ATRIX LABORATORIES INC Form 10-O

October 30, 2001

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

FORM 10-0

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

FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2001

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)

(I.R.S. Employer Identification No.)

2579 MIDPOINT DRIVE FORT COLLINS, COLORADO 80525 (Address of principal executive office) (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 X No

The number of shares outstanding of the registrant's common stock as of October 26, 2001 was 18,923,473.

1

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ATRIX LABORATORIES, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)

ASSETS

CURRENT ASSETS: Cash and cash equivalents Marketable securities available for sale, at fair market value Notes receivable - stock subscription and license fee Accounts receivable, net of allowance for doubtful accounts of \$172,386 and \$209,659 Interest receivable Inventories Prepaid expenses and deposits Total current assets PROPERTY, PLANT AND EQUIPMENT, NET OTHER ASSETS: Intangible assets, net of accumulated amortization of \$3,160,077 and \$2,399,431 Deferred finance costs, net of accumulated amortization of \$163,439 and \$628,379 Other assets, net TOTAL ASSETS LIABILITIES AND SHAREHOLDERS' EQUITY CURRENT LIABILITIES: Accounts payable - trade Interest payable Accrued salaries and payroll taxes Other accrued liabilities Deferred revenue Total current liabilities DEFERRED REVENUE CONVERTIBLE SUBORDINATED NOTES PAYABLE COMMITMENTS AND CONTINGENCIES 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 Series A convertible exchangeable preferred stock, \$.001 par value, 20,000 shares

authorized; 12,439 and 12,015 shares issued and outstanding. Liquidation

Septemb

\$

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preference \$13,053,426 and \$12,397,505

Common stock, \$.001 par value; 45,000,000 shares authorized; 18,911,232 and 13,341,681 shares issued and 18,858,732 and 13,341,681 shares outstanding Treasury stock, 52,500 and -0- shares, at cost Additional paid-in capital

Accumulated other comprehensive income (loss)

Accumulated deficit

Total shareholders' equity

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY

See notes to the consolidated financial statements.

2

ATRIX LABORATORIES, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000 (Unaudited)

	2001	2000 (RESTATED)
REVENUE:		
Net sales and royalties	\$ 290,924	
Contract research and development revenue	1,994,456	347,934
Licensing, marketing rights and milestone revenue	971 , 169	469,385
Total revenue	3,256,549	2,584,883
OPERATING EXPENSES:		
Cost of goods sold	112,603	810,416
Research and development	7,162,995	4,575,479
Research and development - licensing fees	2,445,000	
Administrative and marketing	1,156,152	1,058,186
Administrative - stock option compensation	2,000,000	
Total operating expenses	12,876,750	6,444,081
LOSS FROM OPERATIONS	(9,620,201)	(3,859,198)
OTHER INCOME (EXPENSE):		
Equity in loss of joint venture	(1,007,786)	(12,035,025)
Investment income	976,876	522,672
Interest expense	(157,005)	
Debt conversion expense	(57,290)	
Other	2,532	9,002
Net other expense	(242,673)	(12,148,151)
LOSS BEFORE EXTRAORDINARY ITEM	(9,862,874)	(16,007,349)

Extraordinary gain (loss) on extinguished debt	(3,810)		79 , 906	
NET LOSS BEFORE PREFERRED STOCK DIVIDEND Accretion of dividend on preferred stock			4) (15,927,44 9) (170,51	
NET LOSS APPLICABLE TO COMMON STOCK	\$(10,092,283) =======			
Basic and diluted earnings per common share: Loss before extraordinary item Extraordinary item	\$	(.58)	\$	(1.33)
Net loss before preferred stock dividend Accretion of dividend on preferred stock		(.58) (.01)		(1.32)
Net loss applicable to common stock	\$ =====	(.59)		(1.33)
Basic and diluted weighted average common shares outstanding	•	966,110		,097,565 ======

See notes to the consolidated financial statements.

3

ATRIX LABORATORIES, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000 (Unaudited)

	2001	2000 (RESTATED)
REVENUE:		
Net sales and royalties	\$ 2,867,303	\$ 4.587.785
Contract research and development revenue	5,427,387	
Licensing, marketing rights and milestone revenue	2,480,253	1,406,273
Total revenue	10,774,943	7,102,142
OPERATING EXPENSES:		
Cost of goods sold	1,152,692	1,933,261
Research and development	19,727,044	11,904,657
Research and development - licensing fees	2,985,000	
Administrative and marketing	3,741,373	3,271,036
Administrative - stock option compensation	2,116,524	
Total operating expenses	29,722,633	17,108,954
LOSS FROM OPERATIONS	(18,947,690)	(10,006,812)
OTHER INCOME (EXPENSE):		
Equity in loss of joint venture	(2,524,447)	(12,035,025)
Investment income	2,432,856	1,410,712
Interest expense	(647,587)	(1,941,260)

Debt conversion expense Other	·	,105,637) (20,818)		 87 , 124
Net other expense		,865,633)	(12	
LOSS BEFORE EXTRAORDINARY ITEM AND CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE	(21	,813,323)		
Extraordinary gain (loss) on extinguished debt Cumulative effect of change in accounting principle		(292,165)		79,906 ,611,526)
NET LOSS BEFORE PREFERRED STOCK DIVIDEND Accretion of dividend on preferred stock	(22,105,488) (655,921)		•	,016,881) (170,514)
NET LOSS APPLICABLE TO COMMON STOCK	\$ (22,761,409) ========		\$ (43	,187,395)
Basic and diluted earnings per common share: Loss before extraordinary item and cumulative effect of change in accounting principle Extraordinary item Cumulative effect of change in accounting principle	\$	(1.41) (.02)		(1.93) .01 (1.77)
Net loss before preferred stock dividend Accretion of dividend on preferred stock		(1.43) (.04)		
Net loss applicable to common stock	\$	(1.47) ======	•	, ,
Basic and diluted weighted average common shares outstanding	15	,434,256 ======	11	,672,434

See notes to the consolidated financial statements.

4

ATRIX LABORATORIES, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2001
(Unaudited)

	Preferred Stock		Common Stock			
	Shares Amount Sh		Shares Amount Shares			Amount
BALANCE, DECEMBER 31, 2000	12,015	\$	12	13,341,681	\$	13,342
Comprehensive loss: Net loss						
Other comprehensive loss: - Cumulative foreign						
currency translation adjustments						
- Unrealized gain on						
investments						

Net comprehensive loss Issuance of Series A convertible exchangeable				
preferred stock to Elan for				
accrued dividends	424			
Accretion on preferred stock Issuance of common stock				
to extinguish debt Issuance of common stock to			1,600,089	1,600
MediGene Non-qualified stock			233,918	234
compensation Exercise of non-qualified				
stock options Exercise of employee stock			5,000	5
options Issuance for employee stock			250 , 958	251
purchase plan			1,486	1
Issuance of restricted stock			28,100	28
Purchase of treasury stock			(52 , 500)	
Offering of common stock			3,450,000	3,450
BALANCE, SEPTEMBER 30, 2001	12,439 ======	\$ 12 =======	18,858,732 =======	\$ 18,911 =======
	Accumulated Other		Total	
		Accumulated	Shareholders'	
	Income (Loss)	Deficit	Equity	
BALANCE, DECEMBER 31, 2000	\$ (471,306)	\$(105,496,590)	\$ 7,809,118	
Comprehensive loss: Net loss		(22,761,409)	(22,761,409)	
Other comprehensive loss: - Cumulative foreign currency translation				
adjustments - Unrealized gain on	(11,300)		(11,300)	
investments	1,290,975		1,290,975	
Net comprehensive loss Issuance of Series A			(21,481,734)	
convertible exchangeable preferred stock to Elan for				
accrued dividends				
Accretion on preferred stock Issuance of common stock			655 , 921	
to extinguish debt Issuance of common stock to			30,784,637	
MediGene Non-qualified stock			3,780,000	
compensation Exercise of non-qualified			2,116,524	
stock options Exercise of employee stock			30,000	
options			2,509,979	
Issuance for employee stock purchase plan			21,502	
Issuance of restricted stock			296,448	

Offering of common	stock			73,875,152
BALANCE, SEPTEMBER	30, 2001	\$ 808,369	\$(128,257,999)	\$ 99,358,092

See notes to the consolidated financial statements.

