

ATRIX LABORATORIES INC

Form 10-Q

November 07, 2002

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, 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 November 4, 2002, was 20,503,899.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS.

ATRIX LABORATORIES, INC. AND SUBSIDIARIES NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS For the Nine Months Ended September 30, 2002 and 2001

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES CONCERNING MARKET RISKS.

Item 4. Controls and Procedures.

PART II OTHER INFORMATION

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

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>September 30,</u> <u>2002</u>	<u>December 31,</u> <u>2001</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$29,565	\$50,058
Marketable securities available-for-sale, at fair value	91,248	87,910
Accounts receivable, net of allowance for doubtful accounts of \$302 and \$5	4,907	3,522
Note receivable - milestone payments	6,450	
Interest receivable	810	995
Inventories	5,182	3,314
Prepaid expenses and deposits	1,901	525
<hr/>		
<hr/>		
Total current assets	140,063	146,324
<hr/>		
<hr/>		
PROPERTY, PLANT AND EQUIPMENT, NET	10,612	7,557
<hr/>		

OTHER ASSETS:

Intangible assets, net of
accumulated amortization of
\$4,043 and \$3,421
4,201 3,527
Deferred finance costs, net of
accumulated amortization of \$0 and
\$121
85

Other assets
4,201 3,612

TOTAL ASSETS
\$154,876 \$157,493

**LIABILITIES AND
SHAREHOLDERS EQUITY**
CURRENT LIABILITIES:

Accounts payable trade
\$4,282 \$3,108
Accrued expenses and other
932 611
Deferred revenue
7,741 7,467

Total current liabilities
12,955 11,186

DEFERRED REVENUE
 38,281 28,373
 CONVERTIBLE
 SUBORDINATED NOTES
 PAYABLE
 5,206

COMMITMENTS AND
 CONTINGENCIES:

CONVERTIBLE
 EXCHANGEABLE PREFERRED
 STOCK:

Series A convertible exchangeable
 preferred stock, \$.001 par value,
 20,000 shares authorized; 13,325
 and 12,871 shares issued and
 outstanding. Liquidation preference
 \$13,983 and \$13,281
 14,271 13,568

SHAREHOLDERS EQUITY:

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;
 20,498,779 and 19,859,807 shares
 issued and 20,013,079 and
 19,782,307 shares outstanding
 20 20

Additional paid-in capital
 242,514 232,903

Treasury stock, 485,700 and 77,500
 shares, at cost
 (7,902) (1,558)

Accumulated other comprehensive
 income (loss)
 448 (4)

Accumulated deficit
 (145,711) (132,201)

Total shareholders equity
 89,369 99,160

TOTAL LIABILITIES AND
SHAREHOLDERS' EQUITY
\$154,876 \$157,493

See notes to the consolidated financial statements.

Table of Contents

ATRIX LABORATORIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
(Unaudited)

	For the Three Months Ended September 30,	
	2002	2001
REVENUES:		
Net sales and royalties		
\$1,587	\$291	
Contract research and development revenue		
4,306	1,995	
Licensing, marketing rights and milestone revenue		
1,731	971	
<hr/>		
<hr/>		
Total revenues		
7,624	3,257	
<hr/>		
<hr/>		
OPERATING EXPENSES:		
Cost of sales		
502	113	
Research and development		
9,438	7,163	
Research and development licensing fees		
2,445		
Administrative and marketing		
2,413	1,156	
Administrative stock option compensation		
2,000		
<hr/>		
<hr/>		
Total operating expenses		
12,353	12,877	

LOSS FROM OPERATIONS

(4,729) (9,620)

OTHER INCOME (EXPENSE):

Equity in loss of joint venture

(195) (1,008)

Investment income and expense, net

1,047 820

Loss on sale and write-down of
marketable securities

(15)

Debt conversion expense

(57)

Other

(27) 2

Net other income (expense)

810 (243)

LOSS BEFORE EXTRAORDINARY
ITEM

(3,919) (9,863)

Extraordinary loss on extinguished debt

(4)

NET LOSS

(3,919) (9,867)

Accretion of dividends on preferred
stock

(242) (225)

NET LOSS APPLICABLE TO
COMMON STOCK
\$(4,161) \$(10,092)

Basic and diluted loss per common
share:

Loss before extraordinary item
\$(.20) \$(.58)
Extraordinary loss on extinguished debt

Net loss
(.20) (.58)
Accretion of dividends on preferred
stock
(.01) (.01)

Net loss applicable to common stock
\$(.21) \$(.59)

Basic and diluted weighted average
common shares outstanding
20,202,479 16,966,110

See notes to the consolidated financial statements.

