

ORPHAN MEDICAL INC
Form 10-Q
November 14, 2003

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 September 30, 2003
- Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission File Number 0-24760

Orphan Medical, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

41-1784594
(I.R.S. Employer Identification Number)

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

(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
(Class)

10,744,703
(Outstanding at November 1, 2003)

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PART II. OTHER INFORMATION

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

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

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PART I FINANCIAL INFORMATION
ITEM 1. Financial Statements

ORPHAN MEDICAL, INC.
BALANCE SHEETS
(In thousands except share data)

	<u>September 30, 2003</u>	<u>December 31, 2002</u>
	<u>(Unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,680	\$ 6,921
Restricted cash	127	251
Accounts receivable, less allowance for doubtful accounts of \$56 and \$25, respectively	1,480	2,215
Inventories	1,232	2,020
Prepaid expenses and other	715	576
	<u>30,234</u>	<u>11,983</u>
Total current assets	30,234	11,983
Property and equipment, net	855	1,156
Total assets	<u>\$ 31,089</u>	<u>\$ 13,139</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 763	\$ 1,380
Accrued royalties	133	235
Accrued compensation	1,080	1,795
Accrued expenses	2,348	1,901
	<u>2,348</u>	<u>1,901</u>

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	September 30, 2003	December 31, 2002
Total current liabilities	4,324	5,311
Capital lease obligation-less current maturities	66	78
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; 3,957 and 3,677 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; 10,744,703 and 10,460,283 issued and outstanding	108	105
Additional paid-in capital	76,665	74,033
Accumulated deficit	(50,074)	(66,388)
Total shareholders' equity	26,699	7,750
Total liabilities and shareholders' equity	\$ 31,089	\$ 13,139

Note: The Balance Sheet at December 31, 2002 has been derived from the audited financial statements at that date but does not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements.

See Accompanying Notes.

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Orphan Medical, Inc.
Statements of Operations
(In thousands except per share data)

(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2003	2002	2003	2002
Revenues, net	\$ 2,982	\$ 4,155	\$ 11,898	\$ 11,337
Cost of sales	501	609	1,965	1,661
Gross Profit	2,481	3,546	9,933	9,676
Operating expenses:				
Research and development	2,540	2,254	6,135	4,668

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	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
Sales and marketing	3,316	3,539	11,103	7,262
General and administrative	1,542	1,922	5,247	4,484
Total operating expenses	7,398	7,715	22,485	16,414
Loss from operations	(4,917)	(4,169)	(12,552)	(6,738)
Interest income, net	40	64	27	215
Other income			30,267	
Net (loss) income before taxes	(4,877)	(4,105)	17,742	(6,523)
Income tax expense	(251)		(509)	
Net (loss) income	(5,128)	(4,105)	17,233	(6,523)
Less: Preferred stock dividends	238	235	704	688
Net (loss) income attributable to common shareholders	\$ (5,366)	\$ (4,340)	\$ 16,529	(\$ 7,211)
(Loss) earnings per common share				
Basic	\$ (0.50)	\$ (0.42)	\$ 1.56	\$ (0.70)
Diluted	\$ (0.50)	(0.42)	1.33	(0.70)
Weighted average number of shares outstanding				
Basic	10,682	10,373	10,573	10,331
Diluted	10,682	10,373	12,912	10,331

See Accompanying Notes.

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Orphan Medical, Inc.
Statements of Cash Flows
(In thousands)

(Unaudited)

	For the Nine Months Ended	
	September 30, 2003	September 30, 2002
Operating activities		
Net income (loss)	\$ 17,233	\$ (6,523)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	394	165
Gain on disposition of products	(30,267)	
Changes in operating assets and liabilities:		
Accounts receivable and current assets	596	(649)
Inventories	787	(634)
Accounts payable and accrued expenses	(871)	2,041
Net cash used in operating activities	(12,128)	(5,600)

Investing activities

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	For the Nine Months Ended	
Purchase of office equipment	(33)	(668)
Decrease in restricted cash	124	
Net proceeds on disposition of products	30,267	
	<u>30,358</u>	<u>(668)</u>
Net cash provided (used in) by investing activities	30,358	(668)
Financing activities		
Employee stock purchase plan	35	31
Stock option exercise proceeds	1,507	335
Payments on capital lease	(12)	
Private common stock placement		(8)
Cash dividends	(1)	(1)
	<u>1,529</u>	<u>357</u>
Net cash provided by financing activities	1,529	357
Increase (decrease) in cash and cash equivalents	19,759	(5,911)
Cash and cash equivalents at beginning of period	6,921	19,011
	<u>6,921</u>	<u>19,011</u>
Cash and cash equivalents at end of period	<u>\$ 26,680</u>	<u>\$ 13,100</u>

See Accompanying Notes.

