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ATRIX LABORATORIES INC  
Form 10-Q  
July 24, 2001

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

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FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2001

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

FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

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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 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  
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The number of shares outstanding of the registrant's common stock as of July 20, 2001 was 15,228,171.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

ATRIX LABORATORIES, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

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(Unaudited)

ASSETS	June 30, 2001	December
	-----	-----
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 19,073,358	\$ 4
Marketable securities available for sale, at fair market value	37,175,684	28
Notes receivable - stock subscription and license fee	--	23
Accounts receivable, net of allowance for doubtful accounts of \$169,431 and \$209,659	2,957,232	2
Interest receivable	417,274	
Inventories	2,787,987	1
Prepaid expenses and deposits	1,416,461	1
	-----	-----
Total current assets	63,827,996	62
	-----	-----
PROPERTY, PLANT AND EQUIPMENT, NET	7,478,584	6
	-----	-----
<b>OTHER ASSETS:</b>		
Intangible assets, net of accumulated amortization of \$2,906,694 and \$2,399,431	3,748,208	4
Deferred finance costs, net of accumulated amortization of \$197,742 and \$628,379	185,684	
	-----	-----
Other assets, net	3,933,892	4
	-----	-----
TOTAL ASSETS	\$ 75,240,472	\$ 74
	=====	=====
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable - trade	\$ 2,929,231	\$ 2
Interest payable	54,939	
Accrued salaries and payroll taxes	362,857	
Other accrued liabilities	145,035	
Deferred revenue	4,538,294	2
	-----	-----
Total current liabilities	8,030,356	5
	-----	-----
DEFERRED REVENUE	28,036,666	24
CONVERTIBLE SUBORDINATED NOTES PAYABLE	9,711,000	36
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
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 preference \$12,827,827 and \$12,397,505	12	
Common stock, \$.001 par value; 45,000,000 shares authorized; 15,204,402 and 13,341,681 shares issued and outstanding	15,204	
Additional paid-in capital	148,171,512	113

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Accumulated other comprehensive loss	(555,204)	
Accumulated deficit	(118,169,074)	(105,000,000)
	-----	-----
Total shareholders' equity	29,462,450	7,000,000
	-----	-----
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 75,240,472	\$ 74,000,000
	=====	=====

See notes to the consolidated financial statements.

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

	2001	2000 (RESTATED)
	-----	-----
REVENUE:		
Net sales and royalties	\$ 1,344,803	\$ 1,663,336
Contract research and development revenue	2,128,653	222,278
Licensing, marketing rights and milestone revenue	791,812	468,444
	-----	-----
Total revenue	4,265,268	2,354,058
	-----	-----
OPERATING EXPENSES:		
Cost of goods sold	609,284	663,860
Research and development	6,340,777	3,609,631
Administrative and marketing	1,431,123	1,187,401
	-----	-----
Total operating expenses	8,381,184	5,460,892
	-----	-----
LOSS FROM OPERATIONS	(4,115,916)	(3,106,834)
	-----	-----
OTHER INCOME (EXPENSE):		
Equity in loss of joint venture	(1,016,018)	--
Investment income	706,936	373,752
Interest expense	(175,839)	(646,603)
Debt conversion expense	(9,184)	--
Other	(22,615)	39,400
	-----	-----
Net other expense	(516,720)	(233,451)
	-----	-----
LOSS BEFORE EXTRAORDINARY ITEM	(4,632,636)	(3,340,285)
Extraordinary loss on extinguished debt	(6,724)	--
	-----	-----
NET LOSS BEFORE PREFERRED STOCK DIVIDEND	(4,639,360)	(3,340,285)
Accretion of dividend on preferred stock	(217,086)	--
	-----	-----
NET LOSS APPLICABLE TO COMMON STOCK	\$ (4,856,446)	\$ (3,340,285)
	=====	=====

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Basic and diluted earnings per common share:		
Loss before extraordinary item	\$ (.31)	\$ (.29)
Extraordinary item	--	--
	-----	-----
Net loss before preferred stock dividend	(.31)	(.29)
Accretion of dividend on preferred stock	(.01)	--
	-----	-----
Net loss applicable to common stock	\$ (.32)	\$ (.29)
	=====	=====
Basic and diluted weighted average common shares outstanding	15,127,406	11,463,355
	=====	=====

See notes to the consolidated financial statements.

