

ATRIX LABORATORIES INC

Form 10-Q

November 09, 2004

Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended September 30, 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 0-18231

ATRIX LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	84-1043826 (I.R.S. Employer Identification No.)
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2579 Midpoint Drive, Fort Collins, Colorado (Address of principal executive offices)	80525 (Zip Code)
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Registrant's telephone number, including area code: **(970) 482-5868**

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 (or for such shorter period that the registrant was required to file such reports), 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

The number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of October 29, 2004, was 21,385,020.

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

TABLE OF CONTENTS

	Page
<u>PART I. FINANCIAL INFORMATION</u>	2
<u>Item 1. Consolidated Financial Statements (unaudited)</u>	2
<u>Consolidated Balance Sheets September 30, 2004 and December 31, 2003</u>	2
<u>Consolidated Statements of Operations Three and Nine Months Ended September 30, 2004 and 2003</u>	3
<u>Consolidated Statements of Cash Flows Nine Months Ended September 30, 2004 and 2003</u>	4
<u>Notes to Consolidated Financial Statements</u>	5
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	33
<u>Item 4. Controls and Procedures</u>	33
<u>PART II. OTHER INFORMATION</u>	34
<u>Item 1. Legal Proceedings</u>	34
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	34
<u>Item 6. Exhibits</u>	35
<u>SIGNATURES</u>	36
<u>Rule 13a-14(a) Certification of CEO</u>	
<u>Rule 13a-14(a) Certification of CFO</u>	
<u>Section 1360 Certification of CEO</u>	
<u>Section 1350 Certifications of CFO</u>	

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

ATRIX LABORATORIES, INC. AND SUBSIDIARIES**CONSOLIDATED BALANCE SHEETS**(In thousands, except share and per share data)
(unaudited)

	September 30, 2004	December 31, 2003
	<hr/>	<hr/>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 30,187	\$ 19,074
Marketable securities available-for-sale, at fair value	80,124	80,688
Accounts receivable, net of allowance for doubtful accounts of \$31 and \$1,019	10,857	10,235
Interest receivable	904	834
Inventories, net	14,673	11,516
Prepaid expenses and deposits	2,182	2,488
	<hr/>	<hr/>
Total current assets	138,927	124,835
	<hr/>	<hr/>
PROPERTY, PLANT AND EQUIPMENT, NET	22,315	21,855
	<hr/>	<hr/>
OTHER ASSETS:		
Goodwill	379	379
Intangible and other assets, net	3,282	2,789
	<hr/>	<hr/>
Other assets	3,661	3,168
	<hr/>	<hr/>
TOTAL ASSETS	\$ 164,903	\$ 149,858
	<hr/>	<hr/>
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable trade	\$ 3,790	\$ 2,488
Accrued expenses and other	1,689	1,644
Deferred revenue	8,500	9,923
	<hr/>	<hr/>

Total current liabilities	<u>13,979</u>	<u>14,055</u>
DEFERRED REVENUE AND OTHER	<u>32,046</u>	<u>32,415</u>
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS EQUITY:		
Series A convertible preferred stock, \$0.001 par value, 20,000 shares authorized; 15,824 and 14,770 shares issued and outstanding. Liquidation preference \$15,958 and \$15,240		
Preferred stock, \$0.001 par value; 5,000,000 shares authorized Series A preferred stock, \$0.001 par value, 200,000 shares authorized, none issued or outstanding issued or outstanding		
Common stock, \$0.001 par value; 45,000,000 shares authorized; 21,345,009 and 21,567,801 shares issued; 21,345,009 and 20,701,001 shares outstanding	21	22
Additional paid-in capital	271,807	270,157
Treasury stock, 0 and 866,800 shares, at cost		(13,616)
Accumulated other comprehensive (loss) / income	(509)	1,035
Accumulated deficit	<u>(152,441)</u>	<u>(154,210)</u>
Total shareholders equity	<u>118,878</u>	<u>103,388</u>
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	<u>\$ 164,903</u>	<u>\$ 149,858</u>

See notes to the consolidated financial statements.

