

ORPHAN MEDICAL INC  
Form 10-Q  
May 10, 2004

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended March 31, 2004

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**  
(State or other jurisdiction of

**41-1784594**  
(I.R.S. Employer Identification

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incorporation or organization)  
**13911 Ridgedale Drive, Suite 250,  
Minnetonka, MN 55305**  
(Address of principal executive office  
and zip code)

Number)  
**(952) 513-6900**  
(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  No

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

Yes  No

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

Common Stock, \$.01 par value

10,811,596

(Class)

(Outstanding at April 23, 2004)

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INDEX

**ORPHAN MEDICAL, INC.®**

**Page No.**

**PART I. FINANCIAL INFORMATION**

**Item 1.**

Financial Statements (Unaudited)

Balance Sheets March 31, 2004 and December 31, 2003.

3

Statements of Operations - Three months ended March 31, 2004 and March 31, 2003.

4

Statements of Cash Flows - Three months ended March 31, 2004 and March 31, 2003.

5

Notes to Financial Statements

6

**Item 2.**

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

10

**Item 3.**

Quantitative and Qualitative Disclosures about Market Risk

24

**Item 4.**

Controls and Procedures

24

**PART II. OTHER INFORMATION**

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

**Item 6.**

Exhibits and Reports on Form 8-K

27

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

## Item 1. Financial Statements

## Orphan Medical, Inc.

## Balance Sheets

(In thousands, except share and per share amounts)

	<u>March 31</u>	<u>December 31,</u>
	<u>2004</u>	<u>2003</u>
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,064	\$ 23,285
Restricted cash	128	128
Accounts receivable, less allowance for doubtful accounts of \$173 and \$112, respectively	1,731	2,552
Inventories	1,558	1,696
Prepaid expenses and other	1,075	907
	<hr/>	<hr/>
Total current assets	22,556	28,568
Office equipment and software	2,170	2,136
Accumulated depreciation	(1,493)	(1,382)
	<hr/>	<hr/>
	677	754
	<hr/>	<hr/>
Total assets	\$ 23,233	\$ 29,322
	<hr/>	<hr/>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 467	\$ 2,923
Accrued compensation	778	881
Deferred revenue	2,500	2,500
Accrued expenses and other	2,774	2,460
	<hr/>	<hr/>
Total current liabilities	6,519	8,764
Capital lease obligation-less current maturities	57	62
Commitments		
Shareholders' equity:		
Senior Convertible Preferred Stock, \$.01 par value; 14,400 shares authorized; 8,706 shares issued and outstanding		
Series B Convertible Preferred Stock, \$.01 par value; 5,000 shares authorized; 4,106 and 3,957 shares issued and outstanding		
Series C Convertible Preferred Stock, \$.01 par value; 4,000 shares authorized; 0 shares issued and outstanding		
Series D Convertible Preferred Stock, \$.01 par value; 1,500,000 shares authorized; 0 shares issued and outstanding		
Common stock, \$.01 par value; 25,000,000 shares authorized;		

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10,805,416 and 10,747,656 issued and outstanding	<b>March 31</b> 108	<b>December 31,</b> 107
Additional paid-in capital	77,378	76,714
Accumulated deficit	(60,829)	(56,325)
	<hr/>	<hr/>
Total shareholders' equity	16,657	20,496
	<hr/>	<hr/>
Total liabilities and shareholders' equity	\$ 23,233	\$ 29,322
	<hr/>	<hr/>

See accompanying notes.

3

**Statements of Operations**

**Orphan Medical, Inc.**

(In thousands, except share and per share amounts)

(Unaudited)

	For the Three Months Ended	
	March 31, 2004	March 31, 2003
	<hr/>	<hr/>
Product revenues	\$ 4,403	\$ 4,568
Licensing and royalty revenues	1,000	
	<hr/>	<hr/>
Total revenues	5,403	4,568
	<hr/>	<hr/>
Operating expenses:		
Cost of sales	631	747
Research and development	4,222	2,166
Sales and marketing	3,398	4,253
General and administrative	1,207	1,264
	<hr/>	<hr/>
Total operating expenses	9,458	8,430
	<hr/>	<hr/>
Loss from operations	(4,055)	(3,862)