5

ATRIX LABORATORIES, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000 (Unaudited)

	2001	2000 (RESTAT
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss applicable to common stock	\$(22,761,409)	\$(43,187
Adjustments to reconcile net loss to net cash used in		
operating activities:		
Accretion of dividend on preferred stock	655 , 921	170
Depreciation and amortization	1,796,166	1,664
Equity in loss of joint venture	2,524,447	12,035
(Gain) loss on sale of property, plant and equipment	19,253	(7
Loss on sale of marketable securities	·	171
Provision for bad debts	(37,272)	
Write-off of obsolete patents	497	2
Stock plan compensation	2,116,524	75
Debt conversion expense	2,105,637	
Interest expense converted to equity	333,241	
Extraordinary (gain) loss on extinguished debt	292,165	(79
Cumulative effect of change in accounting principle	·	20,611
Net changes in operating assets and liabilities:		
Accounts receivable	(835,177)	(1,309
Note receivable - license fee	8,000,000	
Interest receivable	(420,751)	220
Inventories	(830,074)	(390
Prepaid expenses and deposits	(507,020)	(709
Accounts payable	277,459	(758
Interest payable	(40,140)	632
Accrued salaries and payroll taxes	96,254	(32
Other accrued liabilities	13,975	22
Deferred revenue	4,619,537	
Net cash used in operating activities	(2,580,767)	(12,030
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment in unconsolidated joint venture		(12,035
Acquisition of property, plant and equipment	(1,519,014)	
Investments in intangible assets	(330,532)	(157
Proceeds from sale of property, plant and equipment	6 , 904	20
Deceade from sale of property, praint and equipment	0,301	7 400

Proceeds from maturity of marketable securities 22,240,842

Proceeds from sale of marketable securities

7,402

Investment in marketable securities	(74,132,068)	(310
Net cash used in investing activities	(53,733,868)	(5,523
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of equity securities	80,513,082	23,281
Payments to acquire treasury stock	(1,039,455)	
Note receivable - stock subscription	15,000,000	
Extinguished convertible long-term debt		(408
Net cash provided by financing activities	94,473,627	22 , 873
NET EFFECT OF EXCHANGE RATE ON CASH	(46,696)	(127
NET INCREASE IN CASH AND CASH EQUIVALENTS	38,112,296	5 , 191
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	4,484,330	
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 42,596,626	\$ 8,213
Supplemental cash flow information:	=========	======
Cash paid for interest	\$ 354,486	\$ 1,301
•	========	

Non-cash activities:

During the nine months ended September 30, 2001, the Company issued 1,600,089 shares of common stock valued at \$30,784,637 to extinguish \$28,679,000 of the 7% Convertible Subordinated Notes.

See notes to the consolidated financial statements.

6

ATRIX LABORATORIES, INC. AND SUBSIDIARIES NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2001 AND 2000

NOTE 1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying unaudited consolidated financial statements of Atrix Laboratories, Inc. and subsidiaries 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 (which consist 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, 2000, filed with the Securities and Exchange Commission in the Company's Annual Report on Form 10-K.

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. Collectively, Atrix

Laboratories and its subsidiaries are referred to as Atrix or the Company. 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, to develop oncology and pain management compounds. Drug delivery of these compounds will utilize the Company's patented Atrigel and BEMA drug delivery systems and Elan's nanoparticulate delivery technology.

Atrix is an emerging specialty pharmaceutical company focused on advanced drug delivery. With five unique patented drug delivery technologies, the Company is currently developing a diverse portfolio of products, including proprietary oncology, pain management, growth hormone releasing peptide-1 and dermatology products. The Company also partners with several 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 large pharmaceutical companies to use its drug delivery technologies and expertise in the development of new products.

In June 1998, Statement of Financial Accounting Standards (SFAS) No. 133, Accounting for Derivative Instruments and Hedging Activities, was issued which, as amended, was effective for all fiscal years beginning after June 15, 1999. SFAS No. 133 provides new standards for the identification, recognition and measurement of derivative financial instruments, including embedded derivatives. Historically, we have not entered into derivative contracts to hedge existing risks nor have we entered into speculative derivative contracts. Although our convertible debt and preferred stock include conversion features that are considered to be embedded derivatives, accounting for those instruments is not affected by SFAS No. 133. The adoption of SFAS No. 133 on January 1, 2001 did not result in a transition adjustment in the financial statements.

On June 29, 2001, SFAS No. 141, "Business Combinations" was issued by the Financial Accounting Standards Board (FASB). SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. 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. The Company adopted SFAS No. 141 on July 1, 2001. The adoption of this statement did not have an impact on the Company's consolidated financial position or results of operations.

On June 29, 2001, SFAS No. 142, "Goodwill and Other Intangible Assets" was issued by the FASB. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill recorded in past business combinations, will cease upon adoption of this statement. The Company is required to implement SFAS No. 142 on January 1, 2002 and it has not determined the impact, if any, that this statement will have on its 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 supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed of," and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," for the disposal of a segment of business. This statement also amends Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to eliminate the exception to consolidation for a subsidiary for which control is likely to be temporary, SFAS No. 144 retains the requirements of SFAS No. 121 to recognize an impairment loss

when the carrying amount of a long-lived asset is not recoverable and provides for alternative cash flow measurement methods when more than one course of action is available for the recovery of the carrying amount of the asset. SFAS No. 144 also removes goodwill from its scope. The Company is required to adopt SFAS No. 144 on January 1, 2002 and it has not determined the impact, if any, that this statement will have on its consolidated financial position or results of operations.

Effective in the fiscal fourth quarter of 2000, the Company changed its method of accounting for nonrefundable technology access fees and milestone payments to recognize such payments as revenue over the term of the related agreements. The change in accounting principle is based on guidance provided in the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 101 - Revenue Recognition in Financial Statements. Previously, the Company recognized \$24,100,000 for nonrefundable technology access fees and milestone payments as revenue when received and when the Company fulfilled all contractual obligations relating to the fees and milestone payments. There was approximately \$20,612,000 cumulative effect for this change in accounting principle that was reported as a charge in the year ended December 31, 2000. The cumulative effect was recorded as deferred revenue that will be recognized as revenue over the remaining contractual terms for each of the specific agreements.

The following represents the Consolidated Statement of Operations for the three and nine months ended September 30, 2000 as previously reported, the adjustments for the adoption of SAB No. 101, and the resulting Consolidated Statement of Operations as restated for that adoption.