Table of Contents**ATRIX LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS**(In thousands, except share and per share data)
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2004	2003	2004	2003
REVENUE:				
Net sales	\$ 5,090	\$ 2,685	\$ 16,945	\$ 7,488
Net royalties	4,905	2,657	13,110	5,637
Contract research and development	3,885	5,773	13,684	15,772
Licensing, marketing rights and milestone	2,235	2,524	6,472	6,546
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total revenue	16,115	13,639	50,211	35,443
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
OPERATING EXPENSE:				
Cost of sales	3,436	2,901	13,236	6,191
Research and development	8,376	8,738	24,999	26,707
Administrative and marketing	2,502	2,387	8,284	7,901
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total operating expense	14,314	14,026	46,519	40,799
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
INCOME (LOSS) FROM OPERATIONS	<u>1,801</u>	<u>(387)</u>	<u>3,692</u>	<u>(5,356)</u>
OTHER INCOME (EXPENSE):				
Equity in loss of joint venture		(6)		(83)
Investment income, net	702	638	2,008	2,059
Gain on sale of marketable securities, net	167	139	687	567
Gain on exchange rates			348	
Other	(3)	(7)	(39)	(23)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Net other income	866	764	3,004	2,520
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
NET INCOME (LOSS)	<u>2,667</u>	<u>377</u>	<u>6,696</u>	<u>(2,836)</u>
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Accretion of dividends and beneficial	(727)	(424)	(1,459)	(918)

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conversion feature charge on preferred stock				
Allocation of undistributed earnings to participating preferred stock	(105)	_____	(259)	_____
	_____	_____	_____	_____
NET INCOME (LOSS) APPLICABLE TO COMMON STOCK	\$ 1,835	\$ (47)	\$ 4,978	\$ (3,754)
	_____	_____	_____	_____
Net income (loss) applicable to common stock per common share:				
Basic	\$ 0.09	\$ 0.00	\$ 0.24	\$ (0.19)
Diluted	\$ 0.08	\$ 0.00	\$ 0.22	\$ (0.19)
	_____	_____	_____	_____
Weighted average common shares outstanding:				
Basic	21,270,487	20,257,238	21,008,992	19,925,896
Diluted	22,602,624	20,257,238	22,303,240	19,925,896

See notes to the consolidated financial statements.

Table of Contents**ATRIX LABORATORIES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands, unaudited)

	For the Nine Months Ended September 30,	
	2004	2003
	<hr/>	<hr/>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	\$ 6,696	\$ (2,836)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,522	2,488
Amortization of deferred revenue	(7,108)	(7,523)
Provision for doubtful accounts	26	660
Equity in loss of joint venture		83
Gain on sale and write-down of marketable securities, net	(687)	(567)
Gain on exchange rates	(347)	
Other non-cash items	109	92
Net changes in operating assets and liabilities:		
Accounts receivable	(643)	(3,212)
Interest receivable	(71)	77
Inventories, net of provisions	(3,170)	(2,920)
Prepaid expenses and deposits	306	(1,538)
Accounts payable	1,295	(4,957)
Accrued expenses and other	46	157
Deferred revenue	5,317	7,333
	<hr/>	<hr/>
Net cash provided by (used in) operating activities	4,291	(12,663)
	<hr/>	<hr/>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of property, plant and equipment	(2,540)	(7,529)
Investment in intangible and other assets	(734)	(515)
Proceeds from maturity and sale of marketable securities	55,454	32,596
Investment in marketable securities	(55,723)	(26,710)
Investment in joint venture		(302)
	<hr/>	<hr/>
Net cash used in investing activities	(3,543)	(2,460)
	<hr/>	<hr/>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of equity securities	10,368	10,275
Payments to acquire treasury stock		(2,875)

Net cash provided by financing activities	10,368	7,400
NET EFFECT OF EXCHANGE RATE ON CASH	(3)	632
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	11,113	(7,091)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	19,074	30,698
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 30,187	\$ 23,607

Non-cash investing and financing activities (in thousands):

2004

Issued preferred stock par valued at \$1,055 to Elan for accreted dividends for the nine months ended September 30, 2004.

