

ATRIX LABORATORIES INC

Form 10-Q

November 19, 2003

**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, 2003**

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

For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-18231

**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

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 as of October 31, 2003, was 21,455,772 (par value \$0.001 per share).

---

**TABLE OF CONTENTS**

**PART I. FINANCIAL INFORMATION**

**CONSOLIDATED BALANCE SHEETS**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

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

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

**Item 4. CONTROLS AND PROCEDURES.**

**PART II. OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

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

**SIGNATURES**

**EXHIBIT INDEX**

**EX-10.1 Termination Agreement**

**EX-31.1 Rule 13a-14(a) Certification of CEO**

**EX-31.2 Rule 13a-14(a) Certification of CFO**

**EX-32.1 Section 1350 Certification of CEO**

**EX-32.2 Section 1350 Certification of CFO**

---

**Table of Contents**

**ATRIX LABORATORIES, INC. AND SUBSIDIARIES**

**TABLE OF CONTENTS**

	<b>Page</b>
	<b><u>        </u></b>
<b>PART I. FINANCIAL INFORMATION</b>	<b>3</b>
<b>Item 1. Financial Statements</b>	<b>3</b>
Consolidated Balance Sheets December 31, 2002 and September 30, 2003 (unaudited)	3
Consolidated Statements of Operations Three and Nine Months Ended September 30, 2003 and 2002 (unaudited)	4
Consolidated Statements of Cash Flows Nine Months Ended September 30, 2003 and 2002 (unaudited)	5
Notes to Consolidated Financial Statements (unaudited)	6
<b>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</b>	<b>11</b>
<b>Item 3. Quantitative and Qualitative Disclosures About Market Risk</b>	<b>23</b>
<b>Item 4. Controls and Procedures</b>	<b>23</b>
<b>PART II. OTHER INFORMATION</b>	<b>24</b>
<b>Item 1. Legal Proceedings</b>	<b>24</b>
<b>Item 6. Exhibits and Reports on Form 8-K</b>	<b>24</b>

**Table of Contents****PART I. FINANCIAL INFORMATION****ATRIX LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS**

(In thousands, except share data)

(unaudited)

**ASSETS**

	<b>September 30, 2003</b>	<b>December 31, 2003</b>
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 23,607	\$ 30,698
Marketable securities available-for-sale, at fair value	75,663	81,767
Accounts receivable, net of allowance for doubtful accounts of \$1,041 and \$623	8,783	6,140
Interest receivable	601	679
Inventories, net of reserves of \$649 and \$0	11,693	8,694
Prepaid expenses and deposits	3,793	2,253
	<hr/>	<hr/>
Total current assets	124,140	130,231
	<hr/>	<hr/>
<b>PROPERTY, PLANT AND EQUIPMENT, NET</b>	<b>22,258</b>	<b>15,431</b>
	<hr/>	<hr/>
<b>OTHER ASSETS:</b>		
Goodwill	399	399
Intangible and other assets, net of accumulated amortization of \$3,755 and \$3,116	2,971	3,964
	<hr/>	<hr/>
Total other assets	3,370	4,363
	<hr/>	<hr/>
<b>TOTAL ASSETS</b>	<b>\$ 149,768</b>	<b>\$ 150,025</b>
	<hr/>	<hr/>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable trade	\$ 2,857	\$ 7,261
Accrued expenses and other	1,206	1,042
Deferred revenue	9,844	7,889
	<hr/>	<hr/>
Total current liabilities	13,907	16,192
	<hr/>	<hr/>
<b>DEFERRED REVENUE</b>	<b>34,918</b>	<b>37,064</b>
	<hr/>	<hr/>
<b>COMMITMENTS AND CONTINGENCIES</b>		
Series A Convertible Exchangeable Preferred Stock, \$.001 par value, 20,000 shares authorized; 13,787 shares issued and outstanding at December 31, 2002, liquidation preference \$14,227		14,514
		<hr/>
<b>SHAREHOLDERS EQUITY:</b>		
Series A Convertible Exchangeable Preferred Stock, \$.001 par value, 20,000 shares authorized; 14,770 issued and outstanding at September 30, 2003, liquidation preference \$14,979		
Preferred stock, \$.001 par value; 5,000,000 shares authorized Series A Convertible Exchangeable Preferred Stock, \$.001 par value, 200,000 shares authorized, none issued or outstanding		

Edgar Filing: ATRIX LABORATORIES INC - Form 10-Q

Common stock, \$.001 par value; 45,000,000 shares authorized; 21,430,887 and 20,516,069 shares issued and 20,564,087 and 19,858,369 shares outstanding	21	21
Additional paid-in capital	268,428	242,699
Treasury stock, 866,800 and 657,700 shares, at cost	(13,615)	(10,740)
Accumulated other comprehensive income	1,177	1,590
Accumulated deficit	(155,068)	(151,315)
	<u>100,943</u>	<u>82,255</u>
Total shareholders' equity		
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 149,768</u>	<u>\$ 150,025</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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
<b>REVENUE:</b>				
Net sales and royalties	\$ 5,342	\$ 1,587	\$ 13,125	\$ 4,230
Contract research and development revenue	5,773	4,306	15,772	10,314
Licensing, marketing rights, and milestone revenue	2,524	1,731	6,546	4,591
<b>Total revenue</b>	<b>13,639</b>	<b>7,624</b>	<b>35,443</b>	<b>19,135</b>
<b>OPERATING EXPENSES:</b>				
Cost of sales	2,901	502	6,191	1,815
Research and development	8,738	9,438	26,707	23,512
Administrative and marketing	2,387	2,413	7,879	6,597
Administrative stock option compensation			22	1,257
<b>Total operating expenses</b>	<b>14,026</b>	<b>12,353</b>	<b>40,799</b>	<b>33,181</b>
<b>LOSS FROM OPERATIONS</b>	<b>(387)</b>	<b>(4,729)</b>	<b>(5,356)</b>	<b>(14,046)</b>
<b>OTHER INCOME (EXPENSE):</b>				
Equity in loss of joint venture	(6)	(195)	(83)	(940)
Investment income and expense, net	638	1,047	2,059	3,427
Gain (loss) on sale and write-down of marketable securities	139	(15)	567	(1,091)
Debt conversion expense				(125)
Other, net	(7)	(27)	(23)	(32)
<b>Other income, net</b>	<b>764</b>	<b>810</b>	<b>2,520</b>	<b>1,239</b>
<b>NET INCOME (LOSS)</b>	<b>377</b>	<b>(3,919)</b>	<b>(2,836)</b>	<b>(12,807)</b>
Accretion of dividends and beneficial conversion feature charge on preferred stock	(424)	(242)	(918)	(703)
<b>NET LOSS APPLICABLE TO COMMON STOCK</b>	<b>\$ (47)</b>	<b>\$ (4,161)</b>	<b>\$ (3,754)</b>	<b>\$ (13,510)</b>
<b>Basic and diluted loss per common share:</b>				
Net income (loss)	\$ .02	\$ (.20)	\$ (.14)	\$ (.64)
Accretion of dividends and beneficial conversion feature charge on preferred stock	(.02)	(.01)	(.05)	(.03)
<b>Net loss applicable to common stock</b>	<b>\$</b>	<b>\$ (.21)</b>	<b>\$ (.19)</b>	<b>\$ (.67)</b>
<b>Basic and diluted weighted average common shares outstanding</b>	<b>20,257,238</b>	<b>20,202,479</b>	<b>19,925,896</b>	<b>20,122,029</b>



See notes to the consolidated financial statements.