Table of Contents

**ATRIX LABORATORIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
(Unaudited)**

	For the Nine Months Ended September 30,	
	2002	2001
REVENUES:		
Net sales and royalties	\$4,230	\$2,867
Contract research and development revenue	10,314	5,428
Licensing, marketing rights and milestone revenue	4,591	2,480
<hr/>		
<hr/>		
Total revenues	19,135	10,775
<hr/>		
<hr/>		
OPERATING EXPENSES:		
Cost of sales	1,815	1,153
Research and development	23,512	19,727
Research and development licensing fees	2,985	
Administrative and marketing	6,627	3,741
Administrative stock option compensation	1,257	2,117
<hr/>		
<hr/>		
Total operating expenses	33,211	29,723

LOSS FROM OPERATIONS

(14,076) (18,948)

OTHER INCOME (EXPENSE):

Equity in loss of joint venture

(940) (2,524)

Investment income and expense, net

3,427 1,785

Loss on sale and write-down of
marketable securities

(1,091)

Debt conversion expense

(125) (2,105)

Other

(32) (21)

Net other income (expense)

1,239 (2,865)

LOSS BEFORE EXTRAORDINARY

ITEM

(12,837) (21,813)

Extraordinary gain (loss) on
extinguished debt

30 (292)

NET LOSS

(12,807) (22,105)

Accretion of dividends on preferred
stock

(703) (656)

NET LOSS APPLICABLE TO
COMMON STOCK
\$(13,510) \$(22,761)

Basic and diluted loss per common
share:

Loss before extraordinary item
\$(.64) \$(1.41)
Extraordinary loss on extinguished debt
(.02)

Net loss
(.64) (1.43)
Accretion of dividends on preferred
stock
(.03) (.04)

Net loss applicable to common stock
\$(.67) \$(1.47)

Basic and diluted weighted average
common shares outstanding
20,122,029 15,434,256

See notes to the consolidated financial statements.

Table of Contents

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

For the Nine Months Ended
September 30,

2002	2001
------	------

CASH FLOWS FROM OPERATING ACTIVITIES:

Net loss	\$(12,807)	\$(22,105)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	2,437	1,796
Amortization of deferred revenue	(7,928)	(3,685)
Equity in loss of joint venture	940	2,524
Loss on sale and write-down of marketable securities	1,091	
Stock plan compensation	1,257	2,117
Debt conversion expense	125	2,106
Interest expense converted to equity	110	333
Extraordinary (gain) loss on extinguished debt	(30)	292
Other non-cash items	33	(18)
Net changes in operating assets and liabilities:		
Accounts receivable	(1,242)	(835)
Notes receivable - milestone payments and licensing fee	8,000	
Interest receivable	185	(421)
Inventories	(1,810)	(830)
Prepaid expenses and deposits	(1,374)	(507)
Accounts payable	1,177	(455)
Accrued expenses and other	316	70
Deferred revenue	11,661	8,305

Net cash used in operating activities
(5,859) (3,313)

CASH FLOWS FROM INVESTING
ACTIVITIES:

Acquisition and sale of property, plant
and equipment, net
(4,317) (1,512)
Investment in intangible assets
(1,296) (330)
Proceeds from maturity and sale of
marketable securities
51,546 22,241
Investment in marketable securities
(56,185) (74,132)
Investment in joint venture
(1,500) 732

Net cash used in investing activities
(11,752) (53,001)

CASH FLOWS FROM FINANCING
ACTIVITIES:

Proceeds from issuance of equity
securities, net of issuance costs
3,025 80,513
Payments to acquire treasury stock
(6,344) (1,039)
Note receivable stock subscription
15,000

Net cash provided by (used in)
financing activities
(3,319) 94,474

NET EFFECT OF EXCHANGE
RATE ON CASH
437 (47)

NET INCREASE (DECREASE) IN
CASH AND CASH EQUIVALENTS
(20,493) 38,113

CASH AND CASH EQUIVALENTS,
BEGINNING OF PERIOD
50,058 4,484

CASH AND CASH EQUIVALENTS,
END OF PERIOD
\$29,565 \$42,597

CASH PAYMENTS FOR INTEREST
\$ 354

Non-cash activities:

2002

Edgar Filing: ATRIX LABORATORIES INC - Form 10-Q

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
For the Nine Months Ended September 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, dermatology, pain management, growth hormone releasing peptide-1, and oral interferon 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 nine months ended September 30, 2002 and 2001, the Company earned contract research and development revenues from the joint venture of \$1.1 million and \$3.1 million, respectively, and had receivables from the joint venture of \$0.2 million and \$0.9 million at September 30, 2002 and December 31, 2001, respectively. Additionally, the Company had payables to the joint venture at September 30, 2002 and December 31, 2001 of \$0.2 million and \$0.8 million, respectively. During the nine months ended September 30, 2002 and 2001, the Company recognized losses of \$0.9 million and \$2.5 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 nine months ended September 30 (amounts in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
Research and Development Funded	\$4,909	\$2,169	\$11,377	\$6,087
Research and Development Not Funded 4,529 4,994 12,135 13,640				