Retired 866,800 shares of Treasury stock (see Part II Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities).

2003

Issued restricted common stock valued at \$22 as part of employment separation agreements.

Issued preferred stock par valued at \$983 to Elan for accreted dividends for the nine months ended September 30, 2003.

Long-term deposits on equipment of \$869 were reclassified to property, plant and equipment

See notes to the consolidated financial statements.

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 1. BASIS OF PRESENTATION

The accompanying unaudited consolidated financial statements of Atrix Laboratories, Inc. and its subsidiaries (collectively referred to as Atrix or the Company) have been prepared in accordance with generally accepted accounting principles (GAAP) for interim consolidated financial statements and with the instructions to Form 10-Q and Article 10 of Regulation S-X. In the opinion of management, all adjustments considered necessary, including normal recurring accruals, for a fair presentation have been included. The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include allowances for doubtful accounts, reserves for excess or obsolete inventories and the term over which deferred revenues are recognized. Operating results for the nine months ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, for the year ended December 31, 2003, filed with the Securities and Exchange Commission (the SEC), in the Company s Annual Report on Form 10-K.

NOTE 2. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Atrix Laboratories, Inc. was formed in August 1986 as a Delaware corporation. In November 1998, Atrix acquired ViroTex Corporation. In June 1999, Atrix organized its wholly owned subsidiary Atrix Laboratories Limited, which was based in London, England until its closure during the first quarter of 2004. In February 2000, Atrix organized its wholly owned subsidiary Atrix Laboratories GmbH, which is based in Bad Homburg, Germany, to conduct its European operations. In June 2000, the Company entered into a research joint venture, Transmucosal Technologies, Ltd. (TTL), with Elan International Services, Ltd., a wholly owned subsidiary of Elan Corporation, plc. The joint venture was terminated in September 2003 (see Note 7).

Atrix is an emerging specialty pharmaceutical company focused on advanced drug delivery. With unique patented drug delivery technologies, the Company is currently developing a diverse portfolio of products, including proprietary oncology and dermatology products. Atrix is a relatively small but growing company selling pharmaceutical products to specialists, such as oncologists and urologists, as opposed to general practitioners. The Company also forms strategic alliances with a variety of pharmaceutical and biotechnology companies to develop products utilizing various drug delivery systems and/or to commercialize products. These strategic alliances include collaborations with Sanofi-Synthelabo, Inc., Fujisawa Healthcare, Inc., Sandoz Inc., Pfizer Inc., Aventis, Sosei Co. Ltd., MediGene AG, Yamanouchi U.K. Limited, Mayne Pharma, Tecnofarma International, Han All Pharmaceutical Co., Ltd., Arius Pharmaceuticals, Inc. and CollaGenex Pharmaceuticals, Inc.

Significant Accounting Policies

Principles of consolidation

The accompanying consolidated financial statements include the accounts of Atrix Laboratories, Inc. and its wholly owned subsidiary Atrix Laboratories, GmbH. All significant intercompany transactions and balances have been eliminated. While the Company initially owned 80.1% of TTL's outstanding common stock, Elan and its subsidiaries retained significant minority investor rights that were considered participating rights as defined in Emerging Issues Task Force Consensus 96-16, *Investor's Accounting for an Investee When the Investor Has a Majority of the Voting Interest, but the Minority Shareholder or Shareholders Have Certain Approval or Veto Rights*. Elan's significant rights in TTL that were considered participating rights included equal representation in the management of the joint venture and development of its business plan and approval rights on the board of directors as it relates to the business plan. Accordingly, prior to the termination of the joint venture in September 2003, the Company accounted for its investment in TTL under the equity method of accounting. Since September 2003, TTL has been incorporated into the Company's consolidated financial statements.