7

ATRIX LABORATORIES, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2000 AS PREVIOUSLY REPORTED AND RESTATED (Unaudited)

	2000 (AS PREVIOUSLY REPORTED)	SAB No. 101 ADJUSTMENTS
REVENUE: Net sales and royalties Contract research and development revenue Licensing, marketing rights and milestone revenue	\$ 1,767,564 347,934 150,000	\$ 319,385
Total revenue	2,265,498	319,385
OPERATING EXPENSES: Cost of goods sold Research and development Administrative and marketing Total operating expenses	810,416 4,575,479 1,058,186 	
LOSS FROM OPERATIONS	(4,178,583)	319,385

\$

OTHER INCOME (EXPENSE):			
Equity in loss of joint venture	(12,035,025)		(
Investment income	522,672		
Interest expense	(644,800)		
Other	9,002		
Net other expense	(12,148,151)		(
LOSS BEFORE EXTRAORDINARY ITEM	(16.326.734)	319,385	(
Extraordinary gain on extinguished debt	79,906		(
NET LOSS BEFORE PREFERRED STOCK DIVIDEND	(16,246,828)	319,385	(
Accretion of dividend on preferred stock	(170,514)		
NET LOSS	\$(16,417,342)		\$ (==
Basic and diluted earnings per common share:	41.26)		<u>^</u>
Loss before extraordinary item Extraordinary item	\$ (1.36) .01		\$
	(1. 25)		
Net loss before preferred stock dividend	(1.35)		
Accretion of dividend on preferred stock	(.01)		
Net loss applicable to common stock	\$ (1.36)		\$
Basic and diluted weighted average common shares	========		
outstanding	12,097,565		
-	=========		==

8

ATRIX LABORATORIES, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2000 AS PREVIOUSLY REPORTED AND RESTATED (Unaudited)

	2000 (AS PREVIOUSLY REPORTED)	SAB No. 101 ADJUSTMENTS
REVENUE:		
Net sales and royalties	\$ 4,587,785	\$
Contract research and development revenue	1,108,084	
Licensing, marketing rights and milestone revenue	255,000	1,151,273
Total revenue	5,950,869	1,151,273
OPERATING EXPENSES:		
Cost of goods sold	1,933,261	
Research and development	11,904,657	

Administrative and marketing	3,271,036	
Total operating expenses	17,108,954	
LOSS FROM OPERATIONS	(11,158,085)	1,151,273
OTHER INCOME (EXPENSE): Equity in loss of joint venture Investment income Interest expense Other	(12,035,025) 1,410,712 (1,941,260) 87,124	
Net other expense	(12,478,449)	
LOSS BEFORE EXTRAORDINARY ITEM AND CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE Extraordinary gain (loss) on extinguished debt Cumulative effect of change in accounting principle	79,906	1,151,273 (20,611,526)
NET LOSS BEFORE PREFERRED STOCK DIVIDEND Accretion of dividend on preferred stock	(23,556,628) (170,514)	(19,460,253)
NET LOSS APPLICABLE TO COMMON STOCK	\$(23,727,142) =======	
Basic and diluted earnings per common share: Loss before extraordinary item and cumulative effect of change in accounting principle Extraordinary item Cumulative effect of change in accounting principle	\$ (2.03)	
Net loss before preferred stock dividend Accretion of dividend on preferred stock	(2.02)	
Net loss applicable to common stock	\$ (2.03)	
Basic and diluted weighted average common shares outstanding	11,672,434	

9

NOTE 2. 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 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 Bulletin 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." Accordingly, the Company accounts for its investment in Transmucosal Technologies under the equity method of accounting.

NOTE 3. INVENTORIES

Inventories are stated at the lower of cost, determined by the first-in, first-out (FIFO) method, or market. The inventory components at September 30, 2001 and December 31, 2000, are as follows:

	September 30, 2001	December 31, 2000
Raw materials Work in process Finished goods	\$ 1,835,700 539,659 392,806	\$ 1,616,878 144,723 179,328
	\$ 2,768,165 ========	\$ 1,940,929 ========

NOTE 4. PROPERTY, PLANT, AND EQUIPMENT

The components of net property, plant and equipment are as follows:

	Septemb	er 30, 2001	Decer	mber 31, 2000
Land	\$	1,071,018	\$	1,071,018
Building		3,651,249		3,610,068
Leasehold improvements		615,056		470,002
Furniture and fixtures		590,040		440,534
Machinery		5,821,954		5,038,815
Office equipment		1,116,766		813,317
Total property, plant and equipment Accumulated depreciation and		12,866,083		11,443,754
amortization		(5,519,854)		(4,625,382)
Property, plant and equipment, net	\$ ===	7,346,229	\$	6,818,372

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 the earnings. Stock options, warrants outstanding and their equivalents are included in diluted earnings per share computations through the "treasury stock method" unless they are antidilutive. Convertible securities are included in diluted earnings per share computations through the "if converted" method unless they are antidilutive. The effect of assuming conversion of the Series A Convertible Preferred Stock is excluded from the diluted earnings per share computations since the conversion option commences July 18, 2002. Additionally, since the Company has not drawn any proceeds under the convertible promissory note agreement with Elan as of September 30, 2001, there was no effect on earnings per share computations pertaining to this convertible promissory note for the periods presented. Common share equivalents have been excluded from the computations in loss periods, as their effect would be antidilutive. For the nine months ended September 30, 2001 and 2000,

approximately 1.8 million and 2.1 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 basic and diluted net earnings per common share computations as they are antidilutive.

NOTE 6. CONVERTIBLE SUBORDINATED NOTES PAYABLE

During the nine months ended September 30, 2001, the Company completed a series of private transactions involving the exchange of 1,600,089 shares of the Company's common stock for \$28,679,000, or 57% of the principal amount, of the 7% Convertible Subordinated Notes. Of the 1,600,089 shares issued, 1,509,411 shares were valued at the conversion price of \$19.00 per share and the remaining 90,678 shares were valued at the closing market price as of the various exchange dates. As a result, the Company recognized an extraordinary loss of approximately \$292,000, for the write-off of approximately \$625,000 of pro rata unamortized deferred finance charges net of approximately \$333,000 interest expense eliminated as a result of these exchanges. Additionally, as part of the 90,678 shares of common stock which were exchanged for the 7% Convertible Subordinated Notes at prices different than the conversion price of \$19.00, debt conversion expense of approximately \$2,106,000 was recognized for the nine months ended September 30, 2001. As of September 30, 2001 and December 31, 2000, the outstanding principal amount of the 7% Convertible Subordinated Notes was \$7,511,000 and \$36,190,000, respectively.

NOTE 7. NON-QUALIFIED STOCK OPTION GRANT

The Company's Board of Directors awarded a non-qualified stock option to the Company's chief executive officer on August 6, 2001. The options were fully vested on the date of the grant and expire on August 6, 2011. The Company recognized compensation expense of \$2 million for this grant in the current period.

NOTE 8. LEGAL PROCEEDINGS

Effective as of August 24, 2001, the Company entered into an Eighth Amendment to its agreement with Block Drug Corporation pursuant to which the parties settled all disputes relating to the agreement and agreed to terminate all legal proceedings between the parties relating thereto. Accordingly, under the terms of the Eighth Amendment, each party has released the other party from debts, damages or liabilities relating to the agreement, Block has dismissed the pending arbitration it initiated with respect to the agreement, and the Company has dismissed the lawsuit it filed in the U.S. District Court for the District of Colorado in May 2001.