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Other income:		
Interest income	52	21
Interest expense	(22)	(13)
	<hr/>	<hr/>
Net loss	(4,025)	(3,854)
Less: Preferred stock dividends	239	234
	<hr/>	<hr/>
Net loss attributable to common shareholders	\$ (4,264)	\$ (4,088)
	<hr/>	<hr/>
Basic and diluted loss per common share	\$ (0.40)	\$ (0.39)
	<hr/>	<hr/>
Weighted average number of shares outstanding	10,774,798	10,472,263
	<hr/>	<hr/>

*See accompanying notes.*

4

**Statements of Cash Flows**

**Orphan Medical, Inc.**

**(In thousands, except share and per share amounts)**

(Unaudited)

	For the Three Months Ended	
	<hr/> March 31, 2004	<hr/> March 31, 2003
	<hr/>	<hr/>
<b>Operating activities</b>		
Net loss	\$ (4,025)	\$ (3,854)
Adjustments to reconcile net loss to net cash used in operating activities:		

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Depreciation and amortization	111	112
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	653	(744)
Inventories	138	(9)
Accounts payable and accrued expenses	(2,226)	(321)
	<u>          </u>	<u>          </u>
Net cash used in operating activities	(5,349)	(4,816)
<b>Investing activities</b>		
Purchase of property and equipment	(34)	(25)
	<u>          </u>	<u>          </u>
Net cash provided by (used in) investing activities	(34)	(25)
<b>Financing activities:</b>		
Employee stock purchase plan	16	9
Stock option exercise proceeds	150	166
Principal payments on capital lease	(4)	(4)
	<u>          </u>	<u>          </u>
Net cash provided by financing activities	162	171
	<u>          </u>	<u>          </u>
Decrease in cash and cash equivalents	(5,221)	(4,671)
Cash and cash equivalents at beginning of period	23,285	6,921
	<u>          </u>	<u>          </u>
Cash and cash equivalents at end of period	<u>\$ 18,064</u>	<u>\$ 2,250</u>

*See accompanying notes*

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**Orphan Medical, Inc.**

**Notes to Financial Statements**

(Unaudited)



## 1. Basis of Presentation

### *Business*

Orphan Medical, Inc. is a specialty pharmaceutical company focused primarily on sleep disorders, pain and other central nervous system (CNS) disorders. We seek to acquire, develop and market pharmaceutical products that are prescribed by physician specialists and offer a major improvement in the safety or efficacy of patient treatment and have no substantially equivalent substitute. The Company's lead product, Xyrem® (sodium oxybate) solution is approved for the treatment of cataplexy, a debilitating symptom of narcolepsy, a sleep disorder. The Company has two clinical trials that are near completion that may demonstrate that Xyrem treats excessive daytime sleepiness (EDS) and other symptoms of narcolepsy. We also expect to begin a clinical trial in the first half of 2004 to assess Xyrem in treating the symptoms of Fibromyalgia Syndrome (FMS). We are also assessing development of an unrelated product, Butamben (butyl-p-amino benzoate), for the treatment of cancer pain.

Since its inception, the Company has obtained New Drug Application (NDA) approvals from the United States Food and Drug Administration (FDA) for six specialty pharmaceutical products. Each of the NDAs was granted Orphan Drug Status by the FDA. The Company currently markets three other NDA approved drugs: Antizol® (fomepizole) Injection, an antidote for ethylene glycol or suspected ethylene glycol ingestion in humans and an antidote for methanol or suspected methanol ingestion in humans; Cystadane® (betaine anhydrous for oral solution), for homocystinuria, a genetic disease; and Antizol-Vet® (fomepizole) for injection, an antidote for ethylene glycol or suspected ethylene glycol ingestion in dogs.

### *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, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. For further information, refer to the audited financial statements and accompanying notes contained in the Company's Annual Report filed on Form 10-K/A for the year ended December 31, 2003.

## 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, 2004 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, 2004 or 2003, 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 common 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.