Table of Contents***Revenue recognition***

The Company recognizes revenue on product sales and contract manufacturing in two components; product revenue and royalty revenue.

The first portion of revenue from product sales is recognized at the time of shipment when title to the product transfers and the customer bears risk of loss, the Company has evidence of an agreement, collection is reasonably assured and the price is fixed or determinable. The Company does not maintain a reserve for product returns. Atrix's marketing partners are responsible for all product after shipment from our facility. The Company's marketing agreements do not provide for returns and Atrix has not experienced any significant returns to-date.

The second component of revenue from product sales is royalties. Royalty revenue is recorded when product is shipped by licensees to end customers based on information provided by the licensee and royalty rates and formulas as specified in agreements with licensees. Generally, royalties are based on estimated net sales (gross sales less discounts, allowances and other items) of a product based on information supplied to the Company by the licensee and may require future revisions. Timing issues will frequently cause fluctuations in the Company's reported income / (loss) from operations as a result of product launches and the Company's rapid sales growth. When the Company launches a new product only the first portion of revenue may be recognized as the Company ships product to marketing partners in anticipation of product launch. Later, as marketing partners launch sales efforts, royalties will be recognized with no corresponding cost of goods to Atrix. This timing offset can cause reported income / (loss) from operations to fluctuate especially in periods of rapid sales growth and new product launches.

Contract research and development is performed on a best effort basis under signed contracts. Revenue under contracts with a fixed price is recognized over the term of the agreement on a straight-line basis, which is consistent with the pattern of work performed. Billings are made in accordance with schedules as specified in each agreement, which generally include an up-front payment as well as periodic payments. Payments received in advance of revenue recognition are recorded as deferred revenue. Revenue under other contracts is recognized based on terms as specified in the contracts, including billings for time incurred at rates as specified in the contracts and as reimbursable expenses are incurred. Such arrangements are regularly evaluated on an individual basis. Billings under these contracts are made monthly.

The Company has licensing agreements that generally provide for non-refundable license fees and/or milestone payments. The licensing agreements typically require a non-refundable license fee and allow the Company's partners to sell its proprietary products in a defined territory for a defined period. Non-refundable license fees are initially reported as deferred revenue and recognized as licensing revenue over the remaining contractual term or as covered by patent protection, whichever is earlier, using the straight-line method or until the agreement is terminated. A milestone payment is a payment made by a partner to the Company upon the achievement of a pre-determined event, as defined in the applicable agreement. Milestone payments are initially reported as deferred revenue and subsequently recognized using the straight-line method over the remaining contractual term or the remaining period covered by patent protection, whichever is earlier. No milestone revenue is recognized until the Company has completed the required milestone-related services as set forth in licensing agreements.

The following table summarizes the deferred revenue as of September 30, 2004 to be recognized as revenue during the fourth quarter of 2004 and the years ending December 31, 2005 through December 31, 2016 (amounts in thousands):

Years Ended December 31,	Amortization of Deferred Revenue
---------------------------------	---

2004 (October-December)	\$ 2,106
2005	8,072
2006	5,362
2007	5,341
2008	5,325
2009	5,325
Thereafter	6,619
	<hr/>
Total	\$ 38,150
	<hr/>

Table of Contents***Research and Development***

Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on the Company's behalf. Additionally, license fees paid by the Company to acquire technology are expensed as incurred if no alternative future use exists. A portion of overhead costs is allocated to research and development on a weighted-average percentage basis among all projects under development.

