

ATRIX LABORATORIES INC

Form 10-Q/A

November 07, 2002

**Table of Contents**

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

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FORM 10-Q/A

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

For the Quarterly Period Ended June 30, 2002

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.)

**2579 Midpoint Drive Fort Collins, Colorado**  
(Address of principal executive office)

**80525**  
(Zip Code)

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

The number of shares outstanding of the registrant's common stock as of July 25, 2002, was 20,458,816.

**EXPLANATORY NOTE**

This Form 10-Q/A amends the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002. This Form 10-Q/A reflects the restatement of the Registrant's consolidated financial statements discussed in Note 6 to the consolidated financial statements included in Item 1 of Part I.

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**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

**Item 1. FINANCIAL STATEMENTS.**

**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES CONCERNING MARKET RISKS.**

**PART II OTHER INFORMATION**

**Item 2. CHANGES IN SECURITIES AND USE OF PROCEEDS.**

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

**Item 6. EXHIBITS AND REPORTS ON FORM 8-K.**

**SIGNATURES**

**CERTIFICATIONS**

**EXHIBIT INDEX**

**EX-99.1 Certification of Chief Executive Officer**

**EX-99.2 Certification of Chief Financial Officer**

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**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. FINANCIAL STATEMENTS.**

**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**(IN THOUSANDS, EXCEPT SHARE DATA)**  
(Unaudited)

	<u>June 30, 2002</u>	<u>December 31, 2001</u>
	(As Restated, see Note 6)	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 35,739	\$ 50,058
Marketable securities available-for-sale, at fair value	99,241	87,910
Accounts receivable, net of allowance for doubtful accounts of \$2 and \$5	3,613	3,522
Interest receivable	887	995
Inventories	4,844	3,314
Prepaid expenses and deposits	1,967	606
	<u>          </u>	<u>          </u>
Total current assets	146,291	146,405
	<u>          </u>	<u>          </u>
PROPERTY, PLANT AND EQUIPMENT, NET	8,562	7,557
	<u>          </u>	<u>          </u>
<b>OTHER ASSETS:</b>		
Intangible assets, net of accumulated amortization of \$3,838 and \$3,421	3,447	3,446
Deferred finance costs, net of accumulated amortization of \$0 and \$121		85
	<u>          </u>	<u>          </u>
Other assets	3,447	3,531
	<u>          </u>	<u>          </u>
<b>TOTAL ASSETS</b>	<b>\$ 158,300</b>	<b>\$ 157,493</b>
	<u>          </u>	<u>          </u>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable trade	\$ 2,886	\$ 3,108
Accrued expenses and other	1,499	611
Deferred revenue	7,356	7,467
	<u>          </u>	<u>          </u>
Total current liabilities	11,741	11,186
	<u>          </u>	<u>          </u>
DEFERRED REVENUE	34,304	28,373
CONVERTIBLE SUBORDINATED NOTES PAYABLE		5,206
<b>COMMITMENTS AND CONTINGENCIES:</b>		
SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK, \$.001 par value, 20,000 shares authorized; 12,871 and 12,871 shares issued and outstanding. Liquidation preference \$13,741 and \$13,281	14,029	13,568
<b>SHAREHOLDERS EQUITY:</b>		

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Preferred stock, \$.001 par value; 5,000,000 shares authorized Series A preferred stock, \$.001 par value, 200,000 shares authorized and no shares issued or outstanding		
Common stock, \$.001 par value; 45,000,000 shares authorized; 20,447,674 and 19,859,807 shares issued and 20,336,674 and 19,782,307 shares outstanding	20	20
Additional paid-in capital	242,021	232,903
Treasury stock, 111,000 and 77,500 shares, at cost	(2,229)	(1,558)
Accumulated other comprehensive loss	(20)	(4)
Accumulated deficit	(141,566)	(132,201)
	<u>          </u>	<u>          </u>
Total shareholders equity	98,226	99,160
	<u>          </u>	<u>          </u>
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 158,300	\$ 157,493
	<u>          </u>	<u>          </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)

	<b>For the Three Months Ended June 30,</b>	
	<b>2002</b>	<b>2001</b>
<b>REVENUES:</b>		
Net sales and royalties	\$ 1,474	\$ 1,345
Contract research and development revenue	3,513	2,128
Licensing, marketing rights and milestone revenue	1,497	792
	<u>6,484</u>	<u>4,265</u>
<b>OPERATING EXPENSES:</b>		
Cost of sales	792	609
Research and development	7,512	6,341
Administrative and marketing	2,407	1,431
	<u>10,711</u>	<u>8,381</u>
<b>LOSS FROM OPERATIONS</b>	<u>(4,227)</u>	<u>(4,116)</u>
<b>OTHER INCOME (EXPENSE):</b>		
Equity in loss of joint venture	(335)	(1,016)
Investment income and expense, net	1,154	531
Loss on sale and write-down of marketable securities	(1,005)	
Debt conversion expense		(9)
Other	(6)	(22)
	<u>(192)</u>	<u>(516)</u>
<b>LOSS BEFORE EXTRAORDINARY ITEM</b>	<u>(4,419)</u>	<u>(4,632)</u>
Extraordinary gain (loss) on extinguished debt	44	(7)
	<u>(4,375)</u>	<u>(4,639)</u>
<b>NET LOSS</b>	<u>(4,375)</u>	<u>(4,639)</u>
Accretion of dividends on preferred stock	(233)	(217)
	<u>(4,608)</u>	<u>(4,856)</u>
<b>NET LOSS APPLICABLE TO COMMON STOCK</b>	<u>\$ (4,608)</u>	<u>\$ (4,856)</u>
Basic and diluted loss per common share:		
Loss before extraordinary item	\$ (.22)	\$ (.31)
Extraordinary gain (loss) on extinguished debt		
	<u>(.22)</u>	<u>(.31)</u>
Net loss	(22)	(31)
Accretion of dividends on preferred stock	(01)	(01)
	<u>(23)</u>	<u>(32)</u>
<b>Net loss applicable to common stock</b>	<u>\$ (.23)</u>	<u>\$ (.32)</u>
	<u>20,229,830</u>	<u>15,127,406</u>
<b>Basic and diluted weighted average common shares outstanding</b>	<u>20,229,830</u>	<u>15,127,406</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)

	<b>For the Six Months Ended June 30,</b>	
	<b>2002</b>	<b>2001</b>
<b>REVENUES:</b>		
Net sales and royalties	\$ 2,632	\$ 2,576
Contract research and development revenue	6,008	3,433
Licensing, marketing rights and milestone revenue	2,859	1,509
	<u>          </u>	<u>          </u>
Total revenues	11,499	7,518
	<u>          </u>	<u>          </u>
<b>OPERATING EXPENSES:</b>		
Cost of sales	1,303	1,043
Research and development	14,074	12,564
Research and development licensing fees		540
Administrative and marketing	4,230	2,702
Administrative stock option compensation	1,256	
	<u>          </u>	<u>          </u>
Total operating expenses	20,863	16,849
	<u>          </u>	<u>          </u>
<b>LOSS FROM OPERATIONS</b>	<b>(9,364)</b>	<b>(9,331)</b>
	<u>          </u>	<u>          </u>
<b>OTHER INCOME (EXPENSE):</b>		
Equity in loss of joint venture	(745)	(1,517)
Investment income and expense, net	2,380	965
Loss on sale and write-down of marketable securities	(1,076)	
Debt conversion expense	(125)	(2,048)
Other	(5)	(23)
	<u>          </u>	<u>          </u>
Net other income (expense)	429	(2,623)
	<u>          </u>	<u>          </u>
<b>LOSS BEFORE EXTRAORDINARY ITEM</b>	<b>(8,935)</b>	<b>(11,954)</b>
Extraordinary gain (loss) on extinguished debt	30	(288)
	<u>          </u>	<u>          </u>
<b>NET LOSS</b>	<b>(8,905)</b>	<b>(12,242)</b>
Accretion of dividends on preferred stock	(461)	(430)
	<u>          </u>	<u>          </u>
<b>NET LOSS APPLICABLE TO COMMON STOCK</b>	<b>\$ (9,366)</b>	<b>\$ (12,672)</b>
	<u>          </u>	<u>          </u>
Basic and diluted loss per common share:		
Loss before extraordinary item	\$ (.45)	\$ (.82)
Extraordinary loss on extinguished debt		(.02)
	<u>          </u>	<u>          </u>
Net loss	(.45)	(.84)
Accretion of dividends on preferred stock	(.02)	(.03)
	<u>          </u>	<u>          </u>
Net loss applicable to common stock	\$ (.47)	\$ (.87)
	<u>          </u>	<u>          </u>
Basic and diluted weighted average common shares outstanding	20,079,496	14,655,378



See notes to the consolidated financial statements.