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

(In thousands, Unaudited)

	<b>Nine Months Ended September 30,</b>	
	<b>2003</b>	<b>2002</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (2,836)	\$ (12,807)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,488	2,437
Amortization of deferred revenue	(7,523)	(7,928)
Provision for inventory write-offs	649	
Provision for doubtful accounts	660	303
Equity in loss of joint venture	83	940
Loss (gain) on sale and write-down of marketable securities	(567)	1,091
Stock and stock option compensation	22	1,257
Other non-cash items	70	238
Net changes in operating assets and liabilities:		
Accounts receivable	(3,212)	(1,545)
Interest receivable	77	185
Inventories	(3,569)	(1,810)
Prepaid expenses and deposits	(1,538)	(1,374)
Accounts payable	(4,957)	1,177
Accrued expenses and other	157	316
Deferred revenue	7,333	11,661
Net cash used in operating activities	<u>(12,663)</u>	<u>(5,859)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Acquisition of property, plant and equipment	(7,529)	(4,317)
Investment in intangible and other assets	(515)	(1,296)
Proceeds from maturity and sale of marketable securities	32,596	51,546
Investment in marketable securities	(26,710)	(56,185)
Investment in joint venture	(302)	(1,500)
Net cash used in investing activities	<u>(2,460)</u>	<u>(11,752)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of equity securities, net of issuance costs	10,275	3,025
Payments to acquire treasury stock	(2,875)	(6,344)
Net cash provided by (used in) financing activities	<u>7,400</u>	<u>(3,319)</u>
NET EFFECT OF EXCHANGE RATE ON CASH	<u>632</u>	<u>437</u>
NET DECREASE IN CASH AND CASH EQUIVALENTS	<u>(7,091)</u>	<u>(20,493)</u>
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	<u>30,698</u>	<u>50,058</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 23,607	\$ 29,565

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

**2003**

Reclassified \$15,432 of Series A Convertible Exchangeable Preferred Stock to permanent equity

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

Issued preferred stock valued at \$983 to Elan for accreted dividends

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

**2002**

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

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

Issued preferred stock valued at \$917 to Elan for accreted dividends

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, consisting of 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 and inventory reserves. Operating results for the nine months ended September 30, 2003 are not necessarily indicative of the results that may be expected for the year ending December 31, 2003. These consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, for the year ended December 31, 2002, 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, 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 formed a joint venture, Transmucosal Technologies, Ltd., with Elan International Services, Ltd. (EIS) and Elan Corporation plc (together with EIS, Elan) to develop and commercialize oncology and pain management products. The joint venture agreement was terminated in September 2003, see below.

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, dermatology and pain management products. The Company also forms strategic alliances with a variety of pharmaceutical and biotechnology companies to develop and/or commercialize products utilizing various drug delivery systems. These strategic alliances presently include collaborations with Pfizer Inc., Sanofi-Synthelabo Inc., Fujisawa Healthcare, Inc., Geneva Pharmaceuticals, Inc., Sosei Co. Ltd., MediGene AG, and CollaGenex Pharmaceuticals, Inc.

**Critical Accounting Policies**

***Principles of consolidation***

The accompanying consolidated financial statements include the accounts of Atrix 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 owned 80.1% of Transmucosal Technologies, Ltd.'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 Transmucosal Technologies, Ltd. 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, the Company accounted for its investment in Transmucosal Technologies, Ltd. under the equity method of accounting. Additionally, the joint venture contracted with Atrix to perform certain research and development activities. The joint venture agreement was terminated in September 2003. During the period the joint venture was in operation, the Company accounted for its investment in Transmucosal Technologies, Ltd. using the

**Table of Contents**

equity method. Because the Company obtained the control of Transmucosal Technologies, Ltd. in September 2003, Transmucosal Technologies, Ltd. has been consolidated with the Company's consolidated financial statements since that date. See Note 7 for further information related to the termination.

**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. Royalty revenue is recorded when product is shipped by licensees 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.

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 the 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 strategic alliance 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. Milestone revenue subsequently is recognized using the straight-line method over the remaining contractual term or the remaining period covered by patent protection, whichever is earlier, following occurrence of the milestone event. No milestone revenue is recognized until the Company has completed the required milestone-related services.

**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 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:

	Three months ended September 30,		Nine months ended September 30,	
	2003	2002	2003	2002
	(In thousands)			
Research and Development				
Funded, in whole or in part	\$8,351	\$4,909	\$21,944	\$11,377
Not funded	387	4,529	4,763	12,135
Total	\$8,738	\$9,438	\$26,707	\$23,512

**Table of Contents****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. In accordance with the interim disclosure provisions of SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure, an Amendment of SFAS No. 123*, the following table illustrates the effect on net loss applicable to common stock and basic and diluted loss per common stock if the Company had applied the fair value based method of SFAS No. 123 to stock-based compensation:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2003	2002	2003	2002
	<b>(In thousands, except per share data)</b>			
Net loss applicable to common stock, as reported	\$ (47)	\$(4,161)	\$ (3,754)	\$(13,510)
Add: Stock-based compensation expense included in reported net loss, net of related tax effects			22	1,257
Deduct: Total stock-based compensation expense determined under fair-value based method, net of related tax effects	(2,551)	(1,805)	(8,310)	(9,525)
Pro forma net loss applicable to common stock	\$ (2,598)	\$ (5,966)	\$ (12,042)	\$ (21,778)
Basic and diluted net loss per share:				
As reported	\$	\$ (.21)	\$ (.19)	\$ (.67)
Pro forma	\$ (.13)	\$ (.30)	\$ (.60)	\$ (1.08)

**NOTE 3. RECENT ACCOUNTING PRONOUNCEMENTS**

In April 2002, SFAS No. 145 (SFAS 145), *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections* was issued by the Financial Accounting Standards Board (FASB). FAS 145 rescinds FASB Statement No. 4, *Reporting Gains and Losses from Extinguishment of Debt*, and an amendment of that Statement, FASB Statement No. 64, *Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements*. This Statement also rescinds FASB Statement No. 44, *Accounting for Intangible Assets of Motor Carriers*. This Statement amends FASB Statement No. 13, *Accounting for Leases*, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. This Statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The Company adopted FAS 145 in the first quarter of 2003 and, as a result, the comparative financial statements were restated to reclassify the extraordinary loss on extinguishment of debt to be included in loss from operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS 150). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It generally requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances), many of which were previously classified as equity. The provisions of SFAS 150 are effective for financial instruments entered into or modified after May 31, 2003 and, with one exception, is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 did not have a material effect on the Company's consolidated financial statements.