The following table summarizes research and development activities funded, in whole or in part, by our collaborators, as well as research and development activities funded by the Company (amounts in thousands):

		Three months ended September 30,		Nine months ended September 30,	
		2004	2003	2004	2003
Research and Development	Funded, in whole or				
in part		\$6,031	\$8,351	\$18,522	\$21,944
Research and Development	Funded, 100% by				
Atrix		2,345	387	6,477	4,763
Research and Development	Total	\$8,376	\$8,738	\$24,999	\$26,707

Stock-Based Compensation

As permitted under Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, the Company accounts for stock-based compensation using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* and related interpretations. Accordingly, no compensation expense has been recognized for fixed stock option grants to employees with an exercise price equal to market value at the date of grant. The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS No. 123, and related interpretations.

At September 30, 2004, the Company has four stock-based employee, and non-employee compensation plans, which are described more fully in Note 6 to the Financial Statements included in the Company's Form 10-K for the fiscal year ended December 31, 2003. The Company accounts for those plans under the recognition and measurement principles of APB Opinion No. 25. No stock-based employee compensation cost is reflected in net income for options granted under those plans with an exercise price equal to the market value for the underlying common stock on date of grant. The following table illustrates the effect on net income (loss) applicable to common stock and basic and diluted income (loss) per common share if the Company had applied the fair value based method of SFAS No. 123 to stock-based compensation for the three and nine months ended, September 30 (amounts in thousands, except per share data):

Three Months Ended**Nine Months Ended**

	<u>September 30,</u>		<u>September 30,</u>	
	<u>2004</u>	<u>2003</u>	<u>2004</u>	<u>2003</u>
Net income (loss) applicable to common stock, as reported	\$ 1,835	\$ (47)	\$ 4,978	\$ (3,754)
Add: Stock-based compensation expense included in reported net income (loss), net of related tax effects				22
Deduct: Total stock-based compensation expense determined under fair-value based method	<u>(1,692)</u>	<u>(2,551)</u>	<u>(8,582)</u>	<u>(8,310)</u>
Pro forma net income / (loss) applicable to common stock	<u>\$ 143</u>	<u>\$(2,598)</u>	<u>\$(3,604)</u>	<u>\$(12,042)</u>

Table of Contents

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss) applicable to common stock per common share:				
As reported, basic	\$0.09	\$	\$ 0.24	\$(0.19)
As reported, diluted	\$0.08	\$	\$ 0.22	\$(0.19)
Pro forma, basic	\$0.01	\$(0.13)	\$(0.17)	\$(0.60)
Pro forma, diluted	\$0.01	\$(0.13)	\$(0.16)	\$(0.60)

The weighted-average Black-Scholes fair value per option granted during the nine months ending September 30, 2004 and 2003 was \$14.58 and \$10.05, respectively. The weighted-average Black-Scholes fair value per option granted during the three months ending September 30, 2004 and 2003 was \$12.08 and \$14.43, respectively. The fair value of options was estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants during the three and nine months ending September 30, 2004 and 2003: no dividend yield, expected volatility of 53.3% for 2004 and 60.5% for 2003, risk free interest rates of 3.5% in 2004 and 5.0% in 2003, and expected life of three years for 2004 and five years for 2003.

NOTE 3. RECENT ACCOUNTING PRONOUNCEMENTS

In March 2004, the Emerging Issues Task Force (EITF) reached a consensus on recognition and measurement guidance previously discussed under EITF Issue No. 03-01. The consensus clarifies the meaning of other-than-temporary impairment and its application to investments classified as either available-for-sale or held-to-maturity under SFAS 115, *Accounting for Certain Investments in Debt and Equity Securities*, and investments accounted for under the cost method or the equity method. The recognition and measurement guidance for which the consensus was reached is to be applied to other-than-temporary impairment evaluations in reporting periods beginning after June 15, 2004. We will apply the recognition and measurement guidance of EITF 03-01 in future periods and expect that the adoption will not have a material impact on our results of operations or financial condition.