Research and Development
\$9,438 \$7,163 \$23,512 \$19,727

Research and Development Licensing Fees-Not Funded
\$ 2,445 \$ 2,985

New Accounting Pronouncements

In June 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 June 2001, SFAS No. 143, "Accounting for Asset Retirement Obligations" was issued by the FASB. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs and applies to all entities. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction,

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. There was no diluted effect on earnings per share computations for the assumed conversion of the Series A Convertible Preferred Stock shares under the if converted method. Additionally, since the Company has not drawn any proceeds under the convertible promissory note agreement with Elan, as of September 30, 2002, there was no effect on earnings per share computations pertaining to this convertible promissory note for the periods presented. Common share

Table of Contents

equivalents are excluded from the computations in loss periods, as their effect would be antidilutive. For the nine months ended September 30, 2002 and 2001, approximately 0.9 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 the remainder of the outstanding 7% Convertible Subordinated Notes. All of the outstanding notes were converted into shares of the Company's common stock prior to the redemption date of May 15, 2002.

During the nine months ended September 30, 2002, the Company exchanged 279,901 shares of its common stock for \$5.2 million in principal amount of its 7% Convertible Subordinated Notes. Of the 279,901 shares of common stock issued, 273,984 shares of common stock 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 \$110,000 interest expense payable eliminated as a result of these exchanges. Additionally, of the 279,901 shares exchanged, a debt conversion expense of \$125,000 was recognized for the nine months ended September 30, 2002. As of September 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 September 30, 2002 and December 31, 2001, respectively.

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, Ltd. 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.

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, dermatology, pain management, growth hormone releasing peptide-1, and oral interferon 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 nine months ended September 30, 2002:

Eligard 7.5-mg one-month product

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 announced the marketing launch of our Eligard one-month product and we subsequently received a \$6.0 million milestone payment from Sanofi-Synthelabo in June 2002. The \$6.0 million milestone payment from Sanofi-Synthelabo 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

Eligard 22.5-mg three-month product

In July 2002, we received approval from the FDA for our Eligard 22.5-mg three-month product. In September 2002, we announced the marketing launch of our Eligard three-month product. As a result, a \$6.0 million milestone payment due from Sanofi-Synthelabo was recorded as a note receivable milestone payment and deferred revenue in September 2002 and will be recognized as revenue over the remaining term of the agreement using the straight-line method. We subsequently received the \$6.0 million milestone payment from Sanofi-Synthelabo in October 2002.

Eligard 30-mg four-month product

We 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 \$3.0 million milestone payment from Sanofi-Synthelabo was recorded as deferred revenue and will be recognized as revenue over the remaining term of the agreement using the straight-line method.

Eligard unique dosage formulation product

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 submitted an Investigational New Drug Application, or IND, to the FDA in August 2002. In September 2002, we commenced enrollment of the Phase III clinical study for this unique dosage Eligard formulation. Additionally, we may receive payments for certain regulatory and sales milestones, a royalty based on sales of the product and a manufacturing margin.

Eligard International

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.

In March 2002, we entered into an exclusive licensing agreement with Luxembourg Pharmaceuticals for the Israeli marketing rights of our four Eligard products. We entered into exclusive licensing agreements in the third quarter of 2002 with the following marketing partners for our four Eligard products: Biosintetica will market in Brazil, Tecnofarma will market in the rest of Latin America including Mexico, and Key Oncologics will market in South Africa.

In October 2002, we received a \$0.5 million milestone payment from Mayne Pharma PTY Limited for the Australian governmental filing acceptance of our Eligard one-, three-, and four-month products. As a result, the \$0.5 million milestone payment due from Mayne Pharma was recorded as a note receivable milestone payment and deferred revenue in September 2002 and will be recognized as revenue over the remaining term of the agreement using the straight-line method.

Other Products

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

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

Table of Contents

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.

In August 2002, Pfizer submitted an IND to the FDA for a bone growth product that uses our proprietary Atrigel drug delivery technology. Pfizer will conduct all clinical trials of the Atrigel formulation and we will continue to support this product through production of clinical supplies and consultation.

In September 2002, we submitted two ANDAs to the FDA for approval of generic formulations of topical dermatology products.

Significant Capital Events

In March 2002, we called for redemption our outstanding 7% Convertible Subordinated Notes. Subsequently, \$2.9 million in principal amount of the outstanding notes were converted into 151,300 shares of our common stock valued at a \$19.00 per share conversion price. The conversion of the outstanding notes occurred prior to the redemption date of May 15, 2002. For the nine months ended September 30, 2002, we exchanged a total of \$5.2 million in principal amount of our 7% Convertible Subordinated Notes for 279,901 shares of our common stock.