**Table of Contents**

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. FIN 45 also requires additional disclosures about the guarantees an entity has issued, including a roll-forward of the entity's product warranty liabilities. The Company will apply the recognition provisions of FIN 45 prospectively to guarantees issued or modified after December 31, 2002. The disclosure requirements were effective for the Company's financial statements for the year ended December 31, 2002. The adoption of FIN 45 did not have an impact on the Company's consolidated financial statements.

In January 2003, the FASB issued Financial Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities*. FIN 46 provides guidance on how to identify a variable interest entity (VIE) and determine when the assets, liabilities, and results of operations of a VIE need to be included in a company's consolidated financial statements. FIN 46 also requires additional disclosures by primary beneficiaries and other significant variable interest holders in a VIE. The provisions of FIN 46 are effective immediately for all VIEs created or acquired after January 31, 2003. For VIEs created or acquired prior to February 1, 2003, the provisions of FIN 46 must be adopted at the beginning of the first interim or annual reporting period beginning after December 15, 2003. The Company does not have VIEs and, as such, the adoption of FIN 46 did not have a material effect on the Company's consolidated financial statements.

In November 2002, the FASB issued Emerging Issues Task Force Issue No. 00-21 (EITF 00-21), *Accounting for Revenue Arrangements with Multiple Deliverables*. EITF 00-21 addresses how to determine whether a revenue arrangement involving multiple deliverables contains more than one unit of accounting for the purposes of revenue recognition and how the revenue arrangement consideration should be measured to the separate units of accounting. EITF 00-21 provides guidance with respect to the effect of certain customer rights due to company non-performance on the recognition of revenue allocated to delivered units of accounting. EITF 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or the Company. Finally, EITF 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting arrangement. EITF 00-21 applies to revenue arrangements that the Company enters into after June 15, 2003. The Company does not expect EITF 00-21 to have a material effect on its consolidated financial statements.

**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 pre-clinical and clinical products that are expensed as research and development costs, as used, if those inventories have alternative use either in products or other research and development projects. The components of inventory are as follows:

	September 30, 2003	December 31, 2002
	(In thousands)	
Raw materials	\$ 10,566	\$ 6,590
Work in process	129	1,035
Finished goods	1,647	1,069
Reserves	(649)	
	<u>\$ 11,693</u>	<u>\$ 8,694</u>

The Company increased its inventory reserves by \$0.2 million and \$0.6 million for the three and nine months ended September 30, 2003, respectively, as a result of its evaluation of obsolete or potential unmarketable inventory. The Company manufactured launch quantities of a generic dermatology product during the fourth quarter of 2002 and first quarter of 2003 prior to receiving FDA approval. During the three months ended September 30, 2003, the Company booked a reserve allowance for this inventory in response to a non-approval letter received from the FDA. This amount was charged to research and development expense. The Company believes it followed the guidelines provided by the FDA in the submission and is currently appealing the non-approval. Pending the outcome of the appeal, the Company may incur additional write-offs or may reverse the reserve.

**Table of Contents**

**NOTE 5. 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 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. Common share equivalents are excluded from the computations in loss periods, as their effect would be antidilutive.

For the nine months ended September 30, 2003 and 2002, approximately 1.5 million and 1.7 million equivalent dilutive securities (primarily related to the assumed conversion of the Series A Convertible Exchangeable Preferred Stock, incentive stock options and stock warrants held by Elan), 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. For the three months ended September 30, 2003 and 2002, approximately 2.2 million and 0.8 million equivalent dilutive securities (primarily related to the assumed conversion of the Series A Convertible Exchangeable Preferred Stock, incentive stock options and stock warrants held by Elan), 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 6. COMPREHENSIVE INCOME (LOSS)**

Comprehensive income (loss) comprises net income (loss) and certain changes in equity that are excluded from net income (loss), such as foreign currency translation adjustments and unrealized holding gains and losses on available-for-sale marketable securities. Comprehensive loss for the three months ended September 30, 2003 and 2002 was \$1.2 million and \$3.5 million, respectively. Comprehensive loss for the nine months ended September 30, 2003 and 2002 was \$3.2 million and \$12.4 million, respectively.

**NOTE 7. TERMINATION OF JOINT VENTURE**

On September 10, 2003, the Company entered into a termination agreement with Elan for the termination of the Company's joint venture, Transmucosal Technologies, Ltd. Pursuant to the terms of the agreement, the Company acquired Elan's preferred shares in Transmucosal Technologies, Ltd. in exchange for a royalty interest on certain future revenues and payments to the Company, if any, related to certain technology rights retained by the Company. The Company now owns 100% of Transmucosal Technologies, Ltd. The Company estimated that the fair value of the future contingent royalty payments is not material and, accordingly, no liability has been reflected in the Company's financial statements.

In connection with the termination, Elan and its affiliates agreed to forego the exchange right included in the Series A Convertible Exchangeable Preferred Stock of the Company (which is held by a wholly-owned subsidiary of Elan). Additionally, the Company plans to transfer all of the assets of Transmucosal Technologies, Ltd. to the Company or an affiliate of the Company. As a result, as of September 30, 2003, the Company has reclassified the Series A Convertible Exchangeable Preferred Stock to permanent equity, which increased equity by \$15.4 million.

**NOTE 8. LEGAL PROCEEDINGS**

On November 3, 2003, TAP Pharmaceutical Products, Inc. and two additional plaintiffs filed suit in U.S. District Court, Northern District of Illinois, Eastern Division, *Tap Pharmaceutical Products, Inc., et al v. Atrix Laboratories, Inc., et al*, alleging that the Eligard delivery system infringes a patent that claims, among other things, a biodegradable high molecular polymer, which patent is licensed to TAP Pharmaceuticals by the two other plaintiffs. The plaintiffs seek an injunction and unspecified damages. We believe the claims are without merit and intend to defend against them vigorously.

**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. Words such as expects, anticipates, intends, plans, believes, seeks, estimates, and variations of such words and similar expressions are intended to identify such forward-looking statements. Such statements involve known and unknown risks, uncertainties, and other factors which may cause the actual results, performance or achievements of the Company to be materially different from the results of operations or plans expressed or implied by such forward-looking statements. Such factors include, 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; and (7) the timing of new product launches. 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 for the year ended December 31, 2002.*

**Overview**

Atrix Laboratories, Inc. and its subsidiaries are collectively referred to herein as Atrix, the Company, we, our or us. We are an emerging specialty pharmaceutical company focused on advanced drug delivery. With five unique patented drug delivery technologies, we are currently working on the development of a diverse portfolio of products, including proprietary oncology, dermatology and pain management products. We also form strategic alliances with a variety of pharmaceutical and biotechnology companies to develop products utilizing our various drug delivery systems and/or to commercialize our products. Current strategic alliances include collaborations with Pfizer, Inc., Sanofi-Synthelabo Inc., Fujisawa Healthcare, Inc., Geneva Pharmaceuticals, Inc., Sosei Co. Ltd., MediGene AG 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. We believe that the Atrigel system may provide benefits over traditional methods of drug administration such as safety and effectiveness, ease of use, site-specific or systemic delivery, customized release rates and biodegradability. Our four additional drug delivery systems include: BEMA, SMP, MCA and BCP.