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

	2001	2000 (RESTATED)
	-----	-----
REVENUE:		
Net sales and royalties	\$ 2,576,323	\$ 2,820,652
Contract research and development revenue	3,432,933	760,150
Licensing, marketing rights and milestone revenue	1,509,084	936,888
	-----	-----
Total revenue	7,518,340	4,517,690
	-----	-----
OPERATING EXPENSES:		
Cost of goods sold	1,043,486	1,123,084
Research and development	13,104,238	7,330,384
Administrative and marketing	2,701,500	2,211,568
	-----	-----
Total operating expenses	16,849,224	10,665,036
	-----	-----
LOSS FROM OPERATIONS	(9,330,884)	(6,147,346)
	-----	-----
OTHER INCOME (EXPENSE):		
Equity in loss of joint venture	(1,516,661)	--
Investment income	1,455,979	888,038
Interest expense	(490,582)	(1,296,460)
Debt conversion expense	(2,048,347)	--
Other	(23,312)	78,122
	-----	-----
Net other expense	(2,622,923)	(330,300)
LOSS BEFORE EXTRAORDINARY ITEM AND CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE	(11,953,807)	(6,477,646)

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Extraordinary loss on extinguished debt	(288,355)	--
Cumulative effect of change in accounting principle	--	(20,611,526)
	-----	-----
NET LOSS BEFORE PREFERRED STOCK DIVIDEND	(12,242,162)	(27,089,172)
Accretion of dividend on preferred stock	(430,322)	--
	-----	-----
NET LOSS APPLICABLE TO COMMON STOCK	\$ (12,672,484)	\$ (27,089,172)
	=====	=====
Basic and diluted earnings per common share:		
Loss before extraordinary item and cumulative effect of change in accounting principle	\$ (.82)	\$ (.56)
Extraordinary item	(.02)	--
Cumulative effect of change in accounting principle	--	(1.80)
	-----	-----
Net loss before preferred stock dividend	(.84)	(2.36)
Accretion of dividend on preferred stock	(.03)	--
	-----	-----
Net loss applicable to common stock	\$ (.87)	\$ (2.36)
	=====	=====
Basic and diluted weighted average common shares outstanding	14,655,378	11,457,533
	=====	=====

See notes to the consolidated financial statements.

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

	Preferred Stock		Common Stock	
	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 loss 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	--	--	1,482,031	1,482
Issuance of common stock to				

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MediGene	--	--	233,918	234
Non-qualified stock compensation	--	--	--	--
Exercise of non-qualified stock options	--	--	5,000	5
Exercise of stock options	--	--	114,074	114
Issuance for employee stock purchase plan	--	--	1,198	1
Issuance of restricted stock	--	--	26,500	26
	-----	-----	-----	-----
BALANCE, JUNE 30, 2001	12,439	\$ 12	15,204,402	\$ 15,204
	=====	=====	=====	=====

	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity
	-----	-----	-----	-----
BALANCE, DECEMBER 31, 2000	\$ 113,763,660	\$ (471,306)	\$ (105,496,590)	\$ 7,809,118
Comprehensive loss:				
Net loss	--	--	(12,672,484)	(12,672,484)
Other comprehensive loss:				
- Cumulative foreign currency translation adjustments	--	(39,046)	--	(39,046)
- Unrealized loss on investments	--	(44,852)	--	(44,852)
				-----
Net comprehensive loss				(12,756,382)
Issuance of Series A convertible exchangeable preferred stock to Elan for accrued dividends	--	--	--	--
Accretion on preferred stock	430,322	--	--	430,322
Issuance of common stock to extinguish debt	28,525,865	--	--	28,527,347
Issuance of common stock to MediGene	3,779,766	--	--	3,780,000
Non-qualified stock compensation	116,524	--	--	116,524
Exercise of non-qualified stock options	29,995	--	--	30,000
Exercise of stock options	1,242,035	--	--	1,242,149
Issuance for employee stock purchase plan	16,715	--	--	16,716
Issuance of restricted stock	266,630	--	--	266,656
	-----	-----	-----	-----
BALANCE, JUNE 30, 2001	\$ 148,171,512	\$ (555,204)	\$ (118,169,074)	\$ 29,462,450
	=====	=====	=====	=====

See notes to the consolidated financial statements.

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## CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE SIX MONTHS ENDED JUNE 30, 2001 AND 2000 (Unaudited)

	2001
	-----
CASH FLOWS FROM OPERATING ACTIVITIES:	
Net loss applicable to common stock	\$(12,672,484)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:	
Accretion of dividend on preferred stock	430,322
Depreciation and amortization	1,189,378
Equity in loss of joint venture	1,516,661
Loss on sale of property, plant and equipment	23,392
Loss on sale of marketable securities	--
Provision for bad debts	(40,228)
Write-off of obsolete patents	497
Stock compensation	116,524
Debt conversion expense	2,048,347
Extraordinary loss on extinguished debt	288,355
Cumulative effect of change in accounting principle	--
Net changes in operating assets and liabilities:	
Accounts receivable	(358,524)
Note receivable - license fee	8,000,000
Interest receivable	54,927
Inventories	(871,070)
Prepaid expenses and deposits	(332,118)
Accounts payable	(531,952)
Interest payable	136,096
Accrued salaries and payroll taxes	85,547
Other accrued liabilities	(115,559)
Deferred revenue	5,360,108
	-----
Net cash provided by (used in) operating activities	4,328,219
	-----
CASH FLOWS FROM INVESTING ACTIVITIES:	
Acquisition of property, plant and equipment	(1,323,557)
Investments in intangible assets	(206,368)
Proceeds from sale of property, plant and equipment	904
Proceeds from sale of marketable securities	--
Proceeds from maturity of marketable securities	18,740,841
Investment in marketable securities	(27,066,960)
	-----
Net cash provided by (used in) investing activities	(9,855,140)
	-----
CASH FLOWS FROM FINANCING ACTIVITIES:	
Proceeds from issuance of equity securities	5,335,521
Note receivable - stock subscription	15,000,000
	-----
Net cash provided by financing activities	20,335,521
	-----
NET EFFECT OF EXCHANGE RATE ON CASH	(219,572)
	-----
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	14,589,028
	-----
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	4,484,330
	=====