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 (if approved by the FDA), 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 construction is completed, an extensive FDA certification of the plant and equipment is required, which could take up to five months.

In July 2002, our Board of Directors amended our stock repurchase program to provide that we may acquire up to a maximum of \$15.0 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 \$15.0 million of our common stock or December 31, 2002. Since the inception of the stock repurchase program through September 30, 2002, we have repurchased a total of 485,700 shares of our common stock in the open market for \$7.9 million, or an average price per share of \$16.27. During the nine months ended September 30, 2002, we repurchased 408,200 shares of our common stock in the open market for \$6.3 million, or an average price per share of \$15.54 under the program. As of September 30, 2002, \$7.1 million remains available to repurchase our common stock under the stock repurchase program.

Results of Operations

Three Months Ended September 30, 2002 Compared to Three Months Ended September 30, 2001

Total revenue for the three months ended September 30, 2002 was \$7.6 million compared to \$3.3 million for the three months ended September 30, 2001, representing a 130% increase. This increase is primarily related to increases in sales and royalties revenue, contract research and development revenue and licensing, marketing rights and milestone revenue.

Net sales and royalties were \$1.6 million for the three months ended September 30, 2002 compared to \$0.3 million for the three months ended September 30, 2001, representing a 433% increase. This increase is primarily related to sales and royalties on our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products launched in May 2002 and September 2002, respectively, from our marketing partner Sanofi-Synthelabo. Additionally, sales

Table of Contents

and royalties on our Atridox product increased in the third quarter of 2002 from our marketing partner CollaGenex. We expect sales and royalty revenues to increase in the fourth quarter of 2002 as a result of the 2002 marketing launch of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products.

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 \$4.3 million for the three months ended September 30, 2002 compared to \$2.0 million for the three months ended September 30, 2001, representing a 115% increase. This increase is primarily related to the recognition of \$1.4 million in revenue from Sanofi-Synthelabo for funding of an Eligard unique dosage formulation, \$1.0 million increase in revenue from Geneva for efforts under the generic dermatology program and \$0.8 million increase in revenue from Fujisawa for partial funding of Atritone research costs. 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. The two joint venture projects are currently under review for further development. We expect that contract revenue from 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.

Licensing, marketing rights and milestone revenue for the three months ended September 30, 2002 was \$1.7 million compared to \$1.0 million for the three months ended September 30, 2001, representing a 70% increase. This increase is primarily related to the recognition of \$0.4 million in additional milestone revenue for our Eligard products under the Sanofi-Synthelabo agreement and the recognition of \$0.3 million of additional revenue for the net effects of our 2001 amendment to our agreement with Block Drug Corporation and the subsequent agreement with CollaGenex. We expect licensing, marketing and milestone revenue to increase in 2002 as a result of the licensing and milestone payments received from our marketing partners. Other than the receipts of \$6.0 million from Sanofi-Synthelabo and \$0.5 million from Mayne in October 2002, no additional milestone payments are anticipated during the fourth quarter of 2002. As we enter into future collaborative arrangements, we may receive licensing fees and/or marketing rights payments as part of such arrangements; however, we cannot predict if or when that will happen or what the potential payments will be.

Cost of sales for the three months ended September 30, 2002 was \$0.5 million compared to \$0.1 million for the three months ended September 30, 2001, representing a 400% increase. This increase relates to the costs associated with sales of our Eligard 7.5-mg one-month and our Eligard 22.5-mg three-month products. We expect that cost of sales will increase in the future as they relate to expected increases in sales of our products.

Research and development expenses, excluding research and development licensing fees, for the three months ended September 30, 2002 were \$9.4 million compared to \$7.2 million for the three months ended September 30, 2001, representing a 31% increase. An increase of \$1.6 million was related to progress in the development of our generic dermatology products. An increase of \$0.7 million was related to our research and development activities for various BEMA products. An increase of \$0.3 million was related to research activities for our octreotide project. Additionally, an increase of \$0.3 million was related to research activities for our growth hormone releasing peptide-1, or GHRP-1, product. These increases were offset by a decrease in research and development of \$0.4 million on joint venture activities as the two projects under this arrangement are currently under review for further development and a decrease of \$0.5 million on the Eligard products as a result of clinical study completions for Eligard 22.5-mg three-month and Eligard 30.0-mg four-month products. While future research and development expense recognized in conjunction with our joint venture is uncertain at this time, we expect that 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 were \$0 for the three months ended September 30, 2002 compared to \$2.4 million for the three months ended September 30, 2001. This expense represents \$1.9 million in licensing fees paid to Tulane University for rights to GHRP-1 and \$0.5 million paid to Amarillo Biosciences, Inc. for rights to an oral low-dose interferon-alpha product. These fees were expensed as incurred, as the technology

Table of Contents

licensed was for research and development purposes with no future alternative uses. We did not incur any licensing fees during the three months ended September 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.