**Recent Developments**

The following discussion highlights significant events for our company during the nine months ended September 30, 2003:

*Atrisone acne product*

In June 2003, we announced completion of enrollment for the pivotal Phase III clinical trials for our Atrisone acne product. Final patient evaluations are expected to conclude by the end of 2003 followed by a data collection/processing effort. We expect to file a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, for the Atrisone acne product in mid-2004.



**Table of Contents**

*Eligard 30-mg four-month product*

We received approval from the FDA for our Eligard 30-mg four-month product in February 2003. In March 2003, Sanofi-Synthelabo Inc. launched the product into the U.S. market and we received a \$6.0 million milestone payment in April 2003 for the first commercial sale of the Eligard 30-mg four-month product.

*Eligard 45-mg six-month product*

In June 2003, we reported that all of the patients in our Eligard 45-mg six-month product Phase III clinical trials have completed the first six months of treatment and have received the second injection required under the clinical protocol. We expect to complete the pivotal Phase III clinical trials by the end of 2003 and submit an NDA to the FDA in the first quarter of 2004.

*Eligard International*

In January 2003, we entered into an exclusive licensing agreement with Sosei Co., Ltd. to develop and commercialize our Eligard products in Japan. Sosei paid us a one-time non-refundable license fee of \$1.0 million, and we may receive additional payments for research and development support and payments for specific regulatory and sales milestones. In addition to the milestone payments, we will receive royalty payments based on sales of the Eligard products, if approved for marketing by the Japanese Ministry of Health, Labor and Welfare, or MHLW. Sosei will be responsible for any pre-clinical and clinical studies required for approval and will be responsible for submission of the necessary documents to obtain marketing authorization from the MHLW. We will manufacture the Eligard products for Sosei at our Fort Collins facility.

Additionally, in November 2003, Sanofi-Synthelabo Canada has received a notice of compliance from the Therapeutic Products Directorate of Health Canada for Eligard 7.5mg one-month and 22.5mg three-month products. Sanofi-Synthelabo Canada will be responsible for marketing the products in Canada.

*Other Products*

In August 2003, we submitted an investigational new drug application, or IND, to the FDA for an Atrigel formulation of octreotide, which is designed to deliver the pharmaceutical over a 30-day period for the long term treatment of severe diarrhea and flushing episodes associated with metastatic carcinoid tumors.

We received approval from the FDA for our Abbreviated New Drug Application, or ANDA, for lidocaine/prilocaine cream in August 2003. Our product is the AB-rated generic to EMLA Anesthetic Cream (lidocaine 2.5% and prilocaine 2.5%). Our partner Geneva Pharmaceuticals is marketing this product.

In August 2003, we received a non-approval letter from the FDA indicating that a generic dermatology product was not approved. We are currently appealing this action through the FDA; however, there can be no assurance that our appeal will be successful.

In January 2003, we announced the submission of three ANDAs to the FDA, and in September 2003 one additional ANDA was submitted to the FDA for approval of generic formulations of certain dermatology products, bringing our total ANDA submissions currently under FDA review to seven.

An agreement to terminate our joint venture with a subsidiary of Elan Corporation was reached in September 2003. Termination of the joint venture returns the BEMA-fentanyl product to us. Upon termination, we acquired Elan's ownership interest in the joint venture, Transmucosal Technologies Ltd., in exchange for Elan receiving a portion of any consideration we receive from the licensing of BEMA-fentanyl and a royalty based on net sales of BEMA-fentanyl if the product is commercialized.

**Table of Contents****Principal Consolidated Statements of Operations Items***Revenue*

Net sales and royalties consist principally of sales and royalties from our Eligard products, the Atridox product and the Doxirobe product.

**Contract research and development revenue consists principally of revenue we earn from unaffiliated third parties.**

Licensing, marketing rights and milestone revenue consists principally of revenue earned on our Eligard products, our dental products, and the Atrisone topical dermatological product for the rights granted to our partners to sell our proprietary products in a defined territory for a defined period or for the achievement of a pre-determined milestone as defined in the applicable agreement.

*Operating Expenses*

Cost of sales consists principally of costs associated with the manufacture, packaging, storage, shipping, stability, and other product-related fees for the Eligard products, the Atridox product and the Doxirobe product.

Research and development expenses consist principally of funds paid for services and materials during development, manufacturing and formulation enhancements, clinical trials, statistical analysis, report writing, regulatory compliance costs and associated overhead for both partner-funded and internally-funded projects.

Administrative and marketing expenses consist principally of personnel salaries and benefits, direct marketing costs, business development and corporate relations costs, professional, legal and consulting fees, insurance and general office expenses.

Investment income and expense, net, consists principally of interest and dividends earned on marketable securities available for sale and money market accounts net of commissions, fees and other charges.

**Results of Operations****Three Months Ended September 30, 2003 Compared to Three Months Ended September 30, 2002**

<b>Revenue</b>	<b>Three Months Ended September 30,</b>		
	<b>2003</b>	<b>2002</b>	<b>% Change</b>
	<b>(In thousands)</b>		
Net sales and royalties	\$ 5,342	\$ 1,587	237%
Contract research and development revenue	5,773	4,306	34%
Licensing, marketing rights and milestone revenue	2,524	1,731	46%
	\$ 13,639	\$ 7,624	79%

Total revenue for the three months ended September 30, 2003 was \$13.6 million compared to \$7.6 million for the three months ended September 30, 2002, representing a 79% increase. Net sales and royalties were \$5.3 million for the three months ended September 30, 2003 compared to \$1.6 million for the three months ended September 30, 2002, representing a 237% increase. For the third quarter of 2003, we received \$4.4 million in sales and royalty revenue for our Eligard products in the US market. This is a \$3.8 million increase in sales and royalties of our Eligard products compared to the third quarter of 2002. This was offset by a decrease of \$0.1 million in other product sales. We expect net sales and royalty revenues to increase in 2003 as a result of the Eligard product line as a result of a full year of product sales of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products launched in May 2002 and September 2002, respectively. Additionally, the FDA approved our Eligard 30-mg four-month product in February 2003 and the product was launched in March 2003.

**Table of Contents**

Contract research and development revenue was \$5.8 million for the three months ended September 30, 2003 compared to \$4.3 million for the three months ended September 30, 2002, representing a 34% increase. This increase is primarily related to a \$2.0 million increase in revenue from Fujisawa Healthcare, Inc. for partial funding of research costs for the Atrisone acne product. This increase was offset by a \$0.5 million decrease in revenues primarily related to Sanofi-Synthelabo Inc. and Transmucosal Technologies, Ltd. We cannot be certain whether contract research and development revenue from our partner-funded research and development expenses will increase or decrease for the foreseeable future as the timing of such expenses being incurred may vary. Accordingly, the amount and timing of revenue recognition may vary depending on the terms of the corresponding agreements.