In December 2003, the Staff of the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition*, which supercedes SAB No. 101, *Revenue Recognition in Financial Statements*. SAB No. 104's primary purpose is to rescind accounting guidance contained in SAB No. 101 related to multiple-element revenue arrangements and to rescind the SEC's *Revenue Recognition in Financial Statements Frequently Asked Questions and Answers* (FAQ) issued with SAB No. 101. Selected portions of the FAQ have been incorporated into SAB No. 104. The adoption of SAB No. 104 did not have a material impact on the Company's revenue recognition policies.

The EITF has issued EITF Issue No. 03-6, *Participating Securities and the Two-Class Method* under FASB Statement No. 128 *Earnings Per Share* (EITF 03-6). EITF 03-6 provides guidance for the computation of earnings per share using the two-class method for enterprises with participating securities or multiple classes of common stock as required by SFAS No. 128. The two-class method allocates undistributed earnings to each class of common stock and participating securities for the purpose of computing basic earnings per share. The Company adopted EITF 03-6 in the period ended June 30, 2004. The adoption of EITF 03-6 reduced basic earnings per share for the nine month period ended September 30, 2004 by \$0.01. The adoption of EITF 03-6 had no impact on the three-month period ended September 30, 2004 and pre-2004 earnings per share. See Note 5.

NOTE 4. INVENTORIES

Inventories are stated at the lower of cost, determined by the first-in, first-out (FIFO) method, or market. Inventories consist of the cost of materials, direct labor and overhead. Inventories include preclinical and clinical supplies that may be used either in products for sale or research and development activities. As of December 31, 2003 inventories included raw materials of \$4.3 million related to research and development projects and no significant amount of work-in-process or finished goods inventory related to research and development projects. As of September 30, 2004 raw materials inventory of \$4.0 million was related to research and development projects. These supplies are expensed as used in research and development projects. The components of inventories are as follows:

Table of Contents

	September 30, 2004	December 31, 2003
	(In thousands)	
Raw materials	\$12,224	\$ 9,292
Work in process	1,743	1,338
Finished goods	1,311	2,146
Reserves	(605)	(1,260)
	<u>\$14,673</u>	<u>\$11,516</u>

The \$3.2 million increase in inventory during the first three quarters of 2004 is primarily due to the purchase of raw materials related to the Eligard, Atrisone, Mometasone and Fluticasone products. The Company has manufactured at-risk inventory in anticipation of regulatory approval to manufacture certain products at its facility in Fort Collins, Colorado. As of September 30, 2004 the value of this inventory recorded at the Company's cost to manufacture was \$0.2 million and is included in Work-in-process inventory tabulated above. This at-risk inventory was manufactured in anticipation of FDA approval of the Company's manufacturing facility. If the Company does not receive regulatory approval to manufacture these products or if approval is significantly delayed the product may be unsaleable. Approval is anticipated by the end of the first quarter of 2005 and the product had approximately twelve months shelf-life remaining as of September 30, 2004. In the event this inventory, manufactured at-risk, becomes unsaleable it will be destroyed and the Company will record an expense at the time such determination is made. The Company only undertakes the manufacture of inventory at-risk after careful evaluation of the probability and timing of expected regulatory approvals in consultation with its marketing partners and after receiving a commitment from the marketing partner. The Company has a 100% success record in obtaining such approvals over the last four years. This inventory manufactured at-risk did not have a significant effect on the Company's liquidity and the Company expects FDA approval well in advance of product shelf-life expiration and expects to realize benefit from the inventory upon FDA approval and subsequent sale of the inventory.

During the fourth quarter of 2002 and first quarter of 2003 the Company manufactured launch quantities of Erythromycin Benzoyl Peroxide, or E/BP prior to receiving FDA approval. In 2003, the Company recorded a reserve allowance of \$1.0 million for this inventory in response to a non-approval letter received from the FDA. In March 2004, the Company received approval from the FDA for this product. This approval was a reversal of the FDA's previous decision and resulted in a shipment of \$0.3 million of the E/BP product in March 2004. The remaining \$0.7 million of fully reserved inventory for E/BP was outdated in May 2004 and subsequently the Company donated \$0.6 million to charitable organizations and disposed of the remaining \$0.1 million.