**Table of Contents**

**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(IN THOUSANDS)**  
(Unaudited)

	<b>For the Six Months Ended June 30,</b>	
	<b>2002</b>	<b>2001</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (8,905)	\$ (12,242)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,557	1,189
Amortization of deferred revenue	(4,274)	(1,974)
Equity in loss of joint venture	745	1,517
Loss on sale and write-down of marketable securities	1,076	
Stock plan compensation	1,256	117
Debt conversion expense	125	2,048
Interest expense converted to equity	110	
Extraordinary (gain) loss on extinguished debt	(30)	288
Other non-cash items	8	(16)
Net changes in operating assets and liabilities:		
Accounts receivable	6	(359)
Note receivable licensing fee		8,000
Interest receivable	108	55
Inventories	(1,460)	(871)
Prepaid expenses and deposits	(1,361)	(332)
Accounts payable	(249)	194
Accrued expenses and other	882	106
Deferred revenue	10,095	7,334
Net cash provided by (used in) operating activities	(311)	5,054
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of property, plant and equipment	(1,812)	(1,323)
Investment in intangible assets	(419)	(206)
Proceeds from maturity and sale of marketable securities	15,067	18,741
Investment in marketable securities	(27,873)	(27,067)
Investment in joint venture	(1,178)	(726)
Net cash used in investing activities	(16,215)	(10,581)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of equity securities, net of issuance costs	2,532	5,336
Payments to acquire treasury stock	(671)	
Note receivable stock subscription		15,000
Net cash provided by financing activities	1,861	20,336
NET EFFECT OF EXCHANGE RATE ON CASH	346	(220)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(14,319)	14,589
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	50,058	4,484

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CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 35,739</u>	<u>\$ 19,073</u>
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Non-cash activities:

**2002**

Issued common stock valued at \$5,331,000 in exchange for \$5,206,000 of the 7% Convertible Subordinated Notes.

Vested incentive stock options valued at \$1,257,000 for an executive officer in conjunction with his termination agreement.

**2001**

Issued common stock valued at \$28,527,000 in exchange for \$26,479,000 of the 7% Convertible Subordinated Notes.

See notes to the consolidated financial statements.

**Table of Contents**

**ATRIX LABORATORIES, INC. AND SUBSIDIARIES  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (AS RESTATED)  
For the Six Months Ended June 30, 2002 and 2001**

**NOTE 1. BASIS OF PRESENTATION**

The accompanying unaudited consolidated financial statements of Atrix Laboratories, Inc. and subsidiaries (collectively referred to as Atrix or the Company) have been prepared in accordance with generally accepted accounting principles 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, consisting of normal recurring accruals, for a fair presentation have been included. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, for the year ended December 31, 2001, filed with the Securities and Exchange Commission in the Company's Annual Report on Form 10-K/A.

**NOTE 2. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

Atrix Laboratories, Inc. was formed in August 1986 as a Delaware corporation. In November 1998, the Company acquired ViroTex Corporation. In June 1999, the Company organized its wholly owned subsidiary Atrix Laboratories Limited, which is based in London, England. In February 2000, the Company organized its wholly owned subsidiary Atrix Laboratories GmbH, which is based in Frankfurt, Germany, to conduct its European operations. In June 2000, the Company entered into a research joint venture, Transmucosal Technologies, Ltd., with Elan International Services, Ltd. (Elan), a wholly owned subsidiary of Elan Corporation, plc.

Atrix is an emerging specialty pharmaceutical company focused on advanced drug delivery. With five unique patented drug delivery technologies, the Company is currently developing a diverse portfolio of products, including proprietary oncology, pain management, growth hormone releasing peptide-1, oral interferon and dermatology products. The Company also partners with large pharmaceutical and biotechnology companies to apply its proprietary technologies to new chemical entities or to extend the patent life of existing products. The Company has strategic alliances with several pharmaceutical companies to use its drug delivery technologies and expertise in the development of new products.

**Significant Accounting Policies**

*Principles of consolidation*

The accompanying consolidated financial statements include the accounts of Atrix Laboratories, Inc. and its wholly owned subsidiaries Atrix Laboratories Limited and Atrix Laboratories, GmbH. All significant intercompany transactions and balances have been eliminated. While the Company initially owns 80.1% of Transmucosal Technologies' outstanding common stock, Elan and its subsidiaries have retained significant minority investor rights that are 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 Transmucosal Technologies that are considered participating rights include 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, the Company accounts for its investment in Transmucosal Technologies under the equity method of accounting. Additionally, the joint venture contracts with Atrix to perform certain research and development activities. During the six months ended June 30, 2002 and 2001, the Company earned contract research and development revenues from the joint venture of \$0.9 million and \$1.9 million, respectively, and had receivables from the joint venture of \$0.4 million at June 30, 2002. Additionally, the Company had payables to the joint venture at June 30, 2002 of \$0.3 million. During the six months ended June 30, 2002 and 2001, the Company recognized losses of \$0.7 million and \$1.5 million, respectively, for its 80.1% share of the losses of Transmucosal Technologies.

**Table of Contents****Revenue recognition**

The Company recognizes revenue on product sales and contract manufacturing at the time of shipment when title to the product transfers and the customer bears risk of loss. Product sales revenue is recorded net of estimated returns and allowances. Royalty revenue is recorded when product is shipped by licensees based on the invoiced amount by the licensee and royalty rates as specified in the agreement with the licensee.

All 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. Advance payments 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 the contracts are made either monthly or quarterly, depending on the terms of the contract.

Nonrefundable licensing fees, marketing rights and milestone payments received under contractual arrangements are deferred and recognized over the remaining contractual term using the straight-line method.

**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, licensing 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 costs 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 for the three and six months ended June 30 (amounts in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2002	2001	2002	2001
Research and Development Funded	\$3,649	\$1,466	\$ 6,865	\$ 2,568
Research and Development Not Funded	3,863	4,875	7,209	10,536
Research and Development	\$7,512	\$6,341	\$14,074	\$13,104

**New Accounting Pronouncements**

On June 29, 2001, SFAS No. 142, *Goodwill and Other Intangible Assets* was issued by the FASB. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Goodwill and certain intangible assets will remain on the balance sheet and not be amortized. On an annual basis, and when there is reason to suspect that their values have been diminished or impaired, these assets must be tested for impairment, and write-downs may be necessary. Amortization of goodwill, including goodwill recorded in past business combinations, ceased when the Company adopted SFAS No. 142 on January 1, 2002. The adoption of this statement did not have a material impact on the Company's consolidated financial position or results of operations.

In August 2001, SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* was issued by the FASB. SFAS No. 144 provided new guidance on the recognition of impairment losses on long-lived assets to be held and used or to be disposed of and also broadens the definition of what constitutes a discontinued operation and how the results of a discontinued operation are to be measured and presented. The Company adopted SFAS No. 144 on January 1, 2002. The adoption of this statement did not have a material impact on the Company's consolidated financial position or results of operations.

**Table of Contents****NOTE 3. INVENTORIES**

Inventories are stated at the lower of cost, determined by the first-in, first-out (FIFO) method, or market. The inventory components at June 30, 2002 and December 31, 2001, are as follows (in thousands):

	<u>June 30, 2002</u>	<u>December 31, 2001</u>
Raw materials	\$3,153	\$2,399
Work in process	856	201
Finished goods	835	714
	<u>          </u>	<u>          </u>
	\$4,844	\$3,314
	<u>          </u>	<u>          </u>

**NOTE 4. NET INCOME (LOSS) PER COMMON SHARE**

Basic net income (loss) per common share excludes dilution and is computed by dividing net income (loss) by the weighted-average number of common shares outstanding during the periods presented. Diluted net income (loss) per common share reflects the potential dilution of securities that could participate in the earnings. Stock options, warrants outstanding and their equivalents are included in diluted earnings per share computations through the treasury stock method unless they are antidilutive. Convertible securities are included in diluted earnings per share computations through the if converted method unless they are antidilutive. The effect of assuming conversion of the Series A Convertible Preferred Stock is excluded from the diluted earnings per share computations since the shares of Series A Convertible Preferred Stock cannot be converted into common stock until the period commencing July 18, 2002. Additionally, since the Company has not drawn any proceeds under the convertible promissory note agreement with Elan, as of June 30, 2002, there was no effect on earnings per share computations pertaining to this convertible promissory note for the periods presented. Common share equivalents are excluded from the computations in loss periods, as their effect would be antidilutive. For the six month periods ended June 30, 2002 and 2001, approximately 1.2 million and 1.8 million equivalent dilutive securities (primarily convertible notes and common stock options), respectively, have been excluded from the weighted-average number of common shares outstanding for the diluted net loss per share computations as they are antidilutive.