Administrative and marketing expenses, excluding stock option compensation, for the three months ended September 30, 2002 were \$2.4 million compared to \$1.2 million for the three months ended September 30, 2001, representing a 100% increase. The increase is due to the addition of administrative personnel, increased insurance expense, increased depreciation expense on administrative equipment purchases, increased sales and marketing expenses and a write-down of an accounts receivable balance. 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 three months ended September 30, 2002 was \$0 compared to \$2.0 million for the three months ended September 30, 2001. A non-qualified stock option valued at \$2.0 million was granted for long-term compensation to our Chief Executive Officer in August 2001. The options were fully vested on the date of the grant and expire on August 6, 2011.

We recognized 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, our joint venture with Elan, compared to a loss of \$1.0 million for the three months ended September 30, 2001, representing an 80% decrease. The decrease was primarily related to the completion of feasibility work performed through the joint venture. The two joint venture projects are currently under review for further development and as a result, future recognition of equity in loss of our joint venture is uncertain at this time.

Investment income and expense, net for the three months ended September 30, 2002 was \$1.0 million compared to \$0.8 million for the three months ended September 30, 2001, representing a 25% 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 September 30, 2002 compared to the average balances for the three months ended September 30, 2001 and due to the reduction in interest expense as a result of exchanging 405,547 shares of our common stock for \$7.5 million of our 7% Convertible Subordinated Notes since the period ended September 30, 2001. We expect net 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 August and December 2001 resulting in net proceeds of \$87.7 million and to the receipt of \$16.5 million in milestone payments from Sanofi-Synthelabo, MediGene and Mayne during 2002. Additionally, interest expense is expected to decrease due to the conversion of our 7% Convertible Subordinated Notes payable as of May 2002.

We issued shares of 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 September 30, 2002 compared to \$0.2 million for the three months ended September 30, 2001.

For the reasons described above, we recorded a consolidated net loss applicable to common stock of \$4.2 million, or \$0.21 per share, for the three months ended September 30, 2002 compared to a consolidated net loss applicable to common stock of \$10.1 million, or \$0.59 per share, for the three months ended September 30, 2001.

**Nine Months Ended September 30, 2002 Compared to
Nine Months Ended September 30, 2001**

Total revenue for the nine months ended September 30, 2002 was \$19.1 million compared to \$10.8 million for the nine months ended September 30, 2001, representing a 77% increase. This increase is primarily related to increases in sales and royalties revenue, contract research and development revenue and licensing, marketing rights and milestone revenue.

Net sales and royalties were \$4.2 million during the nine months ended September 30, 2002 compared to \$2.9 million for the nine months ended September 30, 2001, representing a 45% increase. This increase is primarily

Table of Contents

related to sales and royalties on our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products launched in May 2002 and September 2002, respectively, from our marketing partner Sanofi-Synthelabo. We expect sales and royalty revenues to increase in the fourth quarter of 2002 as a result of the 2002 marketing launch of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products.

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 \$10.3 million for the nine months ended September 30, 2002 compared to \$5.4 million for the nine months ended September 30, 2001, representing a 91% increase. This increase is primarily related to the recognition of \$2.5 million increase in revenue from Fujisawa for partial funding of Atrisone research costs, \$2.1 million for funding of an Eligard unique dosage formulation by Sanofi-Synthelabo, \$2.0 million increase in revenue from Geneva for efforts under the generic dermatology program, and \$0.3 million increase in revenue from research activities funded by other parties. These increases were offset by a \$2.0 million decrease in revenue recognized in conjunction with our joint venture as a result of the completion of feasibility work performed by us. The two joint venture projects are currently under review for further development. We expect that contract revenue from 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.

Licensing, marketing rights and milestone revenue for the nine months ended September 30, 2002 was \$4.6 million compared to \$2.5 million for the nine months ended September 30, 2001, representing an 84% increase. This increase is primarily related to the recognition of \$1.1 million additional revenue for the net effects of our 2001 amendment to our agreement with Block and the subsequent agreement with CollaGenex, the recognition of \$0.9 million in additional licensing fee and milestone revenue for our Eligard products under the Sanofi-Synthelabo, MediGene and other Eligard marketing agreements, and the recognition of \$0.1 million additional milestone revenue for our Atrisone product under the Fujisawa agreement. We expect licensing, marketing and milestone revenue to increase in 2002 as a result of the licensing and milestone payments received from our marketing partners. Other than the receipts of \$6.0 million from Sanofi-Synthelabo and \$0.5 million from Mayne in October 2002, no additional milestone payments are anticipated during the fourth quarter of 2002. As we enter into future collaborative arrangements, we may receive licensing fees and/or marketing rights payments as part of such arrangements; however, we cannot predict if or when that will happen or what the potential payments will be.