NOTE 5. NET INCOME (LOSS) PER COMMON SHARE

Basic net income (loss) attributable to common shareholders per common share of stock is calculated by dividing net income (loss) attributable to common shareholders by the weighted average of vested common shares outstanding during each period. Diluted net income (loss) attributable to common shareholders is calculated by dividing net income (loss) attributable to common shareholders by the weighted average of common shares outstanding and other dilutive securities

The Emerging Issues Task Force (EITF) issued EITF No. 03-6, Participating Securities and the Two-Class Method under FASB Statement No. 128, Earnings per Share (EITF 03-6). The Company adopted EITF 03-6 in the second

quarter of 2004. The adoption of EITF 03-6 reduced basic earnings per share for the nine-month period ended September 30, 2004 by \$0.01. The adoption of EITF 03-6 had no impact on the three-month period ended September 30, 2004 and pre-2004 earnings per share. The two-class method allocates undistributed earnings to each class of common stock and participating securities for the purpose of computing basic earnings per share. Net income (loss) attributable to common shareholders is calculated by reducing net income (loss) by dividends earned on preferred securities. Our Series A convertible preferred stock dividends, although neither declared nor paid, are considered earned for these calculations. Please see the Recent Accounting Pronouncements, section for more detailed information regarding the Emerging Issues Task Force Issue number 03-6 regarding the calculation of basic net income / (loss) per share. For the three and nine months ended September 30, 2004, 1.3 and 1.3 million equivalent dilutive securities, respectively, were included in the fully diluted weighted-average number of common shares outstanding primarily related to the assumed conversion of incentive stock options and stock warrants held by Elan. Additionally, 0.9 and 0.8 million equivalent dilutive securities have been excluded from the fully diluted weighted average number of common shares outstanding due to the antidilutive effect of the assumed conversion of

Table of Contents

Series A Convertible Preferred Stock for the three and nine months ended September 30, 2004, respectively. For the three and nine months ended September 30, 2003, 1.3 million and 0.6 million equivalent dilutive securities, respectively, were excluded from the weighted-average number of common shares outstanding primarily related to the assumed conversion by Elan of the shares of our Series A Convertible Preferred Stock, exercise by Elan of a stock warrant and the exercise of incentive stock options, due to their antidilutive effect.

The following tables set forth the calculation of basic and diluted earnings per share:

	Three Months Ended (in thousands) September 30,		Nine Months Ended (in thousands) September 30,	
	2004	2003	2004	2003
Net income (loss) as reported	\$2,667	\$ 377	\$ 6,696	\$(2,836)
Less: Accretion of dividends and beneficial conversion feature charge on preferred stock	(727)	(424)	(1,459)	(918)
Income (loss) to be allocated	1,940	(47)	5,237	(3,754)
Less: Allocation of undistributed earnings to participating preferred stock	(105)	—	(259)	—
Net income / (loss) applicable to common stock	<u>\$1,835</u>	<u>\$ (47)</u>	<u>\$ 4,978</u>	<u>\$(3,754)</u>
PER BASIC SHARE				
Net income (loss) , as reported	\$ 0.12	\$ 0.02	\$ 0.32	\$ (0.14)
Less: Accretion of dividends and beneficial conversion feature charge on preferred stock	(0.03)	(0.02)	(0.07)	(0.05)
Less: Allocation of undistributed earnings to participating preferred stock	(0.0)	—	(0.01)	—
Net income / (loss) applicable to common stock	<u>\$ 0.09</u>	<u>\$ 0.0</u>	<u>\$ 0.24</u>	<u>\$ (0.19)</u>
Weighted average BASIC shares outstanding	&			