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CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 19,073,358
	=====
Supplemental cash flow information:	
Cash paid for interest	\$ 354,486
	=====

Non-cash activities:

During the six months ended June 30, 2001, the Company issued common stock valued at \$28,527,347 to extinguish \$26,479,000 of the convertible subordinated notes.

See notes to the consolidated financial statements.

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ATRIX LABORATORIES, INC. AND SUBSIDIARIES  
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE SIX MONTHS ENDED JUNE 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. 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.



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On June 29, 2001, Statement of Financial Accounting Standards (SFAS) No. 141, "Business Combinations" was approved 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 is required to implement SFAS No. 141 on July 1, 2001 and it has not determined the impact, if any, that this statement will have on its consolidated financial position or results of operations.

On June 29, 2001, SFAS No. 142, "Goodwill and Other Intangible Assets" was approved 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.

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 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 six months ended June 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.

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

	2000 (AS PREVIOUSLY REPORTED)	SAB NO. 101 ADJUSTMENTS	2000 (RESTATED)
	-----	-----	-----
REVENUE:			
Net sales and royalties	\$ 1,663,336	\$ --	\$ 1,663,336
Contract research and development revenue	222,278	--	222,278
Licensing, marketing rights and milestone revenue	40,000	428,444	468,444
	-----	-----	-----

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Total revenue	1,925,614	428,444	2,354,058
OPERATING EXPENSES:			
Cost of goods sold	663,860	--	663,860
Research and development	3,609,631	--	3,609,631
Administrative and marketing	1,187,401	--	1,187,401
Total operating expenses	5,460,892	--	5,460,892
INCOME (LOSS) FROM OPERATIONS	(3,535,278)	428,444	(3,106,834)
OTHER INCOME (EXPENSE):			
Investment income	373,752	--	373,752
Interest expense	(646,603)	--	(646,603)
Other	39,400	--	39,400
Net other expense	(233,451)	--	(233,451)
NET LOSS	\$ (3,768,729)	\$ 428,444	\$ (3,340,285)
Basic and diluted earnings per common share:			
Net loss	\$ (.33)		\$ (.29)
Basic and diluted weighted average common shares outstanding			
	11,463,355		11,463,355

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

	2000 (AS PREVIOUSLY REPORTED)	SAB NO. 101 ADJUSTMENTS	2000 (RESTATED)
REVENUE:			
Net sales and royalties	\$ 2,820,652	\$ --	\$ 2,820,652
Contract research and development revenue	760,150	--	760,150
Licensing, marketing rights and milestone revenue	105,000	831,888	936,888
Total revenue	3,685,802	831,888	4,517,690
OPERATING EXPENSES:			
Cost of goods sold	1,123,084	--	1,123,084
Research and development	7,330,384	--	7,330,384
Administrative and marketing	2,211,568	--	2,211,568

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Total operating expenses	10,665,036	--	10,665,036
	-----	-----	-----
INCOME (LOSS) FROM OPERATIONS	(6,979,234)	831,888	(6,147,346)
	-----	-----	-----
OTHER INCOME (EXPENSE):			
Investment income	888,038	--	888,038
Interest expense	(1,296,460)	--	(1,296,460)
Other	78,122	--	78,122
	-----	-----	-----
Net other expense	(330,300)	--	(330,300)
INCOME (LOSS) BEFORE CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE	(7,309,534)	831,888	(6,477,646)
Cumulative effect of change in accounting principle	--	(20,611,526)	(20,611,526)
	-----	-----	-----
NET LOSS	\$ (7,309,534)	\$ (19,779,638)	\$ (27,089,172)
	=====	=====	=====
Basic and diluted earnings per common share:			
Income (loss) before cumulative effect of change in accounting principle	\$ (.64)		\$ (.5)
Cumulative effect of change in accounting principle	--		(1.8)
	-----	-----	-----
Net loss	\$ (.64)		\$ (2.3)
	=====	=====	=====
Basic and diluted weighted average common shares outstanding	11,457,533		11,457,533
	=====	=====	=====

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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 June 30, 2001 and December 31, 2000, are as follows:

	June 30, 2001	December 31, 2000
	-----	-----
Raw materials	\$1,982,248	\$1,616,878
Work in process	495,473	144,723

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Finished goods	310,266	179,328
	-----	-----
	\$2,787,987	\$1,940,929
	=====	=====