Licensing, marketing rights and milestone revenue for the three months ended September 30, 2003 was \$2.5 million compared to \$1.7 million for the three months ended September 30, 2002, representing a 46% increase. This increase is primarily related to the recognition of \$0.3 million in additional milestone revenue for our Eligard products under the agreement with Sanofi-Synthelabo Inc. and the recognition of \$0.5 million of additional revenue as a result of the termination of our endometriosis licensing agreement with EmerGen, Inc. We expect licensing, marketing rights and milestone revenue to increase in 2003 as a result of a full year of revenue recognition from licensing and milestone payments received from our marketing partners in 2002 and recognition of revenue for licensing and milestone payments received in the nine months ended September 30, 2003, including a \$6.0 million milestone payment we received from Sanofi-Synthelabo Inc. in April 2003 for the first commercial sale of our Eligard 30-mg four-month product and recognition of revenue for payments that we may receive from our current or future partners in the fourth quarter of 2003. All licensing, marketing rights and milestone payments received 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.

Operating expenses	Three Months Ended September 30,		
	2003	2002	% Change
	(In thousands)		
Cost of sales	\$ 2,901	\$ 502	478%
Research and development	8,738	9,438	(7)%
Administrative and marketing	2,387	2,413	(1)%
	\$ 14,026	\$ 12,353	14%

Cost of sales for the three months ended September 30, 2003 was \$2.9 million compared to \$0.5 million for the three months ended September 30, 2002, representing a 478% increase. The increase primarily relates to the costs associated with sales of our Eligard 7.5-mg one-month, Eligard 22.5-mg three-month and Eligard 30-mg four-month products. We expect that cost of sales will increase in line with our expected revenue growth.

Research and development expenses for the three months ended September 30, 2003 were \$8.7 million compared to \$9.4 million for the three months ended September 30, 2002, representing a 7% decrease. This decrease primarily relates to a decrease in research and development expenses of \$1.8 million for Eligard projects, \$1.2 million for internally-funded projects and \$0.1 million for partner-funded projects. This decrease was offset by an increase of \$2.4 million in expenses related to Phase III clinical trials for our Atrisone acne product. We expect that research and development expenses for internally-funded activities will be lower in 2003 due to our current focus on completion of Atrisone clinical studies and development of generic dermatology products. In 2004, we expect to return our focus to research activities on non-partnered projects.

Administrative and marketing expenses for the three months ended September 30, 2003 were \$2.4 million compared to \$2.4 million for the three months ended September 30, 2002. We expect that our administrative and marketing expenses will increase for the foreseeable future as we continue to grow.

**Table of Contents**

Other Income (Expense)	Three Months Ended September 30,		
	2003	2002	% Change
	(In thousands)		
Equity in loss of joint venture	\$ (6)	\$ (195)	(97)%
Investment income and expense, net	638	1,047	(39)%
Gain (loss) on sale of marketable securities	139	(15)	1,027%
Other, net	(7)	(27)	(74)%
	<u>\$764</u>	<u>\$ 810</u>	<u>(6)%</u>

We recognized a loss of \$6,000 for the three months ended September 30, 2003 compared to a loss of \$0.2 million for the three months ended September 30, 2002 for our 80.1% equity share in the loss of Transmucosal Technologies, Ltd., our joint venture with Elan. In September 2003, we terminated our joint venture with Elan and, therefore, will not recognize any future equity loss charges for Transmucosal Technologies, Ltd.

Investment income and expense, net, for the three months ended September 30, 2003 was \$0.6 million compared to \$1.0 million for the three months ended September 30, 2002, representing a 39% decrease. The decrease was primarily the result of a decrease in our average cash, cash equivalents and available-for-sale marketable securities balances. Additionally, interest rates on investments in the third quarter of 2003 were lower compared to the third quarter of 2002. We expect investment income to decrease in 2003 as a result of expected lower interest rates and lower balances of cash and cash equivalents and marketable securities as compared to 2002 interest rates and balances.

Gain on sale of marketable securities for the three months ended September 30, 2003 was \$139,000 compared to a loss on sale of marketable securities of \$15,000 for the three months ended September 30, 2002. The gain on sale of marketable securities in the third quarter of 2003 was due to the sale of certain government securities, corporate notes and corporate equities. We cannot be certain whether we will incur gains or losses on the sale of marketable securities in the future.

We recognized \$0.2 million for accretion of dividends on the Series A Convertible Exchangeable Preferred Stock and a charge of \$0.2 million for the related beneficial conversion feature for the three months ended September 30, 2003 compared to \$0.2 million for accretion of dividends for the three months ended September 30, 2002.

**Table of Contents****Nine Months Ended September 30, 2003 Compared to Nine Months Ended September 30, 2002**

Revenue	Nine Months Ended September 30,		
	2003	2002	% Change
	(In thousands)		
Net product sales and royalties	\$ 13,125	\$ 4,230	210%
Contract research and development revenue	15,772	10,314	53%
Licensing, marketing rights and milestone revenue	6,546	4,591	43%
	\$35,443	\$ 19,135	85%

Total revenue for the nine months ended September 30, 2003 was \$35.4 million compared to \$19.1 million for the nine months ended September 30, 2002, representing an 85% increase. Net sales and royalties were \$13.1 million for the nine months ended September 30, 2003 compared to \$4.2 million for the nine months ended September 30, 2002, representing a 210% increase. This increase is primarily related to the increase in sales and royalties of our Eligard products of \$8.2 million and an increase in domestic and European sales of our dental products of \$1.3 million. This increase was offset by a \$0.6 million decrease in other product sales including contract manufacturing. We expect net sales and royalty revenues to increase in 2003 as a result of a full year of product sales of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products launched in May 2002 and September 2002, respectively. Additionally, the FDA approved our Eligard 30-mg four-month product in February 2003, which was launched in March 2003.

Contract research and development was \$15.8 million for the nine months ended September 30, 2003 compared to \$10.3 million for the nine months ended September 30, 2002, representing a 53% increase. This increase is primarily related to a \$6.0 million increase in revenue from Fujisawa Healthcare, Inc. for partial funding of Phase III clinical research costs for our Atrixone acne product and a \$1.0 million increase in revenue from Sanofi-Synthelabo Inc. for funding of the Eligard 45-mg six-month formulation. These increases were offset by a \$1.0 million decrease in revenue recognized in conjunction with our joint venture and a \$0.5 million decrease in revenue from research activities funded by other parties. We cannot be certain whether contract research and development revenue from our partner-funded research and development expenses will increase or decrease for the foreseeable future as the timing of such expenses being incurred may vary. Accordingly, the amount and timing of revenue recognition may vary depending on the terms of the corresponding agreements.

