Inc., a Delaware corporation and wholly owned subsidiary of Jazz Pharmaceuticals, Inc. Under the merger agreement, Jazz Pharmaceuticals would acquire the Company for $10.75 in cash per share of common stock of the Company.

The Company s outstanding shares of preferred stock, consistent with the rights and preferences of the holders of such stock as set forth in the Company s certificate of incorporation, also will be converted into the right to receive cash in the merger. Each outstanding share of Senior Convertible Preferred Stock will be converted into the right to receive $1,320.6386 in cash, together with accrued but unpaid dividends, and each outstanding share of Series B Convertible Preferred Stock will be converted into the right to receive $1,653.8462 in cash, together with accrued but unpaid dividends.

Each outstanding option and warrant to purchase shares of the Company s common and/or preferred stock, to the extent vested as of the effective time of the merger, will also be cancelled in exchange for a cash payment equal to the difference between $10.75 and the exercise price per share of common or preferred stock subject to such option or warrant.

Pursuant to the merger agreement, Jazz Pharmaceutical s obligation to acquire the Company is conditioned upon, among other things, the receipt of the portion of the merger consideration being financed by Jazz Pharmaceuticals, the receipt of regulatory approvals and approval by the

Company s stockholders. A copy of the merger agreement and joint press release announcing the transaction was filed as an exhibit to a Form 8-K filed with the Securities and Exchange Commission on April 20, 2005.

On April 18, 2005, the Company, Jazz Pharmaceuticals, Inc. and Twist Merger Sub, Inc. also entered into a Voting Agreement with the following current stockholders of the Company: Alta BioPharma Partners II, L.P., Alta Embarcadero BioPharma Partners II, LLC, John Howell Bullion, OrbiMed Advisors LLC and UBS Capital II LLC (the Principal Stockholders), whereby the Principal Stockholders agreed to vote in favor of the merger with Jazz Pharmaceuticals and against approval of any proposal made in opposition to, or in competition with, such merger transaction. A copy of the voting agreement was filed as an exhibit to a Form 8-K filed with the Securities and Exchange Commission on April 20, 2005.

Results of Operations

Three Months Ended March 31, 2005 vs. Three Months Ended March 31, 2004

Net loss applicable to common shareholders was $1.5 million for the three months ended March 31, 2005 compared to a net loss applicable to common shareholders of $4.3 million for the three months ended March 31, 2004. The decrease in the net loss applicable to common shareholders was primarily due to an increase in product revenue, specifically Xyrem, and licensing and royalty revenue while total operating expenses remained consistent with the first quarter in the prior year.

Product Revenue Summary

The following is a summary of product revenue for the three months ended March 31, 2005 compared to the three months ended March 31, 2004:

	Three Months Ended March 31,		Variance	
($ in thousands)	**2005**	**2004**	**$**	**%**
Antizol	$ 2,354	$ 2,237	$ 117	5%
Antizol-Vet	65	59	6	10
Cystadane	332	368	(36)	(10)
Xyrem	3,941	1,739	2,202	127
Total	$ 6,692	$ 4,403	$ 2,289	52%

Net product revenues increased 52% to $6.7 million for the three months ended March 31, 2005 compared to $4.4 million for the same period in the prior year. The change was driven by growth in Xyrem revenue. Revenue from Xyrem was $3.9 million for the quarter ended March 31, 2005 compared to $1.7 million for the quarter ended March 31, 2004. The increase is the result of a higher prescription volume resulting from continued market penetration. Over 2,350 physicians had written prescriptions for Xyrem as of March 31, 2005. The number of filled prescriptions in the first quarter of 2005 increased 94 percent over the same quarter the prior year and 10 percent over the previous quarter.

Licensing and royalty revenue for the three months ended March 31, 2005 was $1.5 million. This included a $1.0 million milestone payment made by UCB Pharma in accordance with its licensing agreement with the Company, $0.4 million related to the amortized portion of the upfront payment from UCB Pharma for European registration and marketing of Xyrem for narcolepsy, and $0.1 million of Sucraid royalties, a product which was divested in June 2003.

Cost of product revenues increased $0.4 million or 56% to $1.0 million for the three months ended March 31, 2005 from $0.6 million for the same period in the prior year. The increase is primarily attributable to the increase in product revenues during the first quarter of 2005. The gross margin was relatively consistent at 85.3% and 85.7% for the three months ended March 31, 2005 and 2004, respectively. Cost of product revenues as a percentage of net product revenues will fluctuate from quarter to quarter and from year to year depending on, among other factors, demand for the Company s products, new product introductions and the mix of approved products shipped.