Under the terms of the Eighth Amendment to the Block agreement, the Company reacquired the sales and marketing rights to its Atridox(R), Atrisorb(R) Free Flow and Atrisorb(R) Free Flow with Doxycycline products from Block for \$7.0 million. Of this amount, \$3.3 million was paid upon execution of the Eighth Amendment to the agreement and the balance will generally be payable over a four-year period with the amount payable each year based upon net sales of the Atridox(R), Atrisorb(R) Free Flow and Atrisorb(R) Free Flow with Doxycycline products and/or receipt of licensing fees for the Atridox(R), Atrisorb(R) Free Flow and Atrisorb(R) Free Flow with Doxycycline products. In turn, Block paid the Company \$3.0 million owed for the development and FDA approval of the Company's Atrisorb(R) Free Flow with Doxycycline product.

10

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: (i) whether we will receive, and the timing of, regulatory approvals or clearances to market potential products; (ii) the results of current and future clinical trials; (iii) the time and expenses associated with the regulatory approval process for products; (iv) the safety and effectiveness of our products and technologies; (v) the timing of new product launches; and (vi) expected future additional equity losses for Transmucosal Technologies. The success of our business operations is dependent on factors such as the receipt and timing of regulatory approvals or clearances for potential products, the effectiveness of our marketing strategies to market, our current and any future products, our ability to manufacture products on a commercial scale, the appeal of our mix of products, our success at entering into and collaborating with others to conduct effective strategic alliances and joint ventures, general competitive conditions within the biotechnology and drug delivery industry and general economic conditions. Forward-looking statements are not guarantees of future performance and involve risks and uncertainties. Actual results may differ materially from those projected in the forward-looking statements as a result of various factors, including those described below under the heading "Risk Factors."

OVERVIEW

We are an emerging specialty pharmaceutical company focused on advanced drug delivery. With five unique patented drug delivery technologies, we are currently developing a diverse portfolio of products, including proprietary oncology, pain management, growth hormone releasing peptide-1 and dermatology products. 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, MCA, BCP and SMP.

We also partner with large pharmaceutical and biotechnology companies to apply our proprietary technologies to new chemical entities or to extend the patent life of existing products. We have strategic alliances with several pharmaceutical companies including collaborations with Pfizer, Elan, Sanofi-Synthelabo, MediGene, Faulding Pharmaceuticals, Human Genome Sciences, Geneva Pharmaceuticals, Del Pharmaceuticals, Pharmacia & Upjohn Animal Health, CollaGenex Pharmaceuticals, and J.B. Williams Company.

In January 2001, we acquired an exclusive option from Tulane University Health Sciences Center to license a patented human growth hormone releasing peptide-1 compound, or GHRP-1. Previously we focused on reformulating existing compounds in our drug delivery technologies. GHRP-1 represents our first chemical entity that we would acquire and develop for our own product portfolio, rather than in conjunction with an external partner. Possible applications of GHRP-1 include treatment of patients with AIDS or cancer, promotion of growth in children with short stature, or prevention of muscle wasting and frailty in aged individuals. Our intent is to deliver GHRP-1 for an extended period of time using our patented Atrigel drug delivery system. In September 2001, we exercised our option to license GHRP-1 from Tulane for \$1,960,000. Additionally, under the terms of the Tulane agreement, we will pay Tulane a royalty on sales of any

product that may be developed. We will fund the research and development and perform most of the development effort.

In April 2001, we entered into an exclusive marketing agreement with MediGene AG, a German biotechnology company, to market our Leuprogel products in Europe. Under the terms of the agreement, valued at approximately \$20 million, we received an up-front license fee of \$2 million in April 2001 and will receive additional payments for certain clinical and regulatory matters and sales milestones upon approval for marketing by the European Medicine Evaluation Agency or other competent authority. The \$2 million license fee from MediGene will be recognized as revenue over the term of the agreement using the straight-line method in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101 - Revenue Recognition in Financial Statements, or SAB 101. Additionally, MediGene purchased shares of our common stock for \$3.78 million at a premium to the market in April 2001 as part of the agreement and will provide the resources needed to conduct clinical research and regulatory activities associated with seeking European marketing approvals.

In June 2001, we received \$3 million from Sanofi-Synthelabo upon the acceptance for filing by the FDA of a New Drug Application, or NDA, for our Leuprogel One-month product. The agreement is valued at approximately \$60 million, which includes a license fee, research and development support and payments for certain clinical, regulatory and sales milestones of the Leuprogel products upon approval for marketing by the FDA.

In August 2001, we entered into an agreement with F.H. Faulding & Co. Limited, ABN, trading as Faulding Pharmaceuticals, for marketing rights for our three Leupogel products in Australia and New Zealand. In accordance with the agreement, we received an up-front license fee of \$100,000 in August 2001. The license fee will be recognized as revenue over the term of the agreement using the straight-line method in accordance with SAB 101. The agreement includes certain milestone payments, royalty payments on net sales, and manufacturing margins of the Leuprogel products upon approval for marketing by the Therapeutic Goods Administration of Australia and/or other competent authorities in Australia and New Zealand. Additionally, Faulding will be responsible for regulatory submission and any studies that may be necessary to gain approval with the Australian and New Zealand authorities.

In August 2001, we also entered into an agreement with Human Genome Sciences, Inc., a pioneer in the discovery and development of genomics-base drugs, to develop a sustained-release formulation of a Human Genome Sciences new proprietary protein with our Atrigel drug delivery system. Under the terms of the agreement, Human Genome Sciences will provide funding for the project.

In August 2001, we completed a public offering of three million shares of our common stock sold at an offering price of \$23.00 per share. Additionally, in August 2001, the underwriters of our public offering exercised their option to purchase 450,000 additional shares of our common stock to cover over-allotments. Net proceeds from our public offering and the subsequent underwriters' exercise of the over-allotment option was approximately

11

\$73,875,000, net of issuance costs of approximately \$714,000. We anticipate using the proceeds from this offering to broaden our technologies, supplement our product pipeline, and further current product development efforts.

Under the terms of an amendment to the Block agreement dated August 24, 2001, we reacquired marketing rights of our dental products for \$7 million, of

which \$3.3 million was paid upon execution of the agreement and the balance of the \$3.7 million will generally be payable over a four-year period with the amount payable each year based upon net sales of the dental products and/or from receipt of licensing fees for the dental products. In conjunction with the amendment to the Block agreement, Block paid us \$3 million owed for the September 2000 FDA approval and Block's first commercial sale obligation of Atrisorb(R)-D, a periodontal barrier product with the antibiotic doxycycline for gingival surgery. Finally, each party agreed to terminate all legal proceedings against the other party relating to the Block agreement. Also during August 2001, we licensed the exclusive U.S. marketing rights for Atridox(R), Atrisorb(R)-Free Flow and Atrisorb(R)-D to CollaGenex Pharmaceuticals, Inc., following the reacquisition of the sales and marketing rights from Block. Under the terms of the CollaGenex agreement, we received an up-front licensing fee of \$1 million, and will receive a royalty on sales of the dental products, in addition to the manufacturing margin from the production of the three products. As part of the transaction, we purchased \$3 million of CollaGenex's common stock at a premium to the market, the proceeds of which CollaGenex will use primarily to fund a revitalized marketing campaign for Atridox and the Atrisorb barrier products. We anticipate that CollaGenex will commence U.S. sales of our dental products during the fourth quarter of 2001.