Cost of sales for the nine months ended September 30, 2002 was \$1.8 million compared to \$1.2 million for the nine months ended September 30, 2001, representing a 50% increase. This increase relates to the cost associated with sales of our Eligard 7.5-mg one-month and Eligard 22.5-mg three-month products. We expect that cost of sales will increase in the future as they relate to expected increases in sales of our products.

Research and development expenses, excluding research and development licensing fees, for the nine months ended September 30, 2002 were \$23.5 million compared to \$19.7 million for the nine months ended September 30, 2001, representing a 19% increase. An increase of \$2.5 million was related to progress in the development of our generic dermatology products. An increase of \$2.0 million was related to our research and development activities for various BEMA products. An increase of \$1.2 million was related to research activities for the GHRP-1 product. An increase of \$0.4 million was related to research activities for our octreotide project. An increase of \$0.4 million was related to progress in the development of our Atrisone acne product. Additionally, an increase of \$0.3 was directed to development activities to identify potential pipeline projects using our Atrigel technology. These increases were offset by a decrease of \$2.4 million on the Eligard one-, three-, and four-month products as a result of clinical study completions and to a decrease in research and development of \$0.8 on joint venture activities as the two projects under this arrangement are currently under review for further development. While future research and development expense recognized in conjunction with our joint venture is uncertain at this time, we expect that 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.

Table of Contents

Research and development licensing fees were \$0 for the nine months ended September 30, 2002 compared to \$3.0 million for the nine months ended September 30, 2001, which represents \$2.5 million in licensing fees paid to Tulane University for rights to GHRP-1 and \$0.5 million to Amarillo Biosciences for rights to an oral low-dose interferon-alpha product. 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 nine months ended September 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.

Administrative and marketing expenses, excluding stock option compensation, for the nine months ended September 30, 2002 were \$6.6 million compared to \$3.7 million for the nine months ended September 30, 2001, representing a 78% increase. This increase was primarily related to the addition of administrative personnel, performance-based compensation to key executive personnel, increased insurance, public relations and legal expenses to support the growth of our company, increased depreciation expense on administrative equipment purchases, increased sales and marketing and a write-down of an accounts receivable balance. 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 nine months ended September 30, 2002 was \$1.3 million compared to \$2.1 million for the nine months ended September 30, 2001, representing a 38% decrease. A charge of \$1.3 for the period ended September 30, 2002 was recognized in connection with the retirement of an executive officer. For the period ended September 30, 2001, we granted a \$2.0 million non-qualified stock option grant to our Chief Executive Officer in August 2001. The options were fully vested on the date of the grant and expire on August 6, 2011. 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 \$0.9 million for the nine months ended September 30, 2002 for our 80.1% equity share in the loss of Transmucosal Technologies, our joint venture with Elan, compared to a loss of \$2.5 million for the nine months ended September 30, 2001, representing a 64% decrease. The decrease was primarily related to the completion of feasibility work performed through the joint venture. The two joint venture projects are currently under review for further development, and as a result, future recognition of equity in loss of our joint venture is uncertain at this time.

Investment income and expense, net for the nine months ended September 30, 2002 was \$3.4 million compared to \$1.8 million for the nine months ended September 30, 2001, representing an 89% increase. The increase was primarily the result of an increase in our average cash and cash equivalents and our marketable securities for the nine months ended September 30, 2002 compared to the average balances for the nine months ended September 30, 2001 and due to the reduction in interest expense as a result of exchanging 405,547 shares of our common stock for \$7.5 million in principal amount of our 7% Convertible Subordinated Notes since the period ended September 30, 2001. We expect net 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 August and December 2001 resulting in net proceeds of \$87.7 million and to the receipt of \$16.5 million in milestone payments from Sanofi-Synthelabo, MediGene and Mayne during 2002. Additionally, interest expense is expected to decrease due to the conversion of our 7% Convertible Subordinated Notes as of May 2002.

Loss on sale and write-down of marketable securities for the nine months ended September 30, 2002 was \$1.1 million compared to \$0 for the nine months ended September 30, 2001. This increase 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 market value of our WorldCom Senior Notes as of September 30, 2002 was \$0.1 million, which represents the approximate market value of the notes after the bankruptcy filing by WorldCom.

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 of

Table of Contents

our common stock 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 \$110,000 interest expense payable eliminated as a result of these exchanges. Additionally, of the 5,917 shares of our common stock exchanged, a debt conversion expense of approximately \$125,000 was recognized for the nine months ended September 30, 2002. As of September 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 nine months ended September 30, 2001, we exchanged 1,600,089 shares of our common stock for \$28.7 million of our 7% Convertible Subordinated notes. As a result of this exchange, we recognized a non-cash charge for debt conversion expense of \$2.1 million and \$0.3 million for extraordinary loss on extinguished debt during the nine months ended September 30, 2001.