**NOTE 5. CONVERTIBLE SUBORDINATED NOTES PAYABLE**

In March 2002, the Company announced that it would call for redemption of the remainder of the outstanding 7% Convertible Subordinated Notes. The outstanding notes were fully converted into the Company's common stock prior to the redemption date of May 15, 2002.

During the six months ended June 30, 2002, the Company exchanged 279,901 shares of its common stock for \$5.2 million of its 7% Convertible Subordinated Notes. Of the 279,901 shares issued, 273,984 shares were valued at the conversion price of \$19.00 per share and the remaining 5,917 shares were valued at \$21.09 per share, the closing market price of the Company's common stock on the date of exchange. As a result, the Company recognized an extraordinary gain of \$30,000, for the write-off of \$80,000 of pro rata unamortized deferred finance charges net of \$0.1 million interest expense payable eliminated as a result of these exchanges. Additionally, of the 279,901 shares exchanged, a debt conversion expense of \$0.1 million was recognized for the six months ended June 30, 2002. As of June 30, 2002 and December 31, 2001, the outstanding principal amount of the 7% Convertible Subordinated Notes was \$0 and \$5.2 million, respectively. The estimated fair value of the notes payable, based on quoted market prices or dealer quotes, was \$0 and \$6.0 million at June 30, 2002 and December 31, 2001, respectively.

**NOTE 6. RESTATEMENT**

The Company's Series A Convertible Exchangeable Preferred Stock (the Series A Stock), which was issued in connection with the formation of our joint venture with Elan International, has an exchange feature that allows the holder to convert it into an additional holding in Transmucosal Technologies, which is a redemption feature that is outside the Company's control. Subsequent to the issuance of the June 30, 2002 financial statements, it was determined that Emerging Issues Task Force Topic D-98, *Classification and Measurement of Redeemable Securities*, applies to this preferred stock issuance. As a result, the Company's consolidated balance sheet as of June 30, 2002 has been restated to present the Series A Stock outside of permanent shareholders' equity until such

**Table of Contents**

time as the exchange feature is exercised or expires. A summary of the significant effects of the restatement is as follows:

	<b>As of June 30, 2002 (in thousands)</b>	
	<b>As previously reported</b>	<b>As restated</b>
SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK	\$	\$ 14,029
SHAREHOLDERS EQUITY (DEFICIT)		
Preferred stock	\$	\$
Common stock	20	20
Additional paid in capital	256,050	242,021
Treasury stock	(2,229)	(2,229)
Accumulated other comprehensive loss	(20)	(20)
Accumulated deficit	(141,566)	(141,566)
	<u>          </u>	<u>          </u>
Total shareholders equity (deficit)	\$ 112,255	\$ 98,226
	<u>          </u>	<u>          </u>

**Table of Contents****Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

The following Management's Discussion and Analysis of Financial Condition and Results of Operations, as well as information contained elsewhere in this Report, contains statements that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include statements regarding the intent, belief or current expectations of us, our directors or our officers with respect to, among other things: (1) whether we will receive, and the timing of, regulatory approvals or clearances to market potential products; (2) the results of current and future clinical trials; (3) the time and expenses associated with the regulatory approval process for products; (4) the safety and effectiveness of our products and technologies; (5) the Company's expectation that its marketing partners will be able to successfully market its products; (6) its expectation of receiving royalties on sales of its products and its plans to manufacture certain of its products at its facility in Fort Collins, Colorado; (7) the timing of new product launches; and (8) expected future additional equity losses for Transmucosal Technologies. The success of our business operations is dependent on factors such as the receipt and timing of regulatory approvals or clearances for potential products, the effectiveness of our marketing strategies to market our current and any future products, our ability to manufacture products on a commercial scale, the appeal of our mix of products, our success at entering into and collaborating with others to conduct effective strategic alliances and joint ventures, general competitive conditions within the biotechnology and drug delivery industry and general economic conditions. Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual results may differ materially from those projected in the forward-looking statements as a result of various factors, including those described below under Item 1.-Business-Factors Affecting Our Business and Prospects in our Annual Report on Form 10-K/A for the year ended December 31, 2001.

**Restatement**

Our Series A Convertible Exchangeable Preferred Stock, or the Series A Stock, which was issued in connection with the formation of our joint venture with Elan International, has an exchange feature that allows the holder to convert it into an additional holding in Transmucosal Technologies, which is a redemption feature that is outside our control. Subsequent to the issuance of the June 30, 2002 financial statements, it was determined that Emerging Issues Task Force Topic D-98, *Classification and Measurement of Redeemable Securities*, applies to this preferred stock issuance. As a result, our consolidated balance sheet as of June 30, 2002 has been restated to present our Series A Stock outside of permanent shareholders' equity until such time as the exchange feature is exercised or expires. A summary of the significant effects of the restatement is as follows:

	As of June 30, 2002 (in thousands)	
	As previously reported	As restated
SERIES A CONVERTIBLE EXCHANGEABLE PREFERRED STOCK	\$	\$ 14,029
SHAREHOLDERS' EQUITY (DEFICIT)		
Preferred stock	\$	\$
Common stock	20	20
Additional paid in capital	256,050	242,021
Treasury stock	(2,229)	(2,229)
Accumulated other comprehensive loss	(20)	(20)
Accumulated deficit	(141,566)	(141,566)
	<u>          </u>	<u>          </u>
Total shareholders' equity (deficit)	\$ 112,255	\$ 98,226
	<u>          </u>	<u>          </u>



## **Table of Contents**

### **Overview**

We are an emerging specialty pharmaceutical company focused on advanced drug delivery. With five unique patented drug delivery technologies, we are currently developing a diverse portfolio of products, including proprietary oncology, pain management, growth hormone releasing peptide-1, oral interferon and dermatology products. We also form strategic alliances with large pharmaceutical and biotechnology companies utilizing our various drug delivery systems. These strategic alliances include collaborations with Pfizer, Inc., Sanofi-Synthelabo, Inc., MediGene AG, Fujisawa Healthcare, Inc., Elan International Services, Ltd., Geneva Pharmaceuticals, Inc. and CollaGenex Pharmaceuticals, Inc.

Our drug delivery systems deliver controlled amounts of drugs in time frames ranging from minutes to months to address a range of therapeutic and patient needs. Atrigel is our original proprietary sustained release biodegradable polymer drug delivery system. The Atrigel system may provide benefits over traditional methods of drug administration such as safety and effectiveness, wide array and ease of applications, site-specific or systemic delivery, customized release rates and biodegradability. With the acquisition of ViroTex Corporation in November 1998, we added four additional drug delivery systems: BEMA , SMP , MCA and BCP .

### **Recent Developments**

The following discussion highlights significant events for our company during the six months ended June 30, 2002:

#### *Eligard Products*

In January 2002, we received approval from the United States Food and Drug Administration, or FDA, for our Eligard 7.5-mg one-month product, a subcutaneous injection for the treatment of advanced prostate cancer. In May 2002, we commenced marketing our Eligard one-month product and we subsequently received a \$6.0 million milestone payment from Sanofi-Synthelabo in June 2002 for this marketing launch. We also received a \$3.0 million milestone payment from Sanofi-Synthelabo in June 2002 for our Eligard 30-mg four-month product New Drug Application, or NDA, submission to the FDA in April 2002. The combined \$9.0 million milestone payments from Sanofi-Synthelabo were recorded as deferred revenue and will be recognized as revenue over the remaining term of the agreement using the straight-line method.