NOTE 4. PROPERTY, PLANT, AND EQUIPMENT

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

	June 30, 2001	December 31, 2000
	-----	-----
Land	\$ 1,071,018	\$ 1,071,018
Building	3,616,693	3,610,068
Leasehold improvements	580,563	470,002
Furniture and fixtures	561,404	440,534
Machinery	5,756,210	5,038,815
Office equipment	1,100,188	813,317
	-----	-----
Total property, plant and equipment	12,686,076	11,443,754
Accumulated depreciation and amortization	(5,207,492)	(4,625,382)
	-----	-----
Property, plant and equipment, net	\$ 7,478,584	\$ 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 June 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 six months ended June 30, 2001 and 2000, approximately 1.8 million and 1.9 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 six months ended June 30, 2001, the Company completed a series of private transactions involving the exchange of 1,482,031 issued common shares for \$26,479,000, or 53% of the original offering amount, of the 7% convertible subordinated notes. Of the 1,482,031 shares issued, 1,393,629 shares were valued at the conversion price of \$19.00 per share and the remaining 88,402 were valued at the closing market price as of the various exchange dates. As a

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result, the Company recognized an extraordinary loss of approximately \$288,000, for the write-off of approximately \$585,000 of pro rata unamortized deferred finance charges net of approximately \$297,000 interest expense eliminated as a result of these exchanges. Additionally, as part of the 88,402 shares issued to induce conversion, debt conversion expense of approximately \$2,048,000 was recognized in the six months ended June 30, 2001. As of June 30, 2001 and December 31, 2000, the convertible notes payable balance was \$9,711,000 and \$36,190,000, respectively.

### NOTE 7. PENDING LEGAL ACTION

The Company has been involved in disputes with Block Drug Corporation, a wholly owned subsidiary of GlaxoSmithKline, concerning product pricing and the payments due to the Company upon achievement of milestones under the Company's commercialization agreement with Block. With

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respect to product pricing, arbitration began in December 2000 to resolve the issue as to the minimum price Block must pay for products under the agreement. On April 20, 2001, the Company entered into a settlement agreement with Block resolving the pricing dispute over Block's sale of Atridox. The settlement agreement provides for the payment owed to the Company for sales of the product in 1999. A new pricing schedule for future purchases was also implemented.

With respect to milestone payments, the Company believes that under the agreement, the milestone for the FDA approval of the Atrisorb-Doxy Barrier product was achieved in 2000 and the corresponding payment of \$1,000,000 is due. Block has not made this payment. Pursuant to the Company's agreement with Block, the Company will be entitled to an additional milestone payment of \$2,000,000 upon Block's first commercial sale of the Atrisorb-Doxy Barrier product in the United States. The agreement provides that the first commercial sale of this product in the U.S. must occur within 120 days after FDA approval, subject to certain conditions that have been satisfied. The FDA approved the Atrisorb-Doxy Barrier product in September 2000. The Company has notified Block that it is in breach of the agreement for failure to commence marketing of the Atrisorb-Doxy Barrier product and on May 11, 2001 the Company filed a lawsuit in the U.S. District Court for the District of Colorado seeking injunctive relief based on Block's breach of the agreement. Block has initiated arbitration, and an arbitration hearing has been set for November 13, 2001. The Company intends to vigorously pursue its rights to these milestone payments.

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### ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion relates to the restated interim amounts for the period ended June 30, 2000, a result of the change in accounting principle for the recognition of revenue as discussed in Note 1 to the Consolidated Financial Statements of this report. 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

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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, Ltd. The success of our business operations is in turn 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: safe and effective, wide array and ease of applications, site-specific or systemic delivery, customized release rates and biodegradability. With the acquisition of ViroTex 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, Geneva Pharmaceuticals, Del Pharmaceuticals, Pharmacia & Upjohn Animal Health, Block Drug Company/GlaxoSmithKline, and J.B. Williams Company.

In January 2001, we purchased an exclusive option from Tulane University Health Science Center to license growth hormone releasing peptide-1, or GHRP-1, a patented growth-promoting compound. Previously we focused on reformulating existing compounds in our drug delivery technologies. The 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. We intend to deliver GHRP-1 for an extended period of time using our patented ATRIGEL drug delivery system.

In April 2001, we entered into an exclusive European marketing agreement with MediGene AG, a Germany based biotechnology company, for the Leuprogel products. In the agreement, valued at approximately \$20 million, we received an up-front license fee payment of \$2 million in April 2001 and will receive additional payments for certain clinical, regulatory and sales milestones. The \$2 million license fee from MediGene will be recognized as revenue over a ten-year period using the straight-line method in accordance with

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the Securities and Exchange Commission's Staff Accounting Bulletin No. 101 - Revenue Recognition in Financial Statements. 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, net of \$220,000 for issuance costs, 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 for the filing of the New Drug Application, or NDA, for Leuprogel One-month product in accordance with the exclusive North American marketing agreement entered into with Sanofi-Synthelabo during December 2000. 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.

We continued to devote significant resources during the period ended June 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 2001 for the expeditious advancement of our various products currently in development.