We issued shares of 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 \$0.7 million for accretion of dividends on the shares of preferred stock for the nine months ended September 30, 2002 compared to \$0.7 million for the nine months ended September 30, 2001.

For the reasons described above, we recorded a consolidated net loss applicable to common stock of \$13.5 million, or \$0.67 per share, for the nine months ended September 30, 2002 compared to a consolidated net loss applicable to common stock of \$22.8 million, or \$1.47 per share, for the nine months ended September 30, 2001.

Liquidity and Capital Resources

As of September 30, 2002, we had cash and cash equivalents of \$29.6 million, marketable securities (at fair value) of \$91.2 million, net accounts receivable of \$4.9 million, note receivable milestone payments of \$6.5 million, inventories of \$5.2 million and other current assets of \$2.7 million for total current assets of \$140.1 million. We had accounts payable of \$4.3 million, short-term deferred revenue of \$7.7 million and other current liabilities of \$1.0 million for total current liabilities of \$13.0 million, which resulted in working capital of \$127.1 million.

During the nine months ended September 30, 2002, net cash used in operating activities was \$5.9 million. This was primarily the result of the net loss for the period of \$12.8 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 September 30, 2002 was 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 \$2.4 million of depreciation and amortization expense and \$0.9 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 \$11.7 million, partially offset by amortization of deferred revenue of \$7.9 million. Other significant uses of cash included: (i) \$1.8 million of increased inventories primarily related to the build up of inventory for the launch of the Eligard one-month and three-month products, and (ii) \$1.4 million of increased prepaid expenses and deposits primarily related to prepayments on certain research and development projects, insurance and various operating agreements.

Net cash used in investing activities was \$11.8 million during the nine months ended September 30, 2002. This was primarily due to \$56.2 million used to fund the purchases of various marketable securities available-for-sale offset by proceeds received from the maturity and sale of marketable securities available-for-sale of \$51.5 million. During the third quarter of 2002, we sold various corporate note securities and subsequently reinvested the proceeds in high rated corporate notes, U.S. government securities, and diversified bond mutual funds to minimize our exposure to credit risk. In addition, cash used in investing activities included \$1.8 million for capital expenditures related to our plant expansion as discussed further under Future Capital Requirements below.

Table of Contents

Net cash used in financing activities was \$3.3 million during the nine months ended September 30, 2002. This was primarily the result of the repurchase of \$6.3 million of our common stock in the open market, offset by proceeds of \$3.0 million from the issuance of common stock. In September 2001, our Board of Directors approved a stock repurchase program to acquire up to \$5.0 million of our common stock. On July 23, 2002, our 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 \$5.0 million to a maximum of \$15.0 million. The program terminates on the earlier of the date that we have repurchased \$15.0 million of our common stock or December 31, 2002. Since the inception of the program, we repurchased a total of 485,700 shares of our common stock in the open market for \$7.9 million, or an average price per share of \$16.27. For the nine months ended September 30, 2002, we repurchased 408,200 shares of our common stock in the open market for \$6.3 million, or an average share price per share of \$15.54 under the program. As of September 30, 2002, \$7.1 million remains available to repurchase our common stock under the program.

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 valued at a price of \$19.00 per share. During the nine months ended September 30, 2002 we exchanged 279,901 shares of our common stock for \$5.2 million in principal amount of our 7% Convertible Subordinated Notes. Of the 279,901 shares of our common stock issued, 273,984 shares were valued at the conversion price of \$19.00 per share and the remaining 5,917 shares were valued at the conversion price of \$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 \$110,000 interest expense payable eliminated as a result of these exchanges. Additionally, of the 279,901 shares of common stock exchanged, a debt conversion expense of approximately \$125,000 was recognized for the nine months ended September 30, 2002. As of September 30, 2002 and December 31, 2001, the outstanding principal amount of the 7% Convertible Subordinated Notes was \$0 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 September 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 \$1.5 million for the nine months ended September 30, 2002 and \$0.7 million for the nine months ended September 30, 2001. The two joint venture projects are currently under review for further development and the outcome of the review may effect future funding obligations.

We have a revolving line of credit with a bank that expires on May 20, 2003. 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 June 2002, we established a \$1.0 million bank line of credit that expires on June 15, 2003. Borrowings under the line bear interest at a rate of 5.25%. As of September 30, 2002, there was no obligation outstanding under either of these credit agreements.

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. 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, 2002, we had \$29.6 million of cash and cash equivalent investments and \$91.2 million of marketable securities available-for-sale (at fair value) to fund future operations and capital requirements. Our marketable securities available-for-sale are primarily in U.S. government bonds, diversified bond mutual funds and investment grade corporate notes. Our portfolio of corporate notes is diversified and, under our policy, we only invest in investment grade corporate notes.