Also in January 2002, Sanofi-Synthelabo exercised its right to develop a unique dosage formulation of Eligard for the treatment of prostate cancer. Under the terms of our agreement with Sanofi-Synthelabo, we will receive reimbursement for research and development expenses relating to the unique dosage formulation of Eligard and we expect to submit an Investigational New Drug Application, or IND, to the FDA this year. Additionally, we will receive payments for certain regulatory and sales milestones, a royalty based on sales of the product and a manufacturing margin.

We entered into an exclusive licensing agreement with Luxembourg Pharmaceuticals Ltd. for the Israeli marketing rights of our four Eligard products in March 2002. Under the terms of the agreement, we will receive a royalty on net sales and a manufacturing margin. Luxembourg Pharmaceuticals will be responsible for regulatory submissions and any studies that may be necessary to gain approval with the Israeli regulatory authorities.

MediGene, our European marketing partner, submitted a Marketing Authorization Application, or MAA, for the Eligard 22.5-mg three-month product to the German regulatory authority, Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM, in April 2002, as the reference member state under a mutual recognition process. In June 2002, we received a \$1.0 million milestone payment from MediGene for the MAA submissions of the Eligard one-month and three-month products to BfArM. This milestone payment from MediGene was recorded as deferred revenue and will be recognized as revenue over the remaining term of the agreement using the straight-line method.

**Table of Contents**

*Other Products*

In January 2002, we submitted an Abbreviated New Drug Application, or ANDA, to the FDA for approval of a generic equivalent to an undisclosed topical dermatology product.

In March 2002 we announced that we received positive clinical data from the first Phase III clinical trial of Atrisone for the treatment of acne.

Also in March 2002, we commenced Phase II clinical trials for a proprietary formulation of a low-dose oral interferon-alpha product for the treatment of oral warts caused by human papilloma virus in HIV-infected patients.

In June 2002, we submitted an IND to the FDA to test Sumatriptan, a migraine treatment drug, using our BEMA delivery system to provide rapid relief.

*Significant Capital Events*

In March 2002, we called for redemption of the remainder of our outstanding 7% Convertible Subordinated Notes. The outstanding notes in the principal amount of \$2.9 million were fully converted into shares of our common stock at a conversion price of \$19.00 per share. The conversion of the outstanding notes occurred prior to the redemption date of May 15, 2002.

In April 2002, we announced plans to expand our manufacturing and laboratory facilities to support current and future projects. Our current 26,000 square foot facility will be expanded to 58,000 square feet. In the expanded facility we intend to produce the full line of our Eligard prostate cancer products, Atrisone topical dermatological product, generic dermatology products, dental products and clinical supplies for products currently in development. Approximately 40% of the building expansion will be devoted to production with the remainder allotted for warehousing, quality assurance and laboratory work. Construction began in the second quarter of 2002 and we anticipate completion during the first quarter of 2003. Once the building is complete, an extensive FDA certification of the plant and equipment is required, which could take up to five months.

**Results of Operations**

**Three Months Ended June 30, 2002 Compared to  
Three Months Ended June 30, 2001**

Total revenue for the three months ended June 30, 2002 was \$6.5 million compared to \$4.3 million for the three months ended June 30, 2001, representing a 51% increase. This increase is primarily related to increases in contract research and development revenue and licensing, marketing rights and milestone revenue.

Net sales and royalties were \$1.5 million for the three months ended June 30, 2002 compared to \$1.3 million for the three months ended June 30, 2001, representing a 15% increase. This increase is primarily related to launching our Eligard 7.5-mg one-month product for commercial sale in May 2002. We expect sales and royalty revenues to increase in the second half of 2002 as a result of the marketing launch of our Eligard 7.5-mg one-month product. Additionally, we anticipate a third quarter 2002 launch of our Eligard 22.5-mg three-month product, which was approved by the FDA in July 2002.

Contract research and development revenue represents revenue we earned from unaffiliated third parties and from our joint venture with Elan for performing contract research and development activities using our various patented drug delivery technologies. Contract research and development revenue was \$3.5 million for the three months ended June 30, 2002 compared to \$2.1 million for the three months ended June 30, 2001, representing a 67% increase. This increase is primarily related to the recognition of \$0.9 million in revenue from Fujisawa for partial funding of Atrisone research costs, \$1.0 million increased revenue from Geneva for efforts under the generic dermatology program and \$0.4 million for funding of an Eligard unique dosage formulation by Sanofi-Synthelabo. These increases were offset by a \$0.9 million decrease in revenue recognized in conjunction with our joint venture as a result of the completion of feasibility work performed by us. We expect contract research and development revenue to increase in 2002 as a result of Fujisawa's partial funding of Atrisone costs over the full year in 2002

**Table of Contents**

compared to six months in 2001 in addition to Sanofi-Synthelabo's funding of an Eligard unique dosage formulation product beginning in January 2002 and Geneva's continued support for the development of generic dermatology products.

Licensing, marketing rights and milestone revenue for the three months ended June 30, 2002 was \$1.5 million compared to \$0.8 million for the three months ended June 30, 2001, representing an 88% increase. This increase is primarily related to the recognition of \$0.2 million in additional license fee and milestone revenue for our Eligard products under the Sanofi-Synthelabo agreement and also to the recognition of \$0.4 million additional revenue for the net effects of our 2001 amended agreement with Block Drug Corporation and the subsequent agreement with CollaGenex. The net effects of the amended Block agreement and the subsequent agreement with CollaGenex to transfer U.S. marketing rights of our dental products will be recognized as revenue over the term of the respective agreements using the straight-line method. We expect licensing, marketing and milestone revenue to increase in 2002 as a result of the combined \$10.0 million for 2001 licensing and milestone payments received from Sanofi-Synthelabo, MediGene and Fujisawa being recognized over a full year in 2002 compared to a partial year of recognition in 2001 and as a result of a full year of revenue recognition of the net effects related to the Block agreement in 2002 compared to four months of increased revenue recognition in 2001. Anticipated additional 2002 marketing and milestone payments from Sanofi-Synthelabo include \$6.0 million for the first commercial sales of Eligard 22.5-mg three-month, which was approved by the FDA in July 2002. These potential marketing and milestone payments from Sanofi-Synthelabo will be recorded to deferred revenue and recognized as revenue over the remaining term of the agreement using the straight-line method should we achieve these marketing and milestone events.

Cost of sales for the three months ended June 30, 2002 was \$0.8 million compared to \$0.6 million for the three months ended June 30, 2001, representing a 33% increase. This increase relates to the increase in product sales of Eligard 7.5-mg one-month. We expect that cost of sales will increase in the future as they relate to an increase in sales for the Eligard 7.5-mg one-month sales and possibly the commencement of Eligard 22.5-mg three-month sales.

Research and development expenses excluding research and development licensing fees for the three months ended June 30, 2002 were \$7.5 million compared to \$6.3 million for the three months ended June 30, 2001, representing a 19% increase. An increase of \$0.8 million was related to progress in the development of our generic dermatology products. An increase of \$0.5 million was related to research activities for the growth hormone releasing peptide-1, or GHRP-1, product. Additionally, an increase of \$0.4 million was related to our research and development activities for various BEMA products. These increases were offset by a decrease in research and development of \$0.5 million on the Eligard products as a result of clinical study completions. We expect that our partner funded research and development expenses will increase for the foreseeable future as we continue to develop products under those collaborative agreements, as new products are developed and as new agreements are entered into. Additionally, we expect our research and development expenses for internally funded activities will increase for the foreseeable future as we continue to develop current products and engage in new product discovery and development activities.

Administrative and marketing expenses for the three months ended June 30, 2002 were \$2.4 million compared to \$1.4 million for the three months ended June 30, 2001, representing a 71% increase. The increase is due to the addition of administrative personnel, performance-based compensation to key executive personnel, increased insurance expense, increased depreciation expense on administrative equipment purchases and increased sales and marketing expenses for our international operations. We expect that our administrative and marketing expenses will increase for the foreseeable future as we continue to grow and additional support is required.

We recognized a loss of \$0.3 million for the three months ended June 30, 2002 for our 80.1% equity share in the loss of Transmucosal Technologies, our joint venture with Elan, compared to a loss of \$1.0 million for the three months ended June 30, 2001, representing a 70% decrease. The decrease was primarily related to the completion of feasibility work performed through the joint venture. The two projects in progress through the joint venture are currently under review for further development. We expect to record additional equity losses for Transmucosal Technologies in the foreseeable future.