ORPHAN MEDICAL, INC.

**NOTES TO FINANCIAL STATEMENTS
(Unaudited)**

1. Basis of Presentation

Business

Orphan Medical acquires, develops, and markets products of high medical value intended to treat sleep disorders, pain and other central nervous disorders 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). While three have been divested, 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 is conducting clinical trials to assess Xyrem in treating excessive daytime sleepiness and fragmented nighttime sleep, the other prominent symptoms of narcolepsy. A new compound, Butamben (butyl-p-aminobenzoate) suspension for injection, is being evaluated for development as a treatment of pain. The Company is seeking other approved or development-stage products in the specialty areas it serves.

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 and nine-month period ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ended December 31, 2003. For further information, refer to the audited financial statements and accompanying notes contained in the Company's Annual Report filed on Form 10-K for the year ended December 31, 2002.

2. Disposition of Products

On June 10, 2003, the Company announced the disposition of Busulfex®(busulfan) Injection to ESP Pharma, Inc. for \$29.3 million plus the book value of inventory, approximately \$0.2 million. The Company announced the sale of the product Sucraid®(sacrosidase) oral solution to a specialty pharmaceutical company on May 6, 2003 for \$1.5 million. The Company also divested a third product, Elliotts B Solution®to the same specialty company for proceeds that were not material. Proceeds from these dispositions will be used for further development and marketing of

Xyrem and for the creation of a stronger presence in the sleep and central nervous system (CNS) markets.

3. 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.

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4. Stock-Based Compensation

At September 30, 2003 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 or nine month periods ended September 30, 2003 or 2002, as all options granted under this plan had an exercise price equal to market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net income (loss) and net income (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 September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
(in thousands except per share data)				
Net income (loss) as reported	\$ (5,366)	\$ (4,340)	\$ 16,529	\$ (7,211)
Deduct total stock-based employee compensation expense determined under fair value-based method for all awards	(791)	(489)	(2,049)	(1,457)
Pro forma net income (loss)	\$ (6,157)	\$ (4,829)	\$ 14,480	\$ (8,668)
Earnings (loss) per share				
Basic as reported	\$ (0.50)	\$ (0.42)	\$ 1.56	\$ (0.70)
Basic as pro forma	\$ (0.58)	\$ (0.47)	\$ 1.37	\$ (0.84)
Diluted as reported	\$ (0.50)	\$ (0.42)	\$ 1.33	\$ (0.70)
Diluted as pro forma	\$ (0.58)	\$ (0.47)	\$ 1.24	\$ (0.84)

5. 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 two to four years depending on the product. The Company is not

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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.

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6. 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.

	September 30, 2003	December 31, 2002
Raw materials and packaging	\$ 311	\$ 1,023
Finished goods	921	997
	\$ 1,232	\$ 2,020

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7. Earnings Per Share

Earnings per share is computed in accordance with SFAS No. 128, Earnings Per Share. Basic earnings (loss) per share is computed based on the weighted average number of common shares outstanding during the period. Diluted earnings (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. The following is a reconciliation of net income (loss) and weighted average common shares outstanding for purposes of calculating basic and diluted earnings (loss) per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands except per share data)	2003	2002	2003	2002
<i>Numerator</i>				
Numerator for basic earnings per share				
income available to common shareholders	\$ (5,366)	\$ (4,340)	\$ 16,529	\$ (7,211)
Add back to effect assumed conversions:				
Preferred stock dividends			704	
	\$ (5,366)	\$ (4,340)	\$ 17,233	
Numerator for diluted earnings per share				