In September 2001, we submitted an NDA to the FDA for our Leuprogel Three-month product. Under the terms of our agreement with Sanofi-Synthelabo, a \$3 million milestone payment will be payable, within 30 days after the Company gives notice to Sanofi-Synthelabo of the FDA's acceptance for filing of the NDA for the Three-month product. We anticipate receipt of this milestone payment in the fourth quarter of 2001. The \$3 million milestone payment from Sanofi will be recognized as revenue over the remainder of the contract using the straight-line method in accordance with SAB 101.

Effective September 17, 2001, the Board of Directors approved a new stock repurchase program to acquire up to \$5 million of our common stock. In September 2001, we repurchased a total of 52,500 shares of our common stock in the open market at share prices ranging from a low of \$18.06 to a high of approximately \$23.29 for a total stock repurchase value of approximately \$1,039,000.

We continued to devote significant resources during the period ended September 30, 2001 for the research and development of our Leuprogel prostate cancer treatment products, our Atrisone acne treatment product, and our new GHRP-1 product. Research and development efforts with third-party partnerships, such as Pfizer, Geneva Pharmaceuticals, and our joint venture with Elan continued as well. We anticipate the commitment of significant resources for research and development activities will continue throughout the fourth quarter of 2001 for the expeditious advancement of our various products currently in development.

RESULTS OF OPERATIONS

THREE MONTHS ENDED SEPTEMBER 30, 2001 COMPARED TO THREE MONTHS ENDED SEPTEMBER 30, 2000 (RESTATED)

Total revenues for the three months ended September 30, 2001 were approximately \$3,257,000 compared to approximately \$2,585,000 for the three months ended September 30, 2000, representing a 26% increase.

Product net sales and royalty revenue were approximately \$291,000 during the three months ended September 30, 2001 compared to approximately \$1,768,000 for the three months ended September 30, 2000, representing an 84% decrease. This decrease was primarily related to our legal dispute with Block which was settled during the third quarter 2001. As a result, no new shipments of product to Block occurred during the three months ended September 30, 2001.

The three-month period ending September 30, 2001 also included a return of product in the amount of approximately \$317,000.

Contract research and development revenue represents revenue we received from grants, 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 approximately \$1,994,000 for the three months ended September 30, 2001 compared to approximately \$348,000 for the three months ended September 30, 2000. This increase is primarily related to the recognition of revenue for the three months ended September 30, 2001 of approximately \$1,258,000 for oncology and pain management research activities with our joint venture, Transmucosal Technologies. We entered into the joint venture contract with Elan in July of 2000 and did not recognize any joint venture related contract revenue in the third quarter of 2000. Additionally, research activities increased approximately \$462,000 for five collaborative partners.

Licensing fees, marketing rights and milestone revenue recognized in accordance with SAB No. 101 for the three months ended September 30, 2001 was approximately \$971,000 compared to approximately \$469,000 for the three months ended September 30, 2000, representing a 107% increase. This increase is primarily related to the recognition of approximately \$333,000 in license fee and milestone revenue for our Leuprogel products under the Sanofi-Synthelabo and MediGene agreements. In addition, approximately \$165,000 of additional revenue was recognized for the three months ended September 2001 due to the effects related to the amendment of the Block agreement, (See Part II, Item 1. Legal Proceedings) and the net effects of the CollaGenex \$1 million licensing fee net of a \$500,000 reduction of deferred revenue for the additional premium paid on the CollaGenex stock purchase. The net effects of the amendment of the Block agreement will be recognized as revenue over the term of the amended agreement and the licensing of marketing rights to CollaGenex will be recognized as revenue over the term of the CollaGenex agreement using the straight-line method in accordance with SAB No. 101.

Cost of goods sold recorded for the three months ended September 30, 2001 was approximately \$113,000 compared to approximately \$810,000 for the three months ended September 30, 2000, representing an 86% decrease. This decrease in cost of sales correlates to the decline in sales revenue.

Research and development expenses for the three months ended September 30, 2001 were approximately \$7,163,000 compared to approximately \$4,575,000 for the three months ended September 30, 2000, representing a 57% increase. Approximately \$899,000 of this increase was

12

related to a progression through clinical trials of our Leuprogel prostate cancer treatment products and the filing of an NDA for our Leuprogel Three-month product. Approximately \$536,000 is related to oncology and pain management research activities with our joint venture, Transmucosal Technologies. Additionally, approximately \$1,032,000 of the increase was related to our research and development activities for Atrisone, Geneva Pharmaceuticals and GHRP-1.

Research and development - licensing fees for the three months ended September 30, 2001 were approximately \$2,445,000. This expense represents licensing fees paid by us for Tulane's GHRP-1 of \$1,960,000 and Amarillo Biosciences' oral low-dose interferon-alpha of \$485,000.

Administrative and marketing expenses for the three months ended September 30, 2001 were approximately \$1,156,000 compared to approximately

\$1,058,000 for the three months ended September 30, 2000, representing a 9% increase. This increase is primarily due to our donation of approximately \$110,000 for the American Red Cross Disaster Relief Fund to assist families of the victims of the tragic events of September 11, 2001.

Administrative - stock option compensation for the three months ended September 30, 2001 was \$2,000,000. A \$2 million non-qualified stock option 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 approximately \$1,008,000 for the three months ended September 30, 2001 for our 80.1% equity share in the loss of Transmucosal Technologies, our joint venture with Elan, compared to a loss of approximately \$12,035,000 for the three months ended September 30, 2000. The joint venture was established in July 2000 and included a one-time, non-cash charge of \$15,000,000 in the third quarter 2000 for an exclusive license to use Elan's nanoparticulate drug delivery technology. We expect to record additional equity losses for Transmucosal Technologies in the foreseeable future.

Investment income for the three months ended September 30, 2001 was approximately \$977,000 compared to approximately \$523,000 for the three months ended September 30, 2000, representing an 87% 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, 2001 compared to the average balances for the three months ended September 30, 2000. In January 2001, we received \$8 million for a license fee and \$15 million for purchase of our common stock from Sanofi-Synthelabo. We received \$2 million from MediGene to license Leuprogel in Europe and \$3.8 million for MediGene's purchase of our common stock. In June 2001, we received \$3 million from Sanofi-Synthelabo upon acceptance for filing by the FDA of an NDA for our Leuprogel One-month product. In August 2001, we issued a total of 3,450,000 shares of common stock under the shelf registration statement in an underwritten public offering. We received net proceeds of approximately \$74 million in the public offering.

Interest expense for the three months ended September 30, 2001 was approximately \$157,000 compared to approximately \$645,000 for the three months ended September 30, 2000, representing a 76% decrease. The reduction in interest expense was primarily the result of exchanging 1,600,089 shares of our common stock for \$28,679,000 of our 7% Convertible Subordinated Notes since the period ended September 30, 2000.

We issued shares of Series A Convertible Exchangeable Preferred Stock to Elan in July 2000 in connection with the formation of Transmucosal Technologies. Related to this issuance, we recognized approximately \$226,000 for accretion of dividend on the Series A Preferred Stock for the three months ended September 30, 2001 compared to approximately \$171,000 for the three months ended September 30, 2000.

For the reasons described above, we recorded a net loss applicable to common stock of approximately \$10,092,000, or \$.59 per share, for the three months ended September 30, 2001 compared to a net loss applicable to common stock of approximately \$16,098,000, or \$1.33 per share, for the three months ended September 30, 2000.

NINE MONTHS ENDED SEPTEMBER 30, 2001 COMPARED TO NINE MONTHS ENDED SEPTEMBER 30, 2000 (RESTATED)

Total revenues for the nine months ended September 30, 2001 were approximately \$10,775,000 compared to approximately \$7,102,000 for the nine months ended September 30, 2000, representing a 52% increase.