**Table of Contents**

Investment income and expense, net for the three months ended June 30, 2002 was \$1.2 million compared to \$0.5 million for the three months ended June 30, 2001, representing a 140% increase. The increase was primarily the result of an increase in our average cash and cash equivalents and our marketable securities for the three months ended June 30, 2002 compared to the average balances for the three months ended June 30, 2001 and due to the reduction in interest expense as a result of exchanging 523,605 shares of our common stock for \$9.7 million of our 7% Convertible Subordinated Notes since the period ended June 30, 2001. We expect investment income to increase in 2002 as a result of higher average cash and cash equivalents and marketable securities balances for 2002 compared to 2001. The expected higher balances are primarily due to two underwritten public common stock offerings in 2001 resulting in net proceeds of \$87.7 million. Additionally, interest expense is expected to decrease due to the full conversion of our notes as of May 2002.

Loss on sale and write-down of marketable securities for the three months ended June 30, 2002 was \$1.0 million. This was primarily due to the sale of our \$0.8 million principal WorldCom, Inc. Senior Corporate Notes in May 2002 for proceeds of \$0.4 million which resulted in a loss on sale of marketable securities of \$0.4 million. In June 2002, we incurred a \$0.7 million charge for a write-down of our remaining position in WorldCom Senior Corporate Notes, principal value of \$0.8 million, upon WorldCom's bankruptcy filing in July 2002. The value of our WorldCom Senior Notes as of June 30, 2002 is \$0.1 million, which represents the approximate market value of the notes after the bankruptcy filing by WorldCom.

During the three months ended June 30, 2002 we exchanged 151,300 shares of our common stock for \$2.9 million in outstanding principal amount of our 7% Convertible Subordinated Notes. All of the 151,300 shares issued were valued at the conversion price of \$19.00 per share and were converted prior to the redemption date set for May 15, 2002. As a result of the conversions, we recognized an extraordinary gain of \$44,000, for the write-off of \$42,000 of pro rata unamortized deferred finance charges net of \$86,000 interest expense payable eliminated as a result of these exchanges. As of June 30, 2002 and December 31, 2001, the outstanding principal amount of the 7% Convertible Subordinated Notes was \$0 and \$5.2 million, respectively. In comparison, during the three months ended June 30, 2001, we exchanged 22,359 shares of our common stock for \$0.4 million of the 7% Convertible Subordinated Notes. As a result of this exchange, we recognized a non-cash charge for debt conversion expense of \$9,000 and \$7,000 for extraordinary loss on extinguished debt during the quarter ended June 30, 2001.

We issued Series A Convertible Exchangeable Preferred Stock to Elan in July 2000 in connection with the formation of our joint venture with Elan. Related to this issuance, we recognized \$0.2 million for accretion of dividends on the shares of preferred stock for the three months ended June 30, 2002 compared to \$0.2 million for the three months ended June 30, 2001.

For the reasons described above, we recorded a consolidated net loss applicable to common stock of \$4.6 million, or \$0.23 per share, for the three months ended June 30, 2002 compared to a consolidated net loss applicable to common stock of \$4.9 million, or \$0.32 per share, for the three months ended June 30, 2001.

**Six Months Ended June 30, 2002 Compared to  
Six Months Ended June 30, 2001**

Total revenue for the six months ended June 30, 2002 was \$11.5 million compared to \$7.5 million for the six months ended June 30, 2001, representing a 53% increase. This increase is primarily related to increases in contract research and development revenue and licensing, marketing rights and milestone revenue.

Net sales and royalties were \$2.6 million during the six months ended June 30, 2002 compared to \$2.6 million for the six months ended June 30, 2001. We expect sales and royalty revenues to increase in 2002 as a result of the May 2002 marketing launch of our Eligard 7.5-mg one-month product. Additionally, we anticipate a third quarter 2002 marketing launch of our Eligard 22.5-mg three-month product, which was approved by the FDA in July 2002.

Contract research and development revenue represents revenue we earned from unaffiliated third parties and from our joint venture with Elan for performing contract research and development activities using our various patented drug delivery technologies. Contract research and development revenue was \$6.0 million for the six months ended June 30, 2002 compared to \$3.4 million for the six months ended June 30, 2001, representing a 76%

**Table of Contents**

increase. This increase is primarily related to the recognition of \$1.7 million in revenue from Fujisawa for partial funding of Atrisone research costs, \$1.0 million increased revenue from Geneva for efforts under the generic dermatology program, \$0.6 million for funding of an Eligard unique dosage formulation by Sanofi-Synthelabo and \$0.3 million for revenue from research activities funded by other parties. These increases were offset by a \$1.0 million decrease in revenue recognized in conjunction with our joint venture as a result of the completion of feasibility work performed by us. We expect contract research and development revenue to increase in 2002 as a result of Fujisawa's partial funding of Atrisone costs over the full year in 2002 compared to six months in 2001 in addition to Sanofi-Synthelabo's funding of an Eligard unique dosage formulation product beginning in January 2002 and Geneva's continued support for the development of generic dermatology products.

Licensing, marketing rights and milestone revenue for the six months ended June 30, 2002 was \$2.9 million compared to \$1.5 million for the six months ended June 30, 2001, representing a 93% increase. This increase is primarily related to the recognition of \$0.4 million in additional license fee and milestone revenue for our Eligard products under the Sanofi-Synthelabo and MediGene agreements and also to the recognition of \$0.9 million additional revenue for the net effects of our 2001 amended agreement with Block and the subsequent agreement with CollaGenex. The net effects of the amended Block agreement and the subsequent agreement with CollaGenex to transfer U.S. marketing rights of our dental products will be recognized as revenue over the term of the respective agreements using the straight-line method. We expect licensing, marketing and milestone revenue to increase in 2002 as a result of the combined \$10.0 million for 2001 licensing and milestone payments received from Sanofi-Synthelabo, MediGene and Fujisawa being recognized over a full year in 2002 compared to a partial year of recognition in 2001 and as a result of a full year of revenue recognition of the net effects related to the Block agreement in 2002 compared to four months of increased revenue recognition in 2001. Anticipated additional 2002 marketing and milestone payments from Sanofi-Synthelabo include \$6.0 million for the first commercial sales of Eligard 22.5-mg three-month, which was approved by the FDA in July 2002. These potential marketing and milestone payments from Sanofi-Synthelabo will be recorded to deferred revenue and recognized as revenue over the remaining term of the agreement using the straight-line method should we achieve these marketing and milestone events.

Cost of sales for the six months ended June 30, 2002 was \$1.3 million compared to \$1.0 million for the six months ended June 30, 2001, representing a 30% increase. While overall sales levels were flat for the six months ended June 30, 2002 compared to the six months ended June 30, 2001, the increase in cost of sales relates to product sales of Eligard 7.5-mg one-month. We expect that cost of sales will increase in the future as they relate to an increase in sales for the Eligard 7.5-mg one-month sales and possibly the commencement of Eligard 22.5-mg three-month sales.

Research and development expenses excluding research and development licensing fees for the six months ended June 30, 2002 were \$14.1 million compared to \$12.6 million for the six months ended June 30, 2001, representing a 12% increase. An increase of \$0.5 million was related to progress in the development of our Atrisone acne product. An increase of \$0.9 million was related to progress in the development of our generic dermatology products. An increase of \$0.9 million was related to research activities for the growth hormone releasing peptide-1, or GHRP-1, product. Additionally, an increase of \$0.9 million was related to our research and development activities for various BEMA products. These increases were offset by a decrease in research and development of \$2.0 million on the Eligard products as a result of clinical study completions. We expect that our partner funded research and development expenses will increase for the foreseeable future as we continue to develop products under those collaborative agreements, as new products are developed and as new agreements are entered into. Additionally, we expect our research and development expenses for internally funded activities will increase for the foreseeable future as we continue to develop current products and engage in new product discovery and development activities.

Research and development licensing fees for the six months ended June 30, 2001 was \$0.5 million, which represents licensing fees paid to Tulane University for GHRP-1. These fees were expensed as incurred, as the technology licensed was for research and development purposes with no future alternative uses. We did not incur any licensing fees during the six months ended June 30, 2002. We may, in the future, incur additional costs for the acquisition of licenses, however, we cannot predict if or when that may happen or what the cost may be.