Product development expense was $2.6 million and $4.2 million for the first quarters ended March 31, 2005 and 2004, respectively, a decrease of $1.6 million or 39%. The decrease is a result of the completion of two Xyrem Phase III(b) trials during fiscal 2004. The majority of the spending in the current quarter was associated with the clinical trial designed to evaluate Xyrem in the treatment of Fibromyalgia Syndrome. The Company expects that initial data from this 150 patient placebo controlled trial will be available in the second half of 2005. Trial sites are located throughout the United States and Canada with approximately twenty participating centers. Clinical spending for trials is dependent on a number of factors, including among others, the number of human subjects screened and enrolled in the trial, and the number of active clinical sites. Orphan Medical is also assessing Xyrem as a potential treatment for other indications.

Sales and marketing expense increased 26% to $4.3 million for the three months ended March 31, 2005 from $3.4 million for the three months ended March 31, 2004. This change is due to increased spending on various Xyrem sales and marketing programs.

General and administrative expense increased 35% to $1.6 million for the first quarter ended March 31, 2005 compared to $1.2 million for the first quarter ended March 31, 2004. The increase is the result of merger transaction expenses and higher audit fees primarily associated with the requirements of Section 404 of the Sarbanes-Oxley Act.

Liquidity and Capital Resources

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

Net working capital (current assets less current liabilities) decreased to $9.3 million at March 31, 2005 from $10.4 million at December 31, 2004. Cash and cash equivalents decreased to $9.5 million at March 31, 2005 from $12.7 million at December 31, 2004. The Company invests excess cash in short-term, interest-bearing, investment grade securities.

The primary sources of capital for the three months ended March 31, 2005 were product revenues, licensing and royalty revenues, and existing cash balances.

In October 2003, the Company announced that it had licensed European sales and marketing rights for Xyrem (sodium oxybate) oral solution to UCB Pharma (formerly Celltech Pharmaceuticals). Under the terms of the agreement, UCB Pharma will be responsible for the registration, sales and marketing of Xyrem in Europe. UCB Pharma has made an initial payment of $2.5 million to Orphan Medical. In the first quarter of 2005, the Company received an additional $1.0 million milestone payment as a result of the submission of the sNDA on January 15, 2005.The

Company also received a $1.0 million milestone payment in the first quarter of 2004 as a result of the submission of the marketing application in Europe. UCB Pharma will make further payments of up to $5 million tied to product development and registration milestones and up to $6 million tied to sales-related milestones. UCB Pharma will also pay Orphan Medical a royalty on sales of the product which is expected to begin at the earliest in late 2005. The licensing agreement includes the use of Xyrem in narcolepsy and provides UCB Pharma with rights to negotiate in regard to other potential future indications including fibromyalgia syndrome. The term of this agreement is for 10 years from the date of approval in Europe with automatic extension until UCB Pharma provides 12 month notice to Orphan Medical. The agreement may be terminated under certain conditions including material breach of contract provisions prior to the ten year initial term.

The Company used more capital than its operations generated for the three months ended March 31, 2005. The Company expects to incur a loss from operations in 2005, which will continue to decrease its capital reserves. The Company continues to invest its capital in product development activities that may provide opportunities to enhance the commercial opportunities for Xyrem. The Company has committed $10.1 million to future product development and marketing activities. In addition, the Company also continues to use capital to develop and enhance the commercial programs for Xyrem. The Company expects that these efforts may result in increased Xyrem revenues. The Company expects that its current cash balances, cash flow from product revenues and any milestone payments received in accordance with the terms of the UCB Pharma agreement will be sufficient to fund operations well into 2006. The Company may consider additional sources of capital should it decide to expand its product development programs or acquire additional products.

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

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

The Company s commitments for outside operating expenses decreased to approximately $10.1 million at March 31, 2005 from $12.0 million at December 31, 2004. These commitments are generally for less than one year. The decrease is principally attributable to the completion of the Phase III(b) clinical trials assessing Xyrem for the treatment of EDS in narcolepsy. This is offset by costs and commitments associated with the initiation of the Fibromyalgia trial along with continued spending for other development programs, including the ongoing Xyrem extended release formulation activities and the continued evaluation of Butamben as a treatment for chronic malignant pain. In addition, the Company continues to assess opportunities relating to current products and to new product opportunities, which, if pursued, will increase development spending. Due to the dependence of this estimate on the results of the studies and other variable components, actual results may be different than the Company s estimates.