Licensing, marketing rights and milestone revenue for the nine months ended September 30, 2003 was \$6.5 million compared to \$4.6 million for the nine months ended September 30, 2002, representing a 43% increase. This increase is primarily related to the recognition of \$1.3 million in additional milestone revenue for our Eligard products under the agreement with Sanofi-Synthelabo Inc., the recognition of \$0.5 million as a result of the termination of our licensing agreement with EmerGen, Inc. and the recognition of \$0.1 million of additional revenue for our Eligard products under various international partner agreements. We expect licensing, marketing rights and milestone revenue to increase in 2003 as a result of a full year of revenue recognition from licensing and milestone payments received from our marketing partners in 2002 and recognition of revenue for licensing and milestone payments received in the nine months ended September 30, 2003, including a \$6.0 million milestone payment we received from Sanofi-Synthelabo Inc. in April 2003 for the first commercial sale of our Eligard 30-mg four-month product and recognition of revenue for payments that we may receive from our current or future partners in the fourth quarter of 2003. All licensing, marketing rights and milestone payments received 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.

**Table of Contents**

Operating expenses	Nine Months Ended September 30,		
	2003	2002	% Change
	(In thousands)		
Cost of sales	\$ 6,191	\$ 1,815	241%
Research and development	26,707	23,512	14%
Administrative and marketing	7,879	6,597	19%
Administrative and marketing stock option compensation	22	1,257	(98)%
	<u>\$40,799</u>	<u>\$33,181</u>	<u>23%</u>

Cost of sales for the nine months ended September 30, 2003 was \$6.2 million compared to \$1.8 million for the nine months ended September 30, 2002, representing a 241% increase. The increase primarily relates to the costs associated with sales of our Eligard 7.5-mg one-month, Eligard 22.5-mg three-month and Eligard 30-mg four-month products and domestic and European sales of Atridox. We expect that cost of sales will increase in line with our expected revenue growth.

Research and development expenses for the nine months ended September 30, 2003 were \$26.7 million compared to \$23.5 million for the nine months ended September 30, 2002, representing a 14% increase. An increase of \$7.3 million was related to Phase III clinical trials for our Atrisone acne product and an increase of \$1.7 million was related to the development of our generic dermatology products. These increases were offset by a decrease in research and development expenses of \$1.9 million for Eligard development, \$1.7 million for other externally-funded projects and \$2.2 for internal project research. We cannot be certain whether our partner-funded research and development expenses will increase or decrease for the foreseeable future as the timing of such expenses being incurred may vary depending on the terms of the corresponding agreements. However, we expect that research and development expenses for internally-funded activities will decrease in 2003 due to our current focus on completion of Phase III clinical studies for our Atrisone acne product and development of generic dermatology products. Following completion of these programs, we expect internal product development expenses to increase again in the foreseeable future.

Administrative and marketing expenses, excluding stock and stock option compensation, for the nine months ended September 30, 2003 were \$7.9 million compared to \$6.6 million for the nine months ended September 30, 2002, representing a 19% increase. The increase is primarily related to increased European sales and marketing efforts for Atridox of \$1.6 million offset by decreases in general administrative support of \$0.3 million, including personnel, public relations and legal costs. We expect that our administrative and marketing expenses will increase for the foreseeable future as we continue to grow.

Stock option compensation for the nine months ended September 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.

**Table of Contents**

Other Income (Expense)	Nine Months Ended September 30,		
	2003	2002	% Change
	(In thousands)		
Equity in loss of joint venture	\$ (83)	\$ (940)	(91)%
Investment income and expense, net	2,059	3,427	(40)%
Gain (loss) on sale and write-down of marketable securities	567	(1,091)	152%
Debt conversion expense		(125)	
Other, net	(23)	(32)	(28)%
	\$ 2,520	\$ 1,239	103%

We recognized a loss of \$0.1 million for the nine months ended September 30, 2003 compared to a loss of \$0.9 million for the nine months ended September 30, 2002 for our 80.1% equity share in the loss of Transmucosal Technologies, Ltd., our joint venture with Elan. In September 2003, we terminated our joint venture with Elan and, therefore, will not recognize any future equity loss charges for Transmucosal Technologies, Ltd.

Investment income and expense, net for the nine months ended September 30, 2003 was \$2.1 million compared to \$3.4 million for the nine months ended September 30, 2002, representing a 40% decrease. The decrease was primarily the result of a decrease in our average cash, cash equivalents and available-for-sale marketable securities balances. Additionally, interest rates on investments in the nine months ended September 30, 2003 were lower compared to the nine months ended September 30, 2002. We expect investment income to decrease in 2003 as a result of expected lower interest rates and lower balances of cash and cash equivalents and marketable securities as compared to 2002 interest rates and balances.

Gain on sale of marketable securities for the nine months ended September 30, 2003 was \$0.6 million compared to a loss and write-down of marketable securities of \$1.1 million for the nine months ended September 30, 2002. The gain on sale of marketable securities for the nine months ended September 30, 2003 was primarily due to the sale of certain government securities, corporate notes, and corporate equities. The loss and write-down of marketable securities during the nine months ended September 30, 2002 was 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. We cannot be certain whether we will incur gains or losses on the sale of marketable securities or recognize charges for write-downs in the future.

During the nine months ended September 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 a 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 nine months ended September 30, 2002. The 7% Convertible Subordinated Notes were fully extinguished in May 2002.

We recognized \$0.7 million for accretion of dividends on our Series A Convertible Exchangeable Preferred Stock and \$0.2 million for a beneficial conversion feature charge in July 2003 on the shares of preferred stock for the nine months ended September 30, 2003 compared to \$0.7 million accretion of dividends for the nine months ended September 30, 2002.

**Table of Contents**

**Liquidity and Capital Resources**

As of September 30, 2003, we had cash and cash equivalents of \$23.6 million, available-for-sale marketable securities (at fair value) of \$75.7 million, net accounts receivable of \$8.8 million, inventories of \$11.7 million and other current assets of \$4.3 million for total current assets of \$124.1 million. We had accounts payable of \$2.9 million, short-term deferred revenue of \$9.8 million and other current liabilities of \$1.2 million for total current liabilities of \$13.9 million, which resulted in working capital of \$110.2 million.

During the nine months ended September 30, 2003, we used net cash in operating activities of \$12.7 million. This was primarily the result of the net loss for the period of \$2.8 million, adjusted for certain non-cash income and expenses, and changes in operating assets and liabilities as set forth in the consolidated statements of cash flows. We recognized a cash inflow from the receipt of milestone payments, licensing fees and certain contract research and development payments of \$7.3 million, offset by amortization of deferred revenue of \$7.5 million. Other significant uses of cash included: \$3.2 million due to an increase in accounts receivable primarily related to Eligard product sales and royalty accruals, \$3.6 million due to increasing inventory levels primarily related to the production of our Eligard products and inventory buildup related to our generic dermatology products and \$5.0 million decrease in accounts payable primarily related to payments for inventory raw materials and components and plant expansion costs since December 31, 2002.