**Table of Contents**

Administrative and marketing expenses for the six months ended June 30, 2002 were \$4.2 million compared to \$2.7 million for the six months ended June 30, 2001, representing a 56% increase. This increase was primarily related to the addition of administrative personnel, performance-based compensation to key executive personnel, expenses incurred to recruit additional scientific personnel, increased insurance expense, increased depreciation expense on administrative equipment purchases and increased sales and marketing expenses for our international operations. We expect that our administrative and marketing expenses will increase for the foreseeable future as we continue to grow and additional support is required.

Administrative stock option compensation for the six months ended June 30, 2002 was \$1.3 million, which was recognized in connection with the retirement of an executive officer. We may, in the future, incur additional costs for stock compensation and performance-based compensation activities; however, we cannot predict if or when that may happen or what the cost may be.

We recognized a loss of \$0.7 million for the six months ended June 30, 2002 for our 80.1% equity share in the loss of Transmucosal Technologies, our joint venture with Elan, compared to a loss of \$1.5 million for the six months ended June 30, 2001, representing a 53% decrease. The decrease was primarily related to the completion of feasibility work performed through the joint venture. The two projects in progress through the joint venture are currently under review for further development. We expect to record additional equity losses for Transmucosal Technologies in the foreseeable future.

Investment income and expense, net for the six months ended June 30, 2002 was \$2.4 million compared to \$1.0 million for the six months ended June 30, 2001, representing a 140% increase. The increase was primarily the result of an increase in our average cash and cash equivalents and our marketable securities for the six months ended June 30, 2002 compared to the average balances for the six months ended June 30, 2001 and due to the reduction in interest expense as a result of exchanging 523,605 shares of our common stock for \$9.7 million of our 7% Convertible Subordinated Notes since the period ended June 30, 2001. We expect investment income to increase in 2002 as a result of higher average cash and cash equivalents and marketable securities balances for 2002 compared to 2001. The expected higher balances are primarily due to two underwritten public common stock offerings in 2001 resulting in net proceeds of \$87.7 million. Additionally, interest expense is expected to decrease due to the full conversion of our notes as of May 2002.

Loss on sale and write-down of marketable securities for the six months ended June 30, 2002 was \$1.1 million. This was primarily due to the sale of our \$0.8 million principal amount of WorldCom, Inc. Senior Corporate Notes in May 2002 for proceeds of \$0.4 million which resulted in a loss on sale of marketable securities of \$0.4 million. In June 2002, we incurred a \$0.7 million charge for a write-down of our remaining position in WorldCom Senior Corporate Notes, principal value of \$0.8 million, upon WorldCom's bankruptcy filing in July 2002. The value of our WorldCom Senior Notes as of June 30, 2002 is \$0.1 million, which represents the approximate market value of the notes after the bankruptcy filing by WorldCom.

During the six months ended June 30, 2002 we exchanged 279,901 shares of our common stock for \$5.2 million in outstanding principal amount of our 7% Convertible Subordinated Notes. Of the 279,901 shares issued, 273,984 shares were valued at the conversion price of \$19.00 per share and the remaining 5,917 shares were valued at \$21.09 per share, the closing market price of our common stock on the date of exchange. As a result of the conversions, we recognized an extraordinary gain of \$30,000, for the write-off of \$80,000 of pro rata unamortized deferred finance charges net of \$0.1 million interest expense payable eliminated as a result of these exchanges. Additionally, of the 5,917 shares exchanged, a debt conversion expense of approximately \$0.1 million was recognized for the six months ended June 30, 2002. As of June 30, 2002 and December 31, 2001, the outstanding principal amount of the 7% Convertible Subordinated Notes was \$0 million and \$5.2 million, respectively. In comparison, during the six months ended June 30, 2001, we exchanged 1,482,031 shares of our common stock for \$26.5 million of the 7% Convertible Subordinated notes. As a result of this exchange, we recognized a non-cash charge for debt conversion expense of \$2.0 million and \$0.3 million for extraordinary loss on extinguished debt during the six months ended June 30, 2001.

We issued Series A Convertible Exchangeable Preferred Stock to Elan in July 2000 in connection with the formation of our joint venture with Elan. Related to this issuance, we recognized \$0.5 million for accretion of

## **Table of Contents**

dividends on the shares of preferred stock for the six months ended June 30, 2002 compared to \$0.4 million for the six months ended June 30, 2001.

For the reasons described above, we recorded a consolidated net loss applicable to common stock of \$9.4 million, or \$0.47 per share, for the six months ended June 30, 2002 compared to a consolidated net loss applicable to common stock of \$12.7 million, or \$0.87 per share, for the six months ended June 30, 2001.

## **Liquidity and Capital Resources**

As of June 30, 2002, we had cash and cash equivalents of \$35.7 million, marketable securities (at fair value) of \$99.2 million, net accounts receivable of \$3.6 million, inventories of \$4.8 million and other current assets of \$3.0 million for total current assets of \$146.3 million. We had accounts payable of \$2.9 million, short-term deferred revenue of \$7.4 million and other current liabilities of \$1.4 million for total current liabilities of \$11.7 million, which resulted in working capital of \$134.6 million.

During the six months ended June 30, 2002, net cash used in operating activities was \$0.3 million. This was primarily the result of the net loss for the period of \$8.9 million, adjusted for certain non-cash expenses, and changes in operating assets and liabilities as set forth in the consolidated statements of cash flows. We recognized a non-cash charge of \$1.3 million for the vesting of incentive stock options in conjunction with the retirement of an executive officer in the first quarter of 2002. We recorded a loss on sale and write-down of marketable securities of \$1.1 million primarily as a result of the sale of half of our \$1.5 million principal amount of WorldCom Senior Notes and the subsequent write-down of \$0.7 million on the remaining half of the WorldCom Senior Notes upon WorldCom's bankruptcy filing in July 2002. The value of our WorldCom Senior Notes as of June 30, 2002 is approximately \$0.1 million, which represents the approximate market value of the notes after the bankruptcy filing by WorldCom. Additionally, we recognized non-cash charges of \$1.6 million of depreciation and amortization expense and \$0.7 million for our equity in the loss of Transmucosal Technologies. We recognized a cash inflow from the advanced receipt of milestone payments, licensing fees and certain contract research and development payments of \$10.1 million, partially offset by amortization of deferred revenue of \$4.3 million. Other significant uses of cash included: (i) \$1.5 million of increased inventories primarily related to the build up of inventory for the launch of the Eligard one-month product and the expected third quarter launch of the Eligard three-month product, and (ii) \$1.4 million of increased prepaid expenses and deposits primarily related to prepayments on certain research and development projects, insurance and deposits on equipment.

Net cash used in investing activities was \$16.2 million during the six months ended June 30, 2002. This was primarily due to the proceeds received from the maturity and sale of marketable securities of \$15.1 million, net of \$27.9 million used to fund the purchases of various marketable securities available-for-sale during the first half of 2002.

Net cash provided by financing activities was \$1.9 million during the six months ended June 30, 2002. This increase is primarily the result of proceeds of \$2.5 million from the issuance of common stock. In September 2001, our Board of Directors approved a stock repurchase program ( Program ) to acquire up to \$5 million of our common stock. As of June 30, 2002, we repurchased a total of 111,000 shares of our common stock in the open market with an average share price of \$20.09 for a total stock repurchase value of \$2.2 million for the six month period ended June 30, 2002 and a total of \$4 million under the Program. The Program terminates on the earlier of the date that we have repurchased \$5 million of our common stock or December 2002. On July 23, 2002, the Board of Directors approved an amendment to the Program to increase the total amount of common stock that can be purchased under the Program from a maximum of \$5 million to a maximum of \$15 million.

In November 1997, we issued \$50.0 million in principal amount of our 7% Convertible Subordinated Notes. Interest was payable semi-annually and the notes were due to mature on December 1, 2004. The notes were convertible, at the option of the holder, into common stock at a conversion price of \$19.00 a share, subject to adjustment in certain events. The notes were redeemable, in whole or in part, at our option at any time on or after December 5, 2000. In March 2002 we announced the redemption date of May 15, 2002 for the remaining outstanding notes. Prior to the redemption date, the remaining notes were converted into our common stock at \$19.00 per share. During the six months ended June 30, 2002 we exchanged 279,901 shares of our common stock for \$5.2 million of our 7% Convertible Subordinated Notes. Of the 279,901 shares issued, 273,984 shares were

## **Table of Contents**

valued at the conversion price of \$19.00 per share and the remaining 5,917 shares were valued at \$21.09 per share, the closing market price of our common stock on date of exchange. As a result, we recognized an extraordinary gain of \$30,000, for the write-off of \$80,000 of pro rata unamortized deferred finance charges net of \$0.1 million interest expense payable eliminated as a result of these exchanges. Additionally, of the 279,901 shares exchanged, a debt conversion expense of approximately \$0.1 million was recognized for the six months ended June 30, 2002. As of June 30, 2002 and December 31, 2001, the outstanding principal amount of the 7% Convertible Subordinated Notes was \$0 million and \$5.2 million, respectively.