Table of Contents

We believe the quality of the notes we hold and the diversity of our portfolio significantly 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, 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.

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.

Research and development

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 nine months ended September 30, 2002, including research and development costs inception-to-date and estimated completion dates and costs (in thousands):

Technology	Expenses	Expenses	Expenses	Expenses	Expenses	Funded	Anticipated
	1999	2000	2001	(as of September 30)	Inception-to-Date	Expenses	Completion Date (to market)
	\$ 10,624	\$ 10,845	\$ 13,727	\$ 10,415	\$ 105,425	\$ 8,036	2003 2009
3,090 4,604 3,805 13,827 3,494 2005 20,000							
9 2,397 2,005 5,214 1,011 2006 2007 5,000							
2,541 4,907 7,287 29,771 9,898 2003 2007 50,000							

Edgar Filing: ATRIX LABORATORIES INC - Form 10-Q

expenses to support them have stabilized and comprised 56%, 25%, 10% and 13% of the 1999, 2000, 2001 and year-to-date 2002 Atrigel expenses, respectively. Of the expenses funded by third parties, 20% of funds received were to support the dental products, 35% of funds have come recently to support the Eligard products domestically as well as internationally, and 45% 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.

Table of Contents

Under the BEMA technology, approximately 55% 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 26% of expenses incurred to date and 37% of funding.

Plant expansion

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. Once construction is completed, an extensive FDA certification of the plant and equipment is required, which could take up to five months. Construction costs are estimated to be approximately \$5.9 million with additional expenditures to be incurred as needed for equipment. As of September 30, 2002, approximately \$1.8 million has been spent on construction costs.

Recent Accounting Pronouncements

In June 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 June 2001, SFAS No. 143, *Accounting for Asset Retirement Obligations* was issued by the FASB. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs and applies to all entities. It applies to legal obligations associated with the retirement of long-lived assets that result from the acquisition, construction, development and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The Company will adopt SFAS No. 143 on January 1, 2003. The adoption of this statement is not expected to 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. 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.

In April 2002, SFAS No. 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections* was issued by the FASB. SFAS No. 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

Table of Contents

changed conditions. We will adopt SFAS No. 145 on January 1, 2003. The adoption of this statement is not expected to have a material impact on our consolidated financial position or results of operations.

In August 2002, SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities was issued by the FASB. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit on Activity (including Certain Costs Incurred in Restructuring). SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity is to be recognized when the liability is incurred. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of this statement is not expected to have a material impact on our consolidated financial position or results of operations.

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/A for the year ended December 31, 2001. The accounting policies used in preparing our interim consolidated financial statements for the nine months ended September 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 such corporate partners and us.

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.

Table of Contents

Dependence on one 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.

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.

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 the majority 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 mutual funds that invest in United States government and agency bonds, corporate bonds, mortgage-backed and asset-backed securities, and possibly foreign securities. The value of these mutual fund investments is also subject to interest rate risk, as well as maturity risks on mortgage-backed securities and possibly foreign market risks.

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 fair values loss risk from the impact of hypothetical interest rate changes 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 September 30, 2002. The fair values that result from these computations are compared with the fair values of these financial instruments at September 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 September 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 \$0.4 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 \$0.4 million per year. We maintain a portion of our financial instruments, including long-term debt instruments of approximately \$26.7 million at September 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.

Table of Contents

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 September 30, 2002 was not material. Based on our overall foreign currency rate exposure at September 30, 2002, we do not believe that a hypothetical 10% change in foreign currency rates would materially affect our financial position.

Item 4. Controls and Procedures.

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of the company's disclosure controls and procedures within ninety days before the filing date of this quarterly report. Based on that evaluation, the CEO and CFO concluded that the company's disclosure controls and procedures were effective. There have been no significant changes in the company's internal controls or in other factors that could significantly affect internal controls subsequent to their evaluation.

Table of Contents

PART II OTHER INFORMATION

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

(a) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Certification of Chief Executive Officer
99.2	Certification of Chief Financial Officer

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

24

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/ David R. Bethune

David R. Bethune
Chairman of the Board and
Chief Executive Officer
(Principal Executive Officer) November 7, 2002 By: /s/ Brian G.
Richmond

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

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;
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;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - (c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

Table of Contents

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 7, 2002

/s/ David R. Bethune

David R. Bethune
Chairman and Chief Executive Officer

Table of Contents

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;
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;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - (c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 7, 2002

/s/ Brian G. Richmond

Brian G. Richmond
Chief Financial Officer

Table of Contents

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Certification of Chief Executive Officer
99.2	
Certification of Chief Financial Officer	