### RESULTS OF OPERATIONS

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

Total revenues for the three months ended June 30, 2001 were approximately \$4,265,000 compared to approximately \$2,354,000 for the three months ended June 30, 2000, representing an 81% increase.

Product net sales and royalty revenue were approximately \$1,345,000 during the three months ended June 30, 2001 compared to approximately \$1,663,000 for the three months ended June 30, 2000, representing a 19% decrease. This decrease was primarily related to a reduction of approximately \$161,000 in sales of our Doxirobe periodontal disease product, which is used in companion animals, as well as a reduction of approximately \$121,000 in sales 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 \$2,129,000 for the three months ended June 30, 2001 compared to approximately \$222,000 for the three months ended June 30, 2000, representing an 859% increase. This increase is primarily related to the recognition of revenue for the three months ended June 30, 2001 of approximately \$1,258,000 for oncology and pain management research activities with our joint venture, Transmucosal Technologies, Ltd., which commenced in October 2000, approximately \$192,000 for dermatology research activities with Geneva Pharmaceuticals, which commenced in August 2000, and an increase of approximately \$371,000 for research projects for Pfizer.

Licensing fees, marketing rights and milestone revenue recognized in

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accordance with SAB No. 101 for the three months ended June 30, 2001 was approximately \$792,000 compared to approximately \$468,000 for the three months ended June 30, 2000, representing a 69% increase. This increase is primarily related to the recognition of approximately \$295,000 in license fee revenue for our Leuprogel products under the Sanofi-Synthelabo December 2000 and MediGene April 2001 agreements. The Block agreement provides for potential milestone payments totaling up to \$50 million to us over a three-to-five year period, as well as manufacturing margins and royalties on sales. Prior to 2001, we had received \$24.1 million in milestone payments from Block. In February 2001, we received a \$1,000,000 Atridox sales milestone payment from Block. These milestone payments will be recognized as revenue over a ten-year period using the straight-line method. We are currently in dispute with Block pertaining to two ATRISORB-DOXY milestone payments. See Part II, Item 1. Legal Proceedings. Additionally, the European Leuprogel license fee from MediGene for \$2 million was received in April 2001 and will be recognized over a ten-year period in accordance with SAB No. 101.

Cost of goods sold recorded for the three months ended June 30, 2001 was approximately \$609,000 compared to approximately \$664,000 for the three months ended June 30, 2000, representing an 8% decrease. This decrease in cost of sales correlates primarily to the decline in sales revenue.

Research and development expenses for the three months ended June 30, 2001 were approximately \$6,341,000 compared to approximately \$3,610,000 for the three months ended June 30, 2000, representing a 76% increase. Approximately \$1,149,000 of this increase was related to a progression through clinical trials for our Leuprogel for prostate cancer treatment products. Approximately \$534,000 is related to oncology and pain management research activities with our joint venture, Transmucosal Technologies, Ltd. Dermatology research and development activities for Geneva Pharmaceuticals related projects increased approximately \$324,000 for the second quarter of 2001. Additionally, Atrisone research and development expenditures increased approximately \$555,000 for the three months ending June 30, 2001. Atrisone Phase III patient enrollment commenced in April 2001.

Administrative and marketing expenses for the three months ended June 30, 2001 were approximately \$1,431,000 compared to approximately \$1,187,000 for the three months ended June 30, 2000, representing a 21% increase. The increase was primarily related to an increase in legal expenses associated with general business planning and activities, including fees for patents/trademark searches and the Block dispute. See Part II, Item 1. Legal Proceedings.

We recognized a loss of approximately \$1,016,000 for the three months ended June 30, 2001 for our 80.1% equity share in the loss of Transmucosal Technologies, our joint venture with Elan compared to -0- for the three months ended June 30, 2000. The joint venture was established in June 2000. Currently, the joint venture is developing two products using our BEMA drug delivery system. We expect to record additional equity losses for Transmucosal Technologies in the foreseeable future.

Investment income for the three months ended June 30, 2001 was approximately \$707,000 compared to approximately \$374,000 for the three months ended June 30, 2000, representing an 89% increase. The increase was primarily the result of a net increase in our cash and cash equivalents and our marketable securities of approximately \$28,019,000 for the second quarter of 2001 in comparison to the second quarter 2000. The increase in our cash and investment balances was primarily the result of receiving an \$8 million license fee and a \$15 million purchase of our common stock from Sanofi-Synthelabo in January 2001 in conjunction with the December 2000 agreement. Additionally, we received a \$2 million payment from MediGene in April 2001 to license Leuprogel in Europe and a \$3 million payment from Sanofi-Synthelabo in June 2001 for the NDA filing of Leuprogel One-month product.



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Interest expense for the three months ended June 30, 2001 was approximately \$176,000 compared to approximately \$647,000 for the three months ended June 30, 2000, representing a 73% decrease. The reduction in interest expense was primarily the result of exchanging 1,482,031 shares of common stock for \$26,479,000 of our 7% convertible subordinated notes since the period ended June 30, 2000.