In July 2000, we formed Transmucosal Technologies, a joint venture, with Elan to develop and commercialize oncology and pain management products. Subject to the satisfaction of certain conditions, Elan has agreed to loan us up to \$8.0 million under a convertible promissory note agreement in support of our 80.1% share of the joint venture's research and development costs. The note has a six-year term, will accrue interest at 7% per annum, compounded semi-annually and added to principal, and is convertible at Elan's option into our common stock at a \$14.60 conversion price. As of June 30, 2002, we had not drawn any amounts under the note. We are required to fund our 80.1% share of the joint venture's obligations, and this cash funding totaled \$1.2 million for the six months ended June 30, 2002 and \$0.7 million for the six months ended June 30, 2001. Our future funding obligations are expected to be consistent with the funding in 2001.

We have historically funded our operations through debt and equity offerings, payments received for licenses, milestones and research and development support under contractual arrangements and, to a lesser extent, product sales and royalties. Additionally, we have historically incurred operating losses and expect to continue to incur operating losses for the foreseeable future. At June 30, 2002, we had \$35.7 million of cash and cash equivalent investments and \$99.2 million of available-for-sale marketable securities (at fair value) to fund future operations and capital requirements. Our available-for-sale marketable securities are primarily in investment grade corporate notes and U.S. government bonds and bond funds. Our portfolio of corporate notes is diversified and, under our policy, we only invest in investment grade corporate notes. We believe the quality of the notes we hold and the diversity of our portfolio significantly mitigates our market risk; however from time to time we have experienced investment losses as some of the issuers of our investment grade corporate notes have declared bankruptcy, i.e. Enron and WorldCom. We believe that we have adequate liquidity and capital resources to fund our operations and capital requirements for the foreseeable future. However, we may have to raise additional funds to complete the development of our technologies as discussed below.

## **Subsequent Events**

In July 2002, the FDA approved the NDA for our Eligard 22.5 mg three-month product, a subcutaneous injection for the treatment of advanced prostate cancer.

## **Future Capital Requirements**

Our long-term capital expenditure requirements will depend on numerous factors, including:

- the progress of our research and development programs,
- the time required to file and process regulatory approval applications,
- the development of our commercial manufacturing facilities,
- our ability to obtain additional licensing arrangements, and
- the demand for our products.

We expect to continue to incur substantial expenditures for research and development, testing, regulatory compliance, market development in European countries, possible repurchases of our common stock and to hire additional management, scientific, manufacturing and administrative personnel. We will also continue to expend a significant amount of funds for our ongoing clinical studies. Depending on the results of our research and development activities, we may determine to accelerate or expand our efforts in one or more proposed areas and may, therefore, require additional funds earlier than previously anticipated. We believe the existing cash and cash equivalent assets in addition to marketable security resources will be sufficient to fund our operations for the foreseeable future. However, underlying assumed levels of revenue and expense may not prove to be accurate.



**Table of Contents**

The following table summarizes research and development activities funded by our collaborators, as well as research and development activities funded by us, for the years ended December 31, 2001, 2000 and 1999 and the six months ended June 30, 2002, including research and development costs inception-to-date and estimated completion dates and costs (in thousands):

**Table of Contents**

Technology	Expenses	Expenses	Expenses	Expenses	Expenses	Funded	Anticipated		Anticipated
	1999	2000	2001	(as of June 30)	Inception-to-Date	Expenses Inception-to-Date	(to market)		Costs to Completion (to market)
Atrigel	\$ 10,624	\$ 10,845	\$ 13,727	\$ 5,869	\$ 100,880	\$ 6,455	2002	2007	\$ 50,000
SMP	2,328	3,090	4,604	2,649	12,670	2,710	2005		20,000
BEMA	553	259	2,397	1,416	4,625	5,232	2006	2007	5,000
Other	2,050	2,541	4,907	4,140	26,623	8,200	2003	2007	50,000
<b>Total</b>	<b>\$ 15,555</b>	<b>\$ 16,735</b>	<b>\$ 25,635</b>	<b>\$ 14,074</b>	<b>\$ 144,798</b>	<b>\$ 22,597</b>	<b>2002</b>	<b>2008</b>	<b>\$ 125,000</b>
Funded	\$ 2,429	\$ 1,921	\$ 10,626	\$ 6,865					
Not Funded	13,126	14,814	15,009	7,209					
<b>Total</b>	<b>\$ 15,555</b>	<b>\$ 16,735</b>	<b>\$ 25,635</b>	<b>\$ 14,074</b>					

The predominate product lines included under the Atrigel technology are the Eligard and dental products which comprise 28% and 66%, respectively, of the expenses incurred to date. Recently, however, the Eligard products comprised more of the research and development effort with 37%, 67%, 75% and 59% of the 1999, 2000, 2001 and year-to-date 2002 Atrigel expenses, respectively. As dental products have moved into market, expenses to support them have stabilized and comprised 56%, 25%, 12% and 13% of the 1999, 2000, 2001 and year-to-date 2002 Atrigel expenses, respectively. Of the expenses funded by third parties, 25% of funds received were to support the dental products, 22% of funds have come recently to support the Eligard products domestically as well as internationally, and 53% of funds have come from direct support of research contracts with various companies.

The Atrisone acne product represents 100% of expenses and funding under the SMP technology.

Under the BEMA technology, approximately 59% of expenses incurred to date relate to the development of two products through our joint venture with Elan and 100% of funding for BEMA research and development has come from the joint venture.

Other research and development expenses incurred to date represent efforts to introduce additional products into our product pipeline. Expenses related to develop generic dermatology products are also included in this category and represent 19% of expenses incurred to date and 30% of funding.

In April 2002, we announced our plans to expand our manufacturing and laboratory facilities to support current and future projects. The current 26,000 square foot facility will be expanded to 58,000 square feet. In the expanded facility we intend to produce the full line of our Eligard prostate cancer products, Atrisone topical dermatological product, generic dermatology products, dental products and clinical supplies for products currently in development. Approximately 40% of the building expansion will be devoted to production with the remainder allotted for warehousing, quality assurance and laboratory work. Construction began in the second quarter of 2002 and we anticipate completion during the first quarter of 2003. Construction costs are estimated to be approximately \$5.5 million with additional expenditures to be incurred as needed for equipment.

**Recent Accounting Pronouncements**

On June 29, 2001, SFAS No. 142, *Goodwill and Other Intangible Assets* was issued by the FASB. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Goodwill and certain intangible assets will remain on the balance sheet and not be amortized. On an annual basis, and when there is reason to suspect that their values have been diminished or impaired, these assets must be tested for impairment, and write-downs may be necessary. Amortization of goodwill, including goodwill recorded in past business combinations, ceased upon adoption of this statement. We adopted SFAS No. 142 on January 1, 2002. The adoption of this statement did not have a material impact on our consolidated financial position or results of operations.

In August 2001, SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* was issued by the FASB. SFAS No. 144 provided new guidance on the recognition of impairment losses on long-lived assets to be held and used or to be disposed of and also broadens the definition of what constitutes a discontinued



**Table of Contents**

operation and how the results of a discontinued operation are to be measured and presented. We adopted SFAS No. 144 on January 1, 2002. The adoption of this statement did not have a material impact on our consolidated financial position or results of operations.

**Critical Accounting Policies**

Our significant accounting policies are described in Note 1 to the Consolidated Financial Statements included in our Annual Report on Form 10-K/A for the year ended December 31, 2001. The accounting policies used in preparing our interim consolidated financial statements for the six months ended June 30, 2002 are the same as those described in our Annual Report on Form 10-K/A.