For continued listing on the NASDAQ National Market, a company must satisfy a number of requirements, which in the Company s case include either: (1) net equity in excess of $10.0 million or (2) a market capitalization of at least $50.0 million. The Company met both the thresholds at March 31, 2005. The Company s market capitalization was approximately $104.7 million as of March 31, 2005 (based on the last sale price of $9.11 and 11,488,024 million shares outstanding). Although the Company does not expect to be profitable in 2005, the Company nevertheless expects to continue to meet the listing requirements for listing on the NASDAQ National Market. However, there can be no assurance that the Company will continue to meet these requirements in the future.

In connection with the 1998 and 1999 private placements of convertible preferred stock, the Company agreed to certain restrictions and covenants, which could limit its ability to obtain additional financing. 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 product revenues by geographic region for the three month periods ended March 31, 2005 and 2004, respectively.

	Three Months Ended March 31,	
($ in thousands)	**2005**	**2004**
Domestic	$ 6,306	$ 4,067
International	386	336
Total	$ 6,692	$ 4,403

Off-Balance Sheet Arrangements

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

RISK FACTORS

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

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

We have been unprofitable since our inception in January 1993, with the exception of 2003 due to the divestment of three products. We expect operating losses at least through 2005 because anticipated gross profits from product revenues and anticipated licensing and royalty revenues will not offset our operating expenses. The amount of these losses may vary significantly from year-to-year and quarter-to-quarter. Our actual

losses will depend on, among other factors, the timing of product development, regulatory approval, and market demand for our Food and Drug Administration approved products. We cannot assure you that we will ever generate sufficient product revenues to achieve profitability.

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

Although we believe that we have sufficient capital to meet our current business objectives at March 31, 2005, we may need additional capital if we expand our business, if business conditions change or results of operations are not as expected. Adequate funds for our operations, continued development, and expansion of our business plans, whether from financial markets or from other sources, may not be available when needed on acceptable terms, or at all. If we issue additional securities your ownership may be diluted.

In addition there are restrictions on our ability to raise additional capital that are part of the terms of the sales of our preferred stock. On July 23, 1998, we completed the private sale to UBS Capital of $7.5 million of Senior Convertible Preferred Stock. On August 2,

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

Possible Price Volatility and Limited Liquidity of Common Stock.

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

general national and international economic and political developments;

governmental approvals, refusals to approve, regulations or actions;

developments or disputes relating to patents or proprietary rights;

public concern over the safety of therapies;

financial performance;

fluctuations in financial performance from period to period; and

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

There is also a risk that the market value and the liquidity of the public float for our common stock could be adversely affected in the event we no longer meet the NASDAQ s requirements for continued listing on the National Market. For continued listing on the NASDAQ National Market, a company must satisfy a number of requirements, which in our case includes either: (1) minimum net equity in excess of $10.0 million as reported on Form 10-Q or Form 10-K or (2) a market capitalization of at least $50.0 million. Market capitalization is defined as total outstanding shares multiplied by the last sales price quoted by NASDAQ. We met both criteria as of March 31, 2005, however, we cannot assure you that the market capitalization threshold will continue to be met or that we will be able to generate adequate capital to meet the net tangible asset requirement.

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

There is a limited market for our products.

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

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

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

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

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

United States

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

The first step in obtaining the limited protection under the Orphan Drug Act is acquiring the FDA s approval of orphan drug designation, which must be requested before submitting a New Drug Application (NDA). After the FDA grants orphan drug designation, it publishes the generic identity of the therapeutic agent and the potential orphan use specified in the request. Orphan drug

designation does not constitute FDA approval. In addition, orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory approval process.

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

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

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

Europe

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

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

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

ability:

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

to preserve the confidentiality of our trade secrets; and

to operate without infringing the proprietary rights of third parties.

We evaluate the desirability of seeking patent or other forms of protection for our products in foreign markets based on the expected costs and relative benefits of attaining such protection. We cannot assure you that any patents will be issued from any applications or that any issued patents will afford us adequate protection or competitive advantage. Also, we cannot assure you that any issued patents will not be challenged, invalidated, infringed or circumvented. Parties not affiliated with us have obtained or may obtain United States or foreign patents or possess or may possess proprietary rights relating to our products. We cannot assure you that patents now in existence or later issued to others will not adversely affect the development or commercialization of our products.

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

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

We seek to protect our proprietary information and technology, in part, through confidentiality agreements and inventors rights

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

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

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

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

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

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

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

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

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

FDA approval does not guarantee financial success.

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

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

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

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

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

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

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

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

We rely on others for product development opportunities.