Product net sales and royalty revenue were approximately \$2,867,000 during the nine months ended September 30, 2001 compared to approximately \$4,588,000 for the nine months ended September 30, 2000, representing a 38% decrease. This decrease was primarily related to the settlement of our legal dispute with Block during the third quarter 2001. As a result, no new shipments of product occurred during the three months ended September 30, 2001 and the period also included a return of product in the amount of approximately \$317,000. Additionally, we experienced a decrease of approximately \$239,000 for our Doxirobe periodontal disease treatment product and a reduction in sales of approximately \$496,000 in our contract manufacturing business.

Contract research and development revenue represents revenue we received from grants, 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 approximately \$5,427,000 for the nine months ended September 30, 2001 compared to approximately \$1,108,000 for the nine months ended September 30, 2000. This increase is primarily related to the recognition of revenue of approximately \$3,142,000 for oncology and pain management research activities with our joint venture, Transmucosal Technologies. Additionally, research activities increased approximately \$1,303,000 for five collaborative partners.

Licensing, marketing rights and milestone revenue recognized in accordance with SAB No. 101 for the nine months ended September 30, 2001 was approximately \$2,480,000 compared to approximately \$1,406,000 for the nine months ended September 30, 2000, representing a 76% increase. This increase is primarily related to the recognition of approximately \$828,000 in license fee and milestone revenue for our Leuprogel products under the Sanofi-Synthelabo December 2000 and MediGene April 2001 agreements. In addition, approximately \$165,000 of additional revenue was recognized for the three months ended September 2001 due to the effects related to the amendment of the Block agreement, (See Part II, Item 1. Legal Proceedings) and the net effects of the CollaGenex \$1 million licensing fee and a \$500,000 reduction of deferred revenue for the additional premium paid on the CollaGenex stock purchase. The net effects of the amendment of the Block agreement will be recognized as revenue over the term of the amended agreement

13

and the transfer of marketing rights to CollaGenex will be recognized as revenue over the term of the CollaGenex agreement using the straight-line method in accordance with SAB No. 101.

Cost of goods sold recorded for the nine months ended September 30, 2001 was approximately \$1,153,000 compared to approximately \$1,933,000 for the nine months ended September 30, 2000, representing a 40% decrease. This decrease in cost of sales correlates to the decline in sales revenue.

Research and development expenses for the nine months ended September 30, 2001 were approximately \$19,727,000 compared to approximately \$11,905,000 for the nine months ended September 30, 2000, representing a 66% increase. Approximately \$3,737,000 of this increase was due to the rapid development progress in our Leuprogel for prostate cancer treatment products and the NDA filings of our Leuprogel One-month and Three-month products. Approximately \$1,306,000 of the increase is related to oncology and pain management research activities with our joint venture, Transmucosal Technologies. Additionally, approximately \$2,767,000 of the increase was related to our research and development activities for Atrisone, Geneva Pharmaceuticals and GHRP-1.

Research and development - licensing fees for the nine months ended

September 30, 2001 was approximately \$2,985,000. This expense represents licensing fees paid by us of \$2,500,000 to Tulane for GHRP-1 and \$485,000 to Amarillo BioSciences for oral low-dose interferon-alpha.

Administrative and marketing expenses for the nine months ended September 30, 2001 were approximately \$3,741,000 compared to approximately \$3,271,000 for the nine months ended September 30, 2000, representing a 14% increase. The increase was primarily related to an increase in legal expenses associated with general business planning and activities, including fees for patent/trademark searches and the Block dispute settlement. See Part II, Item 1 Legal Proceedings. Additionally, approximately \$110,000 of the increase was due to our donation for the American Red Cross Disaster Relief Fund to assist families of the victims of the tragic events of September 11, 2001.

Administrative - stock option compensation for the nine months ended September 30, 2001 was \$2,117,000. The increase was primarily due to a \$2 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. The remaining increase related to non-qualified stock options granted to a non-employee for services rendered.

We recognized a loss of approximately \$2,524,000 for the nine months ended September 30, 2001 for our 80.1% equity share in the loss of Transmucosal Technologies, our joint venture with Elan, compared to approximately \$12,035,000 for the nine months ended September 30, 2000. The joint venture was established in July 2000 and recorded a one-time, non-cash charge of \$15,000,000 in the third quarter 2000 for an exclusive license to use Elan's nanoparticulate drug delivery technology. We expect to record additional equity losses for Transmucosal Technologies in the foreseeable future.

Investment income for the nine months ended September 30, 2001 was approximately \$2,433,000 compared to approximately \$1,411,000 for the nine months ended September 30, 2000, representing a 72% 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, 2001 compared to the average balances for the nine months ended September 30, 2000. In January 2001, we received \$8 million for a license fee and \$15 million for purchase of our common stock from Sanofi-Synthelabo in conjunction with the December 2000 agreement. We received \$2 million from MediGene to license Leuprogel in Europe and \$3.8 million for MediGene's purchase of our common stock in conjunction with the April 2001 agreement. In June 2001, we received \$3 million from Sanofi-Synthelabo upon the acceptance for filing by the FDA of an NDA for our Leuprogel One-month product. In August 2001, we issued a total of 3,450,000 shares of common stock under the shelf registration statement in an underwritten public offering. We received net proceeds of approximately \$74 million in the public offering.

Interest expense for the nine months ended September 30, 2001 was approximately \$648,000 compared to approximately \$1,941,000 for the nine months ended September 30, 2000, representing a 67% decrease. The reduction in interest expense was primarily the result of the exchange of shares of our common stock for \$28,679,000 in principal amount of our 7% Convertible Subordinated Notes since the period ended September 30, 2000.

During the nine months ended September 30, 2001, we completed a series of private transactions involving the exchange of 1,600,089 shares of our common stock for \$28,679,000, or 57% of the principal amount of the 7% Convertible Subordinated Notes. Of the 1,600,089 shares issued, 1,509,411 shares were valued at the conversion price of \$19.00 per share and the remaining 90,678 shares were valued at the closing market price as of the various exchange dates. As a result, we recognized an extraordinary loss of approximately \$292,000, for the write-off of approximately \$625,000 of pro rata unamortized deferred finance

charges net of approximately \$333,000 interest expense eliminated as a result of these exchanges. Additionally, part of the 90,678 shares were exchanged for our 7% Convertible Subordinated Notes at prices different than the conversion price of \$19.00, which resulted in debt conversion expense of approximately \$2,106,000 for the nine months ended September 30, 2001. During the nine months ended September 30, 2000, we repurchased a total of \$500,000, or 1% of the offering amount, of the 7% Convertible Subordinated Notes for approximately \$415,000, which included approximately \$7,000 accrued interest paid. As a result, we recognized an extraordinary gain of approximately \$80,000, net of deferred finance charges. As of September 30, 2001 and December 31, 2000, the 7% Convertible Subordinated Notes payable balance was \$7,511,000 and \$36,190,000, respectively.

Effective in the fiscal fourth quarter of 2000, we changed our method of accounting for nonrefundable technology access fees and milestone payments to recognize such payments as revenue over the term of the related agreements. The change in accounting principle is based on guidance provided in SAB No. 101. Previously, we recognized \$24,100,000 for nonrefundable technology access fees and milestone payments as revenue when received and when we fulfilled all contractual obligations relating to the fees and milestone payments. We recorded approximately \$20,612,000 cumulative effect for this change in accounting principle that was reported as a charge in the first quarter of 2000.