We issued Series A convertible exchangeable preferred stock to Elan in July 2000 in connection with the formation of our joint venture with Elan. Related to this issuance, we recognized approximately \$217,000 for accretion of dividend on preferred stock for the three months ended June 30, 2001.

For the reasons described above, we recorded a net loss applicable to common stock of approximately \$4,856,000, or \$.32 per share, for the three months ended June 30, 2001 compared to a net loss applicable to common stock of approximately \$3,340,000, or \$.29 per share, for the three months ended June 30, 2000.

### SIX MONTHS ENDED JUNE 30, 2001 COMPARED TO SIX MONTHS ENDED JUNE 30, 2000 (RESTATED)

Total revenues for the six months ended June 30, 2001 were approximately \$7,518,000 compared to approximately \$4,518,000 for the six months ended June 30, 2000, representing a 66% increase.

Product net sales and royalty revenue were approximately \$2,576,000 during the six months ended June 30, 2001 compared to approximately \$2,821,000 for the six months ended June 30, 2000. This 9% decrease was primarily related to a reduction of sales of approximately \$209,000 for our Doxirobe periodontal disease treatment product, which is used in companion animals, as well as a reduction in sales of approximately \$114,000 for our contract manufacturing business.

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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 \$3,433,000 for the six months ended June 30, 2001 compared to approximately \$760,000 for the six months ended June 30, 2000, representing a 352% increase. This increase is primarily related to the recognition of revenue of approximately \$1,883,000 for oncology and pain management research activities with our joint venture, Transmucosal Technologies, Ltd., approximately \$407,000 for dermatology research activities with Geneva Pharmaceuticals and approximately \$258,000 for research projects with Pfizer.

Licensing, marketing rights and milestone revenue recognized in accordance with SAB No. 101 for the six months ended June 30, 2001 was approximately \$1,509,000 compared to approximately \$937,000 for the six months ended June 30, 2000, representing a 61% increase. This increase is primarily related to the recognition of approximately \$495,000 in license fee revenue for our Leuprogel products under the Sanofi-Synthelabo December 2000 and MediGene April 2001 agreements. The Block agreement provides for potential milestone payments totaling up to \$50 million to us over a three-to-five year period, as well as manufacturing margins and royalties on sales. Prior to 2001, we had received \$24.1 million in milestone payments from Block. In February 2001, we

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received a \$1,000,000 Atridox sales milestone payment from Block. These milestone payments will be recognized as revenue over a ten-year period using the straight-line method. We are currently in a dispute with Block pertaining to two Atrisorb-Doxy milestone payments. See Part II, Item 1. Legal Proceedings. Additionally, the European Leuprogel license fee from MediGene for \$2,000,000 was received in April 2001 and will be recognized over a ten-year period.

Cost of goods sold recorded for the six months ended June 30, 2001 was approximately \$1,043,000 compared to approximately \$1,123,000 for the six months ended June 30, 2000, representing a 7% decrease. This decrease in cost of sales correlates to the decline in sales revenue.

Research and development expenses for the six months ended June 30, 2001 were approximately \$13,104,000 compared to approximately \$7,330,000 for the six months ended June 30, 2000, representing a 79% increase. Approximately \$2,878,000 of this increase was due to the rapid progress in our Leuprogel for prostate cancer treatment products. Approximately \$773,000 is related to oncology and pain management research activities with our joint venture, Transmucosal Technologies, Ltd. Dermatology research and development activities for Geneva Pharmaceuticals related projects increased approximately \$739,000. In January 2001, we purchased an exclusive option from Tulane University Health Science Center to license growth hormone releasing peptide-1, or GHRP-1, a patented growth-promoting compound. Research and development activities for the GHRP-1 were approximately \$818,000 for the six months ended June 30, 2001. Additionally, Atrisone research and development expenditures increased approximately \$725,000. Atrisone Phase III patient enrollment commenced in April 2001.

Administrative and marketing expenses for the six months ended June 30, 2001 were approximately \$2,702,000 compared to approximately \$2,212,000 for the six months ended June 30, 2000, representing a 22% increase. The increase was primarily related to an increase in legal expenses associated with general business planning and activities, including fees for patents/trademark searches and the Block dispute. See Part II, Item 1 Legal Proceedings.

We recognized a loss of approximately \$1,517,000 for the six months ended June 30, 2001 for our 80.1% equity share in the loss of Transmucosal Technologies, our joint venture with Elan, compared to -0- for the six months ended June 30, 2000. The joint venture was established in June 2000. Currently, the joint venture is developing two products using our BEMA drug delivery system. The BEMA with fentanyl compound targets breakthrough cancer pain and management of chronic pain. The second compound also utilizes our BEMA technology with an anti-emetic product, ondansetron, for the prevention of nausea associated with cancer chemotherapy. We expect to record additional equity losses for Transmucosal Technologies in the foreseeable future.