(in thousands except per share data)	Three months ended March 31,	
	2004	2003
Net loss attributable to common shareholders as reported	\$ (4,264)	\$ (4,088)
Deduct total stock-based employee compensation expense determined under fair value-based method for all awards	(743)	(556)
Pro forma net income (loss)	\$ (5,007)	\$ (4,644)
Loss per common share		
Basic and diluted as reported	\$ (0.40)	\$ (0.39)
Basic and diluted as pro forma	\$ (0.46)	\$ (0.44)

#### 4. Revenue Recognition

Sales for all products, except Xyrem, are recognized at the time a product is shipped to the Company's customers and are recorded net of reserves for discounts for prompt payment. Sales of Xyrem are recognized at the time product is shipped from the specialty pharmacy to the patient and are recorded net of discounts for prompt payment. Except for Xyrem, the Company is obligated to accept, for exchange, from all domestic customers products that have reached their expiration date, which range from 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. The Company monitors the exchange of product and modifies its reserve as necessary. Management bases these reserves on historical experience and these estimates are subject to change.

Deferred revenue represents the initial payment received by the Company per the terms of the Company's license agreement with Celltech Pharmaceuticals, a division of Celltech Group plc (Celltech). Upon expiration of the refund conditions, this fee will be recognized over the expected regulatory review period. Beginning April 1, 2004, the Company will recognize this fee over the estimated 18 month review period.

The Company received as new \$1.0 million during the quarter ended March 31, 2004 as payment for the achievement of a milestone in the 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.

## 5. Inventories

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

	March 31, 2004	December 31, 2003
Raw materials and packaging	\$ 728	\$ 690
Finished goods	830	1,006
Total	\$ 1,558	\$ 1,696

## 6. Loss Per Share

Loss per common share is computed in accordance with SFAS No. 128, "Earnings Per Share". Basic loss per common share is computed based on the weighted average number of common shares outstanding during the period. Diluted loss per common 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.

## 7. Commitments

The Company has various commitments under agreements with outside consultants and contractors to provide services relating to drug development, drug acquisition, manufacturing and marketing. At March 31, 2004, the Company estimates that it could incur approximately \$12.5 million of additional expenditures in subsequent periods under existing commitments. Commitments for product 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.

## 8. Borrowings

The Company extended its line of credit facility with a commercial bank to September 30, 2004. This line of credit facility includes a borrowing base equal to 75 percent of eligible accounts receivable up to a maximum amount of \$2.5 million. Certain other assets have also been pledged as collateral for this facility. The interest rate is equal to two points over the bank's prime rate. The Company is also subject to certain other requirements during the term of the facility, including (a) minimum quarterly net tangible equity of \$6.0 million plus 50 percent of the proceeds of any equity securities or subordinated debt offering and (b) maximum monthly operating loss of \$2.7 million for April, May and June 2004 and \$2.0 million for July August and September. The Company was in

compliance with these covenants as of March 31, 2004. The Company had not borrowed under this facility as of March 31, 2004.

#### **9. Income taxes**

The Company had a net operating loss for the quarter ended March 31, 2004, and therefore had no income tax expense for the quarter ended March 31, 2004.

#### **10. Subsequent Event**

On April 14, 2004, the Company filed a "shelf" registration statement on Form S-3 with the Securities and Exchange Commission (SEC) for the registration of 4,000,000 shares of common stock.

#### **11. Reclassifications**

As previously reported, the Company reclassified certain operating expenses to align the financial statements with the Company's current management of its operations. These expenses were reclassified from General and Administrative expenses to Product Development and Sales and Marketing expenses. Certain prior year balances have been reclassified in order to conform to current year presentation. These reclassifications have no impact on net loss or shareholders' equity as previously reported.

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

**Cautionary Statement**

This Quarterly Report on Form 10-Q contains statements that are not descriptions of historical facts. The words or phrases "will likely result", "look for", "may result", "will continue", "is anticipated", "expect", "project", or similar expressions are intended to identify forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements may be forward-looking statements that are subject to risks and uncertainties. Actual results could differ materially from those currently anticipated due to a number of factors, including those identified in the section of this Quarterly Report filed on Form 10-Q for the quarterly period ended March 31, 2004 titled Risk Factors.

**General**

Since its inception, the activities of the Company have consisted primarily of obtaining the rights for developing and marketing proposed pharmaceutical products, managing the development of these products and preparing for and initiating the commercial introduction of six products. The Company operates in a single business segment: pharmaceutical products. The Company has experienced recurring losses from operations and has generated an accumulated deficit through March 31, 2004 of \$56.3 million. In addition, the Company expects to incur additional losses from operations in fiscal years at least through mid 2005.

### **Recent Developments**