We issued shares of our Series A Convertible Exchangeable Preferred Stock to Elan in July 2000 in connection with the formation of Transmucosal Technologies. Related to this issuance, we recognized approximately \$656,000 for accretion of dividend on the Series A Preferred Stock for the nine months ended September 30, 2001 compared to approximately \$171,000 for the nine months ended September 30, 2000.

14

For the reasons described above, we recorded a net loss applicable to common stock of approximately \$22,761,000, or \$1.47 per share, for the nine months ended September 30, 2001 compared to a net loss applicable to common stock of approximately \$43,187,000, or \$3.70 per share, for the nine months ended September 30, 2000.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2001, we had cash and cash equivalents of approximately \$42,597,000, marketable securities (at fair market value) of approximately \$82,063,000 and other current assets of approximately \$8,739,000 for total current assets of approximately \$133,399,000. Current liabilities totaled approximately \$11,958,000, which resulted in working capital of approximately \$121,441,000.

In July 2000, Elan and our company formed Transmucosal Technologies, a joint venture to develop and commercialize oncology and pain management products. Subject to the satisfaction of certain conditions, Elan has agreed to loan us up to \$8,010,000 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. The note also allows us to convert this debt into our common stock at the prevailing market price at maturity. As of September 30, 2001, we had not drawn any amounts under the note.

During the nine months ended September 30, 2001, net cash used in operating activities was approximately \$2,581,000. This was primarily the result of the net loss applicable to common stock for the period of approximately

\$22,761,000, adjusted for certain non-cash expenses, and changes in operating assets and liabilities as set forth in the consolidated statements of cash flows. We received an \$8 million license fee from Sanofi-Synthelabo in January 2001 for payment of the December 2000 Note Receivable - License Fee. Additionally, we recognized non-cash charges for debt conversion expense of approximately \$2,106,000 and approximately \$292,000 as an extraordinary loss on extinguished debt during the nine months ended September 30, 2001 for the exchange of 1,600,089 shares of our common stock to extinguish approximately \$28,679,000 of our 7% Convertible Subordinated Notes. A non-cash charge of \$2 million was recognized in the third quarter of 2001 for the grant of non-qualified stock option to our Chief Executive Officer. The increase of approximately \$4,620,000 for deferred revenue included a \$1 million payment from Block in February 2001 for an Atridox sales milestone payment, a \$3 million payment in June 2001 from Sanofi-Synthelabo for our Leuprogel One-month NDA filing and a \$2 million payment in April 2001 from MediGene for exclusive marketing rights in Europe of our Leuprogel product.

Net cash used in investing activities was approximately \$53,734,000 during the nine months ended September 30, 2001, primarily as a result of investing a portion of the net proceeds from our public stock offering in the third quarter of 2001 in marketable securities.

Net cash provided by financing activities was approximately \$94,474,000 during the nine months ended September 30, 2001. In the third quarter of 2001, we completed our public stock offering that resulted in a net increase in financing funds of approximately \$73,875,000. We received \$15 million from Sanofi-Synthelabo in January 2001 for payment pertaining to Sanofi's common stock purchase in conjunction with the December 2000 collaboration, license and supply agreement. We received \$3.8 million from MediGene for the issuance of our common stock in conjunction with the stock purchase agreement in April 2001. Additionally, approximately \$2,510,000 was received for the issuance of common stock related to employee stock options. Effective September 17, 2001, our Board of Directors approved a new stock repurchase program to acquire up to \$5 million of our common stock. In September 2001, we repurchased a total of 52,500 shares of our common stock in the open market at share prices ranging from a low of \$18.06 to a high of approximately \$23.29 for a total stock repurchase value of approximately \$1,039,000.

In February 2001, we filed a shelf registration statement on Form S-3 with Securities and Exchange Commission registering 4,000,000 shares of our common stock for future issuance. The registration statement was declared effective by the SEC in June 2001. In August 2001, we issued a total of 3,450,000 shares of common stock under the shelf registration statement in an underwritten public offering. We received net proceeds of approximately \$73,875,000 in the public offering, net of issuance costs of approximately \$714,000. There were 550,000 shares available for issuance under the shelf registration as of September 30, 2001.

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

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

o 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 notes or common stock and to hire additional management, scientific, manufacturing and administrative personnel. We will also continue to expend a significant amount of funds in 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. Management believes that 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, we cannot assure you that underlying assumed levels of revenue and expense will prove accurate.

15

RECENT ACCOUNTING PRONOUNCEMENTS

Effective in the fiscal fourth quarter of 2000, we changed our method of accounting for nonrefundable technology access fees and milestone payments to recognize such payments as revenue over the term of the related agreements. The change in accounting principle is based on guidance provided in the Securities and Exchange Commission's Staff Accounting Bulletin No. 101 - Revenue Recognition in Financial Statements. Previously, we recognized \$24,100,000 for nonrefundable technology access fees and milestone payments as revenue when received and when we fulfilled all contractual obligations relating to the fees and milestone payments. We recorded approximately \$20,612,000 cumulative effect for this change in accounting principle that was reported as a charge in the year ended December 31, 2000. The cumulative effect was recorded as deferred revenue that will be recognized as revenue over the remaining contractual terms for each of the specific agreements. During the year ended December 31, 2000, the impact of the change in accounting principle increased net loss applicable to common stock by approximately \$18,734,000, or \$1.58 per share. This amount is comprised of approximately \$20,612,000, or \$1.73 per share, cumulative effect of the change as described above, net of approximately \$1,878,000, or \$0.16 per share, recognized as revenue during the year ended December 31, 2000.

In June 1998, SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, was issued which, as amended, was effective for all fiscal years beginning after June 15, 1999. SFAS No. 133 provides new standards for the identification, recognition and measurement of derivative financial instruments, including embedded derivatives. Historically, we have not entered into derivative contracts to hedge existing risks nor have we entered into speculative derivative contracts. Although our convertible debt and preferred stock include conversion features that are considered to be embedded derivatives, accounting for those instruments is not affected by SFAS No. 133. The adoption of SFAS No. 133 on January 1, 2001 did not result in a transition adjustment in the financial statements.

On June 29, 2001, Statement of Financial Accounting Standards (SFAS) No. 141, "Business Combinations" was issued by the Financial Accounting Standards Board (FASB). SFAS No. 141 requires that the purchase method of accounting be used for all business combinations initiated after June 30, 2001. 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. The Company adopted SFAS No. 141 on July 1, 2001. The adoption of this statement did not have an impact on the Company's consolidated financial position or results of operations.

On June 29, 2001, SFAS No. 142, "Goodwill and Other Intangible Assets" was issued by the FASB. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill recorded in past business combinations, will cease upon adoption of this statement. The Company is required to implement SFAS No. 142 on January 1, 2002 and it has not determined the impact, if any, that this statement will have on its 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 supersedes SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed of," and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," for the disposal of a segment of business. This statement also amends Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to eliminate the exception to consolidation for a subsidiary for which control is likely to be temporary, SFAS No. 144 retains the requirements of SFAS No. 121 to recognize an impairment loss when the carrying amount of a long-lived asset is not recoverable and provides for alternative cash flow measurement methods when more than one course of action is available for the recovery of the carrying amount of the asset. SFAS No. 144 also removes goodwill from its scope. The Company is required to adopt SFAS No 144 on January 1, 2002 and it has not determined the impact, if any, that this statement will have on its consolidated financial position or results of operations.