We engage only in limited research to identify new pharmaceutical compounds. To build our product portfolio, we have adopted a license and acquisition strategy. This strategy for growth requires us to identify and acquire pharmaceutical products targeted at niche markets within our selected therapeutic markets. These products usually require further development and approval by regulatory bodies before they can be marketed. We cannot assure you that any such products can be successfully acquired, developed, approved or marketed. We must rely upon the willingness of others to sell or license pharmaceutical product opportunities to us. Other companies, including those with substantially greater resources, compete with us to acquire such products. We cannot assure you that

we will be able to acquire rights to additional products on acceptable terms, if at all. Our failure to acquire or license any new pharmaceutical products, or our failure to promote and market any products successfully within an existing therapeutic area, could have a material adverse effect on our business and our prospects.

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

for cause if we breach the contract;

if we become insolvent or bankrupt;

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

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

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

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

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

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

The loss of either a bulk drug supplier or drug product manufacturer would require us to obtain regulatory clearance in the form of a pre-approval submission and incur validation and other costs associated with the transfer of the bulk drug or drug product manufacturing process. We believe that it could take as long as two years for the FDA to approve such a submission. Because our products are targeted to relatively small markets and our manufacturing production runs are small by industry standards, we have not incurred the added costs to certify and maintain secondary sources of supply for bulk drug substance or backup drug product manufacturers for some products. Should we lose either a bulk drug supplier or a drug product manufacturer, we could run out of marketable product to meet market demands or investigational product for use in clinical trials, while we wait for the FDA approval of a new bulk drug supplier or drug product manufacturer.

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

Bulk Drug Supply

Bulk drug substance is the active chemical compound used in the manufacture of our drug products. We currently have a single supplier for the supply of bulk drug substance used in Cystadane, Antizol and Antizol-Vet. If we were to lose a company as a supplier, we would be required to identify a new supplier for the bulk drug substance. We also currently use a single supplier for the supply of bulk drug substance used in Xyrem, which is expected to exceed 60% of our revenue in 2005. If we were to lose this company as a supplier, we would be required to identify a new supplier. The contract with the manufacturer of the bulk drug substance for Antizol and Antizol-Vet was terminated in 2004, although the supplier will continue to provide bulk drug substance until May 2006. We have contracted with a new manufacturing source for this product and have begun the transfer of the manufacturing process. While we believe that this transfer will be completed in a timely manner and that there will be no interruption in the supply of our Antizol and Antizol-Vet, there can be no assurance that this process will be completed in the appropriate time period to ensure supply of inventory.

Drug Product Manufacture

From bulk drug substance, drug product manufacturers formulate a finished drug product and package the product for sale or for use in clinical trials. We also use a single supplier for drug product manufacturing of Antizol, Antizol-Vet and a different supplier has been authorized to manufacture Xyrem. If we were to lose either of these companies as a manufacturer, we would be required to identify a new manufacturer. We cannot assure you that our drug product manufacturing arrangements with either or both of these suppliers will not change. We have also decided to change the relationship with the manufacturer of finished drug product for Xyrem. The supply agreement with the Xyrem finished drug product manufacturer has been extended to 2008. The current manufacturer

will continue to manufacturer the product; however, final packaging will be completed by an additional vendor. We have identified a new source for this packaging and have executed an agreement for this service. There can be no assurance that any necessary manufacturing operations or regulatory supplements will be completed in the appropriate time period to ensure supply of inventory.

We cannot control our contractors compliance with applicable regulations.

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

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

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

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

Xyrem is classified as a Schedule III controlled substance.

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

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

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

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

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

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

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

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

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

Our products might be recalled.

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

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

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

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

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

We face intense competition in our industry.

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

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

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

We face substantial product liability and insurance risks.

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes to the Company s market risk since the filing of the Company s Annual Report on Form 10-K as amended.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of the end of the period covered by this report. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

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

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Submission of Matters to a Vote of Security Holders

None

Item 5. Other Information

None

Item 6. Exhibits

Exhibit Number	Description
2.1	

	Agreement and Plan of Merger, dated as of April 18, 2004, by and among the Company, Jazz Pharmaceuticals, Inc. and Twist Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed on April 20, 2005).
10.1	Voting Agreement, dated as of April 18, 2005, by and among the Company, Jazz Pharmaceuticals, Inc. and Twist Merger Sub, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 20, 2005).
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32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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, 2005 By /s/ Timothy G. McGrath
Timothy G McGrath
Chief Financial Officer
(duly authorized officer and principal financial officer)

INDEX TO EXHIBITS

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