We used net cash in investing activities of \$2.5 million during the nine months ended September 30, 2003. Cash used to fund investing activities included \$7.5 million for capital expenditures primarily related to our plant expansion as discussed further under Future Capital Requirements below. Other uses of cash for various investing activities totaled \$0.9 million. Net marketable securities activity resulted in a cash inflow of \$5.9 million as a result of the maturity and sale of marketable securities of \$32.6 million offset by \$26.7 million to fund the purchases of various marketable securities. During the nine months ended September 30, 2003, various marketable securities were sold, matured or were called and the majority of proceeds were subsequently reinvested in high rated corporate notes, U.S. government securities, and diversified bond mutual funds.

Net cash provided by financing activities was \$7.4 million during the nine months ended September 30, 2003. This was primarily the result of proceeds from issuance of equity securities of \$10.3 million in conjunction with the exercise of incentive stock options. This was offset by the repurchase of \$2.9 million of our common stock in the open market. In November 2002, our Board of Directors amended our stock repurchase program to provide that we may acquire up to a maximum of \$20.0 million of our common stock in the open market or in privately negotiated transactions under this program. The program terminates on the earlier of the date that we have repurchased \$20.0 million of our common stock or December 31, 2003. Since the inception of the program, we repurchased a total of 866,800 shares of our common stock in the open market for \$13.6 million, or an average price per share of \$15.71. For the nine months ended September 30, 2003, we repurchased 209,100 shares of our common stock in the open market for \$2.9 million, or an average price per share of \$13.75 under the program. As of September 30, 2003, \$6.4 million remains available to repurchase our common stock under the program.

We have a revolving line of credit with a bank that expires in May 2004. Under the terms of the line of credit, we may borrow up to \$1.0 million. Borrowings under the line bear interest at the prime rate and are subject to financial covenants requiring us to maintain certain levels of net worth and liquidity. Additionally, in July 2003, we established a \$1.0 million line of credit with another bank. The second line of credit expires in June 2004. Borrowings under the second line of credit bear interest at the prime rate plus 1/2%. As of September 30, 2003, there was no obligation outstanding under either of these lines of credit.

We have historically funded our operations through debt and equity offerings, payments received for licenses, milestones, research and development support under contractual arrangements and product sales and royalties. We anticipate future funding of our operations to be achieved through continued licensing fees, milestone payments and net sales and royalties of our products. At September 30, 2003, we had \$23.6 million of cash and cash equivalent investments and \$75.7 million of available-for-sale marketable securities (at fair value) to fund future operations and capital requirements. Our available-for-sale marketable securities include primarily U.S. government bonds, diversified bond mutual funds and investment grade corporate obligations. Our portfolio of corporate debt is diversified and, under our policy, we initially invest only in investment grade corporate obligations. We believe the quality of the notes we hold and the diversity of our portfolio mitigates our credit and market risks; however, from time to time we have experienced investment losses as some of the issuers of our investment grade corporate notes have declared bankruptcy.



**Table of Contents**

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. In the normal course of business, we may investigate, evaluate, and discuss acquisitions, joint ventures, strategic alliance relationships and other business combination opportunities. In the event of any future acquisition or joint venture opportunities, we may consider using then-available cash or cash equivalents or issuing equity or other securities.

At December 31, 2002 we had available for federal income tax purposes, net operating loss carry-forwards of \$92.4 million and \$3.8 million in research and development tax credits, which expire through 2022. Our ability to utilize our net operating loss acquired with the acquisition of ViroTex Corporation, alternative minimum tax, and research and development credit carry-forwards is subject to an annual limitation in future periods. This limitation is pursuant to the change in ownership rules under Section 382 of the Internal Revenue Code of 1986, as amended.

**Future Capital Requirements**

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

- the number of products in our pipeline,
- 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,
- the potential for expenses related to the implementation of a specialty sales force,
- 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, possible repurchases of our common stock and for hiring additional management, scientific, manufacturing and administrative personnel. We will also continue to expend a significant amount of funds for 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 our existing cash and cash equivalent assets in addition to our marketable securities will be sufficient to fund our operations for the foreseeable future. However, our underlying assumed levels of revenue and expense may not prove to be accurate.

*Research and 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 solely by us, for the years ended December 31, 2002, 2001 and 2000 and the nine months ended September 30, 2003, including research and development costs inception-to-date and estimated completion dates and costs (in thousands):

Technology	Expenses 2000	Expenses 2001	Expenses 2002	Expenses 2003*	Expenses Inception-to-Date	Total Funding Inception-to-Date	Anticipated Completion (to market)	Anticipated Costs to Completion (to market)
Atrigel	\$ 10,845	\$ 13,727	\$ 13,011	\$ 7,324	\$ 115,345	\$ 13,404	2004 2009	\$ 35,000
SMP	3,090	4,604	6,547	11,096	27,664	13,817	2005	15,000
BEMA	259	2,397	2,252	281	6,072	1,029	On hold	
Other	2,541	4,907	10,929	8,006	41,089	13,702	2003 2007	55,000
<b>Total</b>	<b>\$ 16,735</b>	<b>\$ 25,635</b>	<b>\$ 32,739</b>	<b>\$ 26,707</b>	<b>\$ 190,170</b>	<b>\$ 41,952</b>	<b>2003 2009</b>	<b>\$ 105,000</b>
Funded, in whole or in part	\$ 1,921	\$ 10,626	\$ 18,721	21,944				

Edgar Filing: ATRIX LABORATORIES INC - Form 10-Q

Not funded	14,814	15,009	14,018	4,763
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Total	\$ 16,735	\$ 25,635	\$ 32,739	\$ 26,707
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>

\*Nine months ended, September 30, 2003

The predominate product lines included under the Atrigel technology are the Eligard products and the dental products which comprised 32% and 57%, respectively, of the expenses from inception-to-date. Recently, the

## **Table of Contents**

Eligard products comprised more of the research and development effort with 68%, 64%, 59% and 59% of the 2000, 2001, 2002 and year-to-date 2003 Atrigel expenses, respectively. As our dental products have moved into the market, research and development expenses have stabilized and comprised 25%, 10%, 7% and 4% of the 2000, 2001, 2002 and year-to-date 2003 Atrigel expenses, respectively. Of the expenses funded by third parties, 13% of funds received were to support the dental products, 55% of funds were to support the Eligard products, and 32% 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, 49% of expenses from inception-to-date relate to the development of two products through our joint venture with Elan, which joint venture has been terminated. One hundred percent of the funding for BEMA research and development has come from the joint venture.

Other research and development expenses from inception-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 40% of expenses inception-to-date and 54% of the funding.

### *Plant expansion*

In April 2002, we announced our plans to expand our manufacturing and laboratory facilities to support current and future projects. The original 26,000 square foot facility was expanded to 58,000 square feet. In the expanded facility we intend to manufacture the full line of our Eligard products, Atrisone topical dermatological product, generic dermatology products, dental products and clinical supplies for products currently in development. Approximately 40% of the building's expansion is devoted to manufacturing with the remainder allocated for warehousing, quality assurance and laboratory work. Construction began in the second quarter of 2002 and was completed during the second quarter of 2003 and validation of the plant and equipment was completed during the third quarter of 2003. As of September 30, 2003, approximately \$9.6 million has been spent on construction costs and \$3.6 million has been spent on equipment.