Investment income for the six months ended June 30, 2001 was approximately \$1,456,000 compared to approximately \$888,000 for the six months ended June 30, 2000, representing a 64% increase. The increase was primarily the result of a net increase in our cash and cash equivalents and our marketable securities of approximately \$28,019,000 for the six months ended June 30, 2001 in comparison to the six months ended June 30, 2000. The increase in our cash and investment balances was primarily the result of receiving an \$8,000,000 license fee and a \$15,000,000 purchase of our common stock from Sanofi-Synthelabo in January 2001 in conjunction with the December 2000 agreement. Additionally, we received a \$2,000,000 payment from MediGene in April 2001 to license Leuprogel in Europe and a \$3,000,000 payment from Sanofi-Synthelabo in June 2001 for the NDA filing of the Leuprogel One-month product.

Interest expense for the six months ended June 30, 2001 was approximately \$491,000 compared to approximately \$1,296,000 for the six months

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ended June 30, 2000, representing a 62% decrease. The reduction in interest expense was primarily the result of exchanges of common stock for \$26,479,000 of our 7% convertible subordinated notes since the period ended June 30, 2000.

During the six months ended June 30, 2001, we completed a series of private transactions involving the exchange of 1,482,031 issued common shares for \$26,479,000, or 53% of the original offering amount, of the 7% convertible subordinated notes. Of the 1,482,031 shares issued, 1,393,629 shares were valued at the conversion price of \$19.00 per share and the remaining 88,402 were valued at the closing market price as of the various exchange dates. As a result, we recognized an extraordinary loss of approximately \$288,000, for the write-off of approximately \$585,000 of pro rata unamortized deferred finance charges net of approximately \$297,000 interest expense eliminated as a result of these exchanges. Additionally, as part of the 88,402 shares issued to induce conversion, debt conversion expense of approximately \$2,048,000 was recognized in the six months ended June 30, 2001. As of June 30, 2001 and December 31, 2000, the convertible notes payable balance was \$9,711,000 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 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 first quarter of 2000.

We issued Series A convertible exchangeable preferred stock to Elan in July 2000 in connection with the formation of our joint venture with

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Elan. Related to this issuance, we recognized approximately \$430,000 for accretion of dividend on preferred stock for the six months ended June 30, 2001.

For the reasons described above, we recorded a net loss applicable to common stock of approximately \$12,672,000, or \$.87 per share, for the six months ended June 30, 2001 compared to a net loss applicable to common stock of approximately \$27,089,000, or \$2.36 per share, for the six months ended June 30, 2000.

### LIQUIDITY AND CAPITAL RESOURCES

As of June 30, 2001, we had cash and cash equivalents of approximately \$19,073,000, marketable securities (at fair market value) of approximately \$37,176,000 and other current assets of approximately \$7,579,000 for total current assets of approximately \$63,828,000. Current liabilities totaled approximately \$8,030,000, which resulted in working capital of approximately \$55,798,000.

We have a revolving line of credit with a bank that expires in August 2001. Under the terms of the line of credit, we may borrow up to \$1,000,000. 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. As of June 30, 2001, we had no outstanding balance under this line of

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credit.

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 June 30, 2001, we had not drawn any amounts under the note.

During the six months ended June 30, 2001, net cash provided by operating activities was approximately \$4,328,000. This was primarily the result of the net loss for the period of approximately \$12,672,000, 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 \$8,000,000 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 \$2,048,000 and approximately \$288,000 as an extraordinary loss on extinguished debt during the six months ended June 30, 2001 for the exchange of 1,482,031 shares of our common stock to extinguish approximately \$26,479,000 our convertible subordinated notes. The increase of approximately \$5,360,000 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 the execution of the collaboration license and supply agreement for exclusive marketing rights in Europe of our Leuprogel product.

Net cash used in investing activities was approximately \$9,855,000 during the six months ended June 30, 2001, primarily as a result of approximately \$27,067,000 for the purchase of six government bond investments and thirteen corporate note investments. This was offset by proceeds of approximately \$18,741,000 for six called government bond investments.

Net cash provided by financing activities was approximately \$20,336,000 during the six months ended June 30, 2001. We received \$15,000,000 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 \$3.78 million from MediGene for the issuance of our common stock in conjunction with the stock purchase agreement in April 2001. Additionally, approximately \$1,242,000 was received for the issuance of common stock related to employee stock options.

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.

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

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facilities,

- o 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 through 2001. However, we cannot assure you that underlying assumed levels of revenue and expense will prove accurate.

### 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

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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. The remainder of the related deferred revenue will be recognized as revenue approximately as follows: \$1,885,000 for each year from 2001 through 2010 and \$11,000 for each year from 2011 through 2015 and \$2,000 in 2016.

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.

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On June 29, 2001, Statement of Financial Accounting Standards (SFAS) No. 141, "Business Combinations" was approved 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. We are required to implement SFAS No. 141 on July 1, 2001 and we have not determined the impact, if any, that this statement will have on our consolidated financial position or results of operations.