Our critical accounting policies are those having the most impact to the reporting of our financial condition and results and those requiring significant judgments and estimates. Our critical accounting policies, which are included in Note 2 in the notes to the accompanying financial statements, include those related to (1) principles of consolidation, (2) revenue recognition and (3) research and development. With respect to these critical accounting policies, our management believes that the application of judgments and assessments is consistently applied and produces financial information, which fairly depicts the results of operations for all periods presented.

**Factors Affecting Our Business and Prospects**

There are many factors that affect our business and the results of our operations, some of which are beyond our control. These factors include:

Our history of operating losses and the likelihood of future losses.

Delay, difficulty, or failure in obtaining regulatory approval or clearance to market additional products, including delays or difficulties in development because of insufficient proof of safety or efficacy.

Failure of corporate partners to develop or commercialize successfully our products or to retain and expand markets served by the commercial collaborations; conflicts of interest, priorities, and commercial strategies that may arise between us and such corporate partners.

Our limited experience in the sale and marketing of our products.

Competitive or market factors that may limit the use or broad acceptance of our products.

Cancellation or termination of material collaborative agreements and the resulting loss of research or other funding, or marketing, sales and distribution capabilities.

Exchange rate fluctuations that may adversely impact net income (loss).

The ability to obtain, maintain and protect intellectual property rights, and the cost of acquiring in-process technology and other intellectual property rights, either by license, collaboration or purchase of another entity.

Limited experience in manufacturing products on a commercial scale, failure to manufacture present and future products in compliance with applicable regulations and at an acceptable cost.

Product liability or other claims against us which may result in substantial damages or reduce demand for our products.

The ability to attract and retain highly qualified management, administrative and scientific personnel.

For a discussion of these and other factors affecting our business and prospects, see Item 1. Business Factors Affecting our Business and Prospects in our Annual Report on Form 10-K/A for the year ended December 31, 2001.

**Table of Contents**

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES CONCERNING MARKET RISKS.**

We own financial instruments that are sensitive to market risks as part of our investment portfolio of cash equivalents and marketable securities. The investment portfolio is used to preserve our capital until it is required to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes and we do not own derivative financial instruments. Our investment portfolio contains instruments that are primarily subject to interest rate risk.

**Interest Rate Risk.** Our investment portfolio includes fixed rate debt instruments that are primarily United States government and agency bonds and corporate notes with maturity dates ranging from one to fifteen years. To mitigate the impact of fluctuations in cash flow, we maintain substantially all of our debt instruments as fixed rate. The market value of these bonds is subject to interest rate risk and could decline in value if interest rates increase. The portion maintained as fixed rate is dependent on many factors including judgments as to future trends in interest rates.

Our investment portfolio also includes equity interests in United States government and agency bond mutual funds. The value of these equity interests is also subject to interest rate risk.

We regularly assess the above described market risks and have established policies and business practices to protect against the adverse effects of these and other potential exposures. Our investment policy restricts investments to U.S. government or government-backed securities or to high rated commercial paper and other high rated investments only. As a result, we do not anticipate any material credit losses in these areas.

For disclosure purposes, we use sensitivity analysis to determine the impacts that market risk exposures may have on the fair values of our debt and financial instruments. The financial instruments included in the sensitivity analysis consist of all of our cash and cash equivalents and short-term and long-term debt instruments.

To perform a sensitivity analysis, we assess the risk of loss in fair values from the impact of hypothetical changes in interest rates on market sensitive instruments. The fair values are computed based on the present value of future cash flows as impacted by the changes in the rates attributable to the market risk being measured. The discount rates used for the present value computations were selected based on market interest rates in effect at June 30, 2002. The fair values that result from these computations are compared with the fair values of these financial instruments at June 30, 2002. The differences in this comparison are the hypothetical gains or losses associated with each type of risk. The results of the sensitivity analysis at June 30, 2002 are as follows:

**Interest Rate Sensitivity:** A 10% decrease in the levels of interest rates with all other variables held constant would result in an increase in the fair value of our financial instruments by approximately \$0.5 million per year. A 10% increase in the levels of interest rates with all other variables held constant would result in a decrease in the fair value of our financial instruments by approximately \$0.5 million per year. We maintain a portion of our financial instruments, including long-term debt instruments of approximately \$17.9 million at June 30, 2002, at variable interest rates. If interest rates were to increase or decrease 10%, the impact of such instruments on cash flows or earnings would not be material.

The use of a 10% estimate is strictly for estimation and evaluation purposes only. The value of our assets may rise or fall by a greater amount depending on actual general market performances and the value of individual securities we own.

**Exchange Rate Risk.** We face foreign exchange rate fluctuations, primarily with respect to the British Pound and the Euro, as the financial results of our foreign subsidiaries are translated into United States dollars for consolidation. As exchange rates vary, these results when translated, may vary from expectations and adversely impact net income (loss) and overall profitability. The effect of foreign exchange rate fluctuation for the period ended June 30, 2002 was not material. Based on our overall foreign currency rate exposure at June 30, 2002, we do not believe that a hypothetical 10% change in foreign currency rates would materially affect our financial position.

**Table of Contents****PART II OTHER INFORMATION****Item 2. CHANGES IN SECURITIES AND USE OF PROCEEDS.**

In March 2002, we announced a call for redemption of the remainder of the outstanding 7% Convertible Subordinated Notes. The outstanding notes were fully converted into our common stock prior to the redemption date of May 15, 2002.

During the three months ended June 30, 2002 we exchanged 151,300 shares of our common stock for \$2.9 million in outstanding principal amount of our 7% Convertible Subordinated Notes. The 151,300 shares issued were valued at the conversion price of \$19.00 per share. As a result, we recognized an extraordinary gain of \$44,000, for the write-off of \$42,000 of pro rata unamortized deferred finance charges net of \$86,000 interest expense payable eliminated as a result of these exchanges. As of June 30, 2002 the outstanding principal amount of the 7% Convertible Subordinated Notes was \$0. Because this transaction constituted an exchange of securities by us exclusively with existing security holders, where no commission or other remuneration was paid or given for soliciting such exchange, the transactions were exempt from registration under the Securities Act of 1933 under Section 3(a)(9) of the Securities Act.

**Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

Our Annual Meeting of Stockholders was held on May 5, 2002. At the meeting the stockholders voted on the re-election of H. Stuart Campbell, C. Rodney O Connor and Dr. George J. Vuturo as Class C directors and the ratification of the appointment of Deloitte & Touche LLP as our independent auditors for the fiscal year ending December 31, 2002. The results of the voting are as follows:

## 1. Election of Class C Directors:

	<u>For</u>	<u>Withheld</u>
H. Stuart Campbell	14,530,646	290,845
C. Rodney O Connor	14,444,817	376,674
Dr. George J. Vuturo	14,567,295	254,196

The other directors whose term continues after the meeting are Sander A. Flaum, Dr. D. Walter Cohen, David R. Bethune, Dr. Nicolas Bazan and Warren L. Troupe.

## 2. Ratification of Appointment of Independent Auditors:

<u>For</u>	<u>Against</u>	<u>Abstain</u>
14,284,072	508,233	29,186

**Table of Contents**

**Item 6. EXHIBITS AND REPORTS ON FORM 8-K.**

(a) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
10.1*	Executive Deferred Compensation Plan
99.1	Certification of Chief Executive Officer
99.2	Certification of Chief Financial Officer

\* Previously filed with, and incorporated by reference to, the Registrant's original Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, as filed with the Securities and Exchange Commission on July 30, 2002 (File No. 000-18321).

(b) Reports on Form 8-K. None.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ATRIX LABORATORIES, INC**  
(Registrant)

November 7, 2002

By: /s/ Brian G. Richmond

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Brian G. Richmond  
Chief Financial Officer, Secretary and Treasurer  
(Principal Financial and Chief Accounting Officer)

25

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**Table of Contents**

**CERTIFICATIONS**

I, David R. Bethune, Chairman and Chief Executive Officer of Atrix Laboratories, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Atrix Laboratories, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.

Date: November 7, 2002

/s/ David R. Bethune

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David R. Bethune  
Chairman and Chief Executive Officer

I, Brian G. Richmond, Chief Financial Officer of Atrix Laboratories, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Atrix Laboratories, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report.

Date: November 7, 2002

/s/ Brian G. Richmond

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Brian G. Richmond  
Chief Financial Officer

**Table of Contents**

**EXHIBIT INDEX**

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