RISK FACTORS

In addition to the other information contained in this Report, we caution stockholders and potential investors that the following important factors, among others, in some cases have affected, and in the future could affect, our actual results of operations and could cause our actual results to differ materially from those expressed in any forward-looking statements made by or on behalf of our company. The following information is not intended to limit in any way the characterization of other statements or information under other captions as cautionary statements for such purpose. These factors include:

- o 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.
- o Substantial manufacturing and marketing expenses to be incurred in the commercial launch of the Atridox and Atrisorb products and commercializing future products.
- o 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 our company and such corporate partners.
- Our limited experience in the sale and marketing of our products; dependence on CollaGenex to establish effective marketing, sales and distribution capabilities for the Atridox, Atrisorb GTR Barrier, and Atrisorb-Doxy products in

the US. Failure to internally develop marketing channels for the Atrisorb GTR Barrier, Atrisorb-Doxy and Atridox products in Europe.

o 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.

16

- o 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.
- o Product liability or other claims against us which may result in substantial damages or reduce demand for our products.
- O Cancellation or termination of material collaborative agreements and the resulting loss of research or other funding, or marketing, sales and distribution capabilities.
- o Access to the pharmaceutical compounds necessary to successfully commercialize the Atrigel system, Atridox and Atrisorb products or other products and delivery systems currently in development.
- o Competitive or market factors that may limit the use or broad acceptance of our products.
- o The ability to attract and retain highly qualified management and scientific personnel.
- Difficulties or high costs of obtaining adequate financing to fund future research, development and commercialization of products.
- o The slow rate of acceptance of new products.
- o The continued growth and market acceptance of our products and our ability to develop and commercialize new products in a timely and cost-effective manner.
- o Exchange rate fluctuations that may adversely impact net income (loss).
- Our ability to enter into strategic alliances or collaborative arrangements with third parties to market and commercialize our products on favorable terms, if at all.
- o The requirement that we must receive separate regulatory approval for each of our product candidates in each indication before we can sell them in North America or internationally.
- Our ability to successfully acquire and integrate technologies and businesses.

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. We do not own derivative financial instruments in our investment portfolio. Due to the nature of our investment portfolio, the investment portfolio contains instruments that are primarily subject to interest rate risk. Our 7% Convertible Subordinated Notes are also subject to interest rate and equity price risks.

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

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

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

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

To perform a sensitivity analysis, we assess the risk of loss in fair values from the impact of hypothetical changes in interest rates on market sensitive instruments. The fair values are computed based on the present value of future cash flows as impacted by the changes in the rates attributable to the market risk being measured. The discount rates used for the present value computations were selected based on market interest rates in effect at September 30, 2001. The fair values that result from these computations are compared with the fair values of these financial instruments at September 30, 2001. 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, 2001 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 \$517,000 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 \$517,000 per year. We maintain a portion of our financial instruments, including long-term debt instruments of approximately \$11,025,000 at September 30, 2001, at

variable interest rates. If interest rates were to increase or decrease 10%, the impact of such instruments on cash flows or earnings would not be material.

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

The market price of our 7% Convertible Subordinated Notes generally changes in parallel with the market price of our common stock. When our stock price increases, the price of these notes generally increases proportionally. Fair market price of the notes can be determined from quoted market prices, where available. The fair value of our long-term debt was estimated to be approximately \$9,285,000 at September 30, 2001 and is higher than the carrying value by approximately \$1,774,000. Market risk was estimated as the potential decrease in fair value resulting from a hypothetical 1% increase in our weighted average long-term borrowing rate and a 1% decrease in quoted market prices, or approximately \$150,000.

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, 2001 was not material. Based on our overall foreign currency rate exposure at September 30, 2001, we do not believe that a hypothetical 10% change in foreign currency rates would materially affect our financial position.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Effective as of August 24, 2001, we entered into an Eighth Amendment to our agreement with Block Drug Corporation pursuant to which the parties settled all disputes relating to the agreement and agreed to terminate all legal proceedings between the parties relating thereto. Accordingly, under the terms of the Eighth Amendment, each party has released the other party from debts, damages or liabilities relating to the agreement, Block has dismissed the pending arbitration it initiated with respect to the agreement, and we have dismissed the lawsuit we filed in the U.S. District Court for the District of Colorado in May 2001.

Under the terms of the Eighth Amendment to the Block agreement, we reacquired the sales and marketing rights to our Atridox(R), Atrisorb(R) Free Flow and Atrisorb(R) Free Flow with Doxycycline products from Block for \$7.0 million. Of this amount, \$3.3 million was paid upon execution of the Eighth Amendment to the agreement and the balance will generally be payable over a four-year period with the amount payable each year based upon net sales of the Atridox(R), Atrisorb(R) Free Flow and Atrisorb(R) Free Flow with Doxycycline products and/or receipt of licensing fees for the Atridox(R), Atrisorb(R) Free Flow and Atrisorb(R) Free Flow with Doxycycline products. In turn, Block paid us \$3.0 million owed for the development and FDA approval of our Atrisorb(R) Free Flow with Doxycycline product.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

For the nine months ended September 30, 2001, we completed a series of private transactions involving the exchange of 1,600,089 shares of common stock

for \$28,679,000, or 57% of the principal amount, of the 7% Convertible Subordinated Notes. Of the 1,600,089 shares of common stock issued, 1,509,411 shares were valued at the conversion price of \$19.00 per share and the remaining 90,678 shares were valued at the closing market price as of the various exchange dates. Because these transactions constituted an exchange of securities by us exclusively with existing security holders, where no commission or other remuneration was paid or given for soliciting such exchange, the transactions were exempt from registration under the Securities Act of 1933 under Section 3(a) (9) of the Securities Act.

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

- (a) Exhibits.
- 10.01* Eighth Amendment to Agreement by and between Atrix Laboratories, Inc. and Block Drug Corporation, dated as of August 24, 2001.
- 10.02* License Agreement by and between Atrix Laboratories, Inc. and CollaGenex Pharmaceuticals, Inc., dated as of August 24, 2001.
- 10.03* Stock Purchase Agreement by and between Atrix Laboratories, Inc. and CollaGenex Pharmaceuticals, Inc., dated as of August 24, 2001.
- 10.04* Collaboration, License and Supply Agreement by and between Atrix Laboratories, Inc. and Fujisawa Healthcare, Inc., dated October 15, 2001.

*Confidential treatment requested

- (b) Reports on Form 8-K: We filed the following Current Reports on Form 8-K during the quarter ended September 30, 2001:
 - o Current Report on Form 8-K dated April 4, 2001, filed with the Securities and Exchange Commission on June 20, 2001, under Item 5. Other Events, and Item 7. Exhibits.
 - o Current Report on Form 8-K dated August 8, 2001, filed with the Securities and Exchange Commission on August 10, 2001, under Item 5. Other Events, and Item 7. Exhibits.

18

O Current Report on Form 8-K dated August 24, 2001, filed with the Securities and Exchange Commission on August 27, 2001, under Item 5. Other Events, and Item 7. Exhibits.

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)

October 29, 2001 By: /s/ David R. Bethune

David R. Bethune

Chairman of the Board of Directors and

Chief Executive Officer

October 29, 2001 By: /s/ Brian G. Richmond

Brian G. Richmond

Chief Financial Officer and Assistant

Secretary

20

INDEX TO EXHIBITS

EXHIBIT	
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21