## **Recent Accounting Pronouncements**

In April 2002, SFAS No. 145 (SFAS 145), *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections* was issued by the Financial Accounting Standards Board (FASB). FAS 145 rescinds FASB Statement No. 4, *Reporting Gains and Losses from Extinguishment of Debt*, and an amendment of that Statement, FASB Statement No. 64, *Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements*. This Statement also rescinds FASB Statement No. 44, *Accounting for Intangible Assets of Motor Carriers*. This Statement amends FASB Statement No. 13, *Accounting for Leases*, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions. This Statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. We adopted FAS 145 in the first quarter of 2003 and, as a result, our comparative financial statements were restated to reclassify the extraordinary loss on extinguishment of debt to be included in loss from operations.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* (SFAS 150). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It generally requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances), many of which were previously classified as equity. The provisions of SFAS 150 are effective for financial instruments entered into or modified after May 31, 2003 and, with one exception, is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS 150 did not have a material effect on our consolidated financial statements.

In November 2002, the FASB issued Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. FIN 45 also requires additional disclosures about the guarantees an entity has issued, including a roll-forward of the entity's product warranty liabilities. We will apply the recognition provisions of FIN 45 prospectively to guarantees issued or modified after

## **Table of Contents**

December 31, 2002. The disclosure requirements were effective for our financial statements for the year ended December 31, 2002. The adoption of FIN 45 did not have an impact on our consolidated financial statements.

In January 2003, the FASB issued Financial Interpretation No. 46 (FIN 46), "*Consolidation of Variable Interest Entities*." FIN 46 provides guidance on how to identify a variable interest entity (VIE) and determine when the assets, liabilities, and results of operations of a VIE need to be included in a company's consolidated financial statements. FIN 46 also requires additional disclosures by primary beneficiaries and other significant variable interest holders in a VIE. The provisions of FIN 46 are effective immediately for all VIEs created or acquired after January 31, 2003. For VIEs created or acquired prior to February 1, 2003, the provisions of FIN 46 must be adopted at the beginning of the first interim or annual reporting period beginning after December 15, 2003. We do not have VIES and, as such, the adoption of FIN 46 did not have a material effect on our consolidated financial statements.

In November 2002, the FASB issued Emerging Issues Task Force Issue No. 00-21 (EITF 00-21), "*Accounting for Revenue Arrangements with Multiple Deliverables*." EITF 00-21 addresses how to determine whether a revenue arrangement involving multiple deliverables contains more than one unit of accounting for the purposes of revenue recognition and how the revenue arrangement consideration should be measured to the separate units of accounting. EITF 00-21 provides guidance with respect to the effect of certain customer rights due to company nonperformance on the recognition of revenue allocated to delivered units of accounting. EITF 00-21 also addresses the impact on the measurement and/or allocation of arrangement consideration of customer cancellation provisions and consideration that varies as a result of future actions of the customer or us. Finally, EITF 00-21 provides guidance with respect to the recognition of the cost of certain deliverables that are excluded from the revenue accounting arrangement. EITF 00-21 applies to revenue arrangements that we enter into after June 15, 2003.

## **Critical Accounting Policies**

Our critical accounting policies are described in Note 1 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2002. The accounting policies used in preparing our interim consolidated financial statements for the nine months ended September 30, 2003 are the same as those described in our Annual Report on Form 10-K.

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 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 possibility 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 such corporate partners and us.

Inability to satisfy governmental regulations relating to the development of our product candidates may prevent us from obtaining or maintaining necessary regulatory approvals to commercialize our products.

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.

**Table of Contents**

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).

Our 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.

Dependence on one contract manufacturer involved in the production of our Eligard products.

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

Our insurance policies are expensive and protect us only from some business risks, which may leave us exposed to significant, uninsured liabilities.

Our operations involve hazardous materials, which could subject us to significant liability.

Our ability to attract and retain highly qualified management, administrative and scientific personnel with pharmaceutical experience.

Failure to manage our rapid growth could harm our business.

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 for the year ended December 31, 2002.

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

For a discussion of the Company's market risks, refer to the Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in the Company's 2002 Annual Report. There have been no material changes to the information provided that would require additional information with respect to the nine months ended September 30, 2003.

**Item 4. CONTROLS AND PROCEDURES.**

As of September 30, 2003, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and our Interim Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Based on this evaluation, our Chief Executive Officer and our Interim Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in our periodic SEC filings. There has been no change in our internal control over financial reporting that occurred during the quarter ended September 30, 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of our financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

**Table of Contents****PART II. OTHER INFORMATION****Item 1. LEGAL PROCEEDINGS**

On November 3, 2003, TAP Pharmaceutical Products, Inc. and two additional plaintiffs filed suit in U.S. District Court, Northern District of Illinois, Eastern Division, *Tap Pharmaceutical Products, Inc., et al v. Atrix Laboratories, Inc., et al*, alleging that the Eligard delivery system infringes a patent that claims, among other things, a biodegradable high molecular polymer, which patent is licensed to TAP Pharmaceuticals by the two other plaintiffs. The plaintiffs seek an injunction and unspecified damages. We believe the claims are without merit and intend to defend against them vigorously.

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

(a) Exhibits.

Exhibit No.	Description
10.1	Termination Agreement, dated as of September 10, 2003, by and among the Company, Elan Pharma International Limited, Elan International Services, Ltd. and Transmucosal Technologies, Ltd.
31.1	Rule 13a-14(a) Certification of Chief Executive Officer
31.2	Rule 13a-14(a) Certification of Interim Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Interim Chief Financial Officer

(b) Reports on Form 8-K. We filed or furnished the following Current Reports on Form 8-K during the quarter ended September 30, 2003. The information provided under Item 12. Results of Operations and Financial Condition is not deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934.:

Current Report on Form 8-K dated July 30, 2003, furnished to the Securities and Exchange Commission on July 30, 2003, under Item 12. Results of Operations and Financial Condition.

Current Report on Form 8-K dated September 22, 2003, filed with the Securities and Exchange Commission on September 23, 2003, under Item 5. Other Events and Item 7. Exhibits

**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 18, 2003

By: /s/ David R. Bethune

\_\_\_\_\_  
David R. Bethune  
Chairman of the Board and  
Chief Executive Officer  
(Principal Executive Officer)

November 18, 2003

By: /s/ Brian G. Richmond

\_\_\_\_\_  
Brian G. Richmond  
Interim Chief Financial Officer  
(Principal Financial and Accounting Officer)

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
<b>10.1</b>	<b>Termination Agreement, dated as of September 10, 2003, by and among the Company, Elan Pharma International Limited, Elan International Services, Ltd. and Transmucosal Technologies, Ltd.</b>
<b>31.1</b>	<b>Rule 13a-14(a) Certification of Chief Executive Officer</b>
<b>31.2</b>	<b>Rule 13a-14(a) Certification of Interim Chief Financial Officer</b>
<b>32.1</b>	<b>Section 1350 Certification of Chief Executive Officer</b>
<b>32.2</b>	<b>Section 1350 Certification of Interim Chief Financial Officer</b>