On June 29, 2001, SFAS No. 142, "Goodwill and Other Intangible Assets" was approved 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. We are required to implement SFAS No. 142 on January 1, 2002 and we have not determined the impact, if any, that this statement will have on our 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.
- o Our limited experience in the sale and marketing of our products; dependence on Block to establish effective marketing, sales and distribution capabilities for the ATRIDOX, ATRISORB GTR Barrier, and ATRISORB-DOXY products in North America. Failure to internally develop marketing channels for the ATRISORB GTR Barrier, ATRISORB-DOXY and ATRIDOX products in Europe.
- o Outcome of our disputes with Block, fees and expenses associated therewith and impact upon Block's marketing, sales and distribution of our products.
- 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.

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- 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 (including the Block agreement) 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.

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- o 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).
- o 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.
- o 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 convertible subordinated notes are also subject to interest rate and equity price risks.

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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 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 June 30, 2001. The fair values that result from these computations are compared with the fair values of these financial instruments at June 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 June 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 \$285,000 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 \$285,000 per year. We maintain a portion of our financial instruments, including long-term debt instruments of approximately \$7,915,000 at June 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 \$12,260,000 at June 30, 2001 and is higher than the carrying value



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by approximately \$2,549,000. 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 \$194,220.

Exchange Rate Risk. We face foreign exchange rate fluctuations, primarily with respect to the British Pound and the Euro, as the financial results of our foreign subsidiaries are translated into United States dollars for consolidation. As exchange rates vary, these results, when translated may vary from expectations and adversely impact net income (loss) and overall profitability. The effect of foreign exchange rate fluctuation for the period ended June 30, 2001 was not material. Based on our overall foreign currency rate exposure at June 30, 2001, we do not believe that a hypothetical

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10% change in foreign currency rates would materially affect our financial position.

### PART II - OTHER INFORMATION

#### ITEM 1. LEGAL PROCEEDINGS.

The Company has been involved in disputes with Block Drug Corporation, a wholly owned subsidiary of GlaxoSmithKline, concerning product pricing and the payments due to the Company upon achievement of milestones under the Company's commercialization agreement with Block. With respect to product pricing, arbitration began in December 2000 to resolve the issue as to the minimum price Block must pay for products under the agreement. On April 20, 2001, the Company entered into a settlement agreement with Block resolving the pricing dispute over Block's sale of Atridox. The settlement agreement provides for the payment owed to the Company for sales of the product in 1999. A new pricing schedule for future purchases was also implemented.

With respect to milestone payments, the Company believes that under the agreement, the milestone for the FDA approval of the Atrisorb-Doxy Barrier product was achieved in 2000 and the corresponding payment of \$1,000,000 is due. Block has not made this payment. Pursuant to the Company's agreement with Block, the Company will be entitled to an additional milestone payment of \$2,000,000 upon Block's first commercial sale of the Atrisorb-Doxy Barrier product in the United States. The agreement provides that the first commercial sale of this product in the U.S. must occur within 120 days after FDA approval, subject to certain conditions that have been satisfied. The FDA approved the Atrisorb-Doxy Barrier product in September 2000. The Company has notified Block that it is in breach of the agreement for failure to commence marketing of the Atrisorb-Doxy Barrier product and on May 11, 2001 the Company filed a lawsuit in the U.S. District Court for the District of Colorado seeking injunctive relief based on Block's breach of the agreement. Block has initiated arbitration, and an arbitration hearing has been set for November 13, 2001. The Company intends to vigorously pursue its rights to these milestone payments.

#### ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

For the six months ended June 30, 2001, the Company completed a series of private transactions involving the exchange of 1,482,031 issued common shares for \$26,479,000, or 53% of the original offering amount, of the 7% convertible subordinated notes. Of the 1,482,031 shares issued, 1,393,629 shares were valued at the conversion price of \$19.00 per share and the remaining 88,402 were valued at the closing market price as of the various exchange dates. Because these

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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.

In April 2001, the Company entered into a collaboration, license and supply agreement with MediGene AG under which MediGene was granted the exclusive right to market our Leuprogel products in Europe. In connection with the transaction, MediGene purchased 233,918 shares of our common stock for approximately \$3.78 million, pursuant to a stock purchase agreement. This transaction was made in reliance on the exemption from the registration requirements of the Securities Act of 1933 provided by Section 4(2) of the Securities Act. This transaction was privately negotiated and the Company made no public solicitation in the placement of these securities.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

An annual meeting of the stockholders of the Company was held on May 7, 2001, in Fort Collins, Colorado, for the purpose of re-electing David R. Bethune, Dr. Richard L. Jackson, and Dr. Nicolas G. Bazan to the Board of Directors as Class B directors, approving the amendment of the 2000 Stock Incentive Plan, approving the amendment of the Company's Amended and Restated Certificate of Incorporation increasing the number of authorized capital shares, and ratifying the appointment of the Company's independent auditors.

The following votes were cast by the stockholders with respect to the election of directors:

	Shares Voted For -----	Shares Voted Against -----	Shares Voted Withhold -----	Shares Voted Abstained -----	Broker Non-Vote -----
David R. Bethune	13,126,764	689,674	--	--	--
Dr. Richard L. Jackson	13,298,781	517,657	--	--	--
Dr. Nicolas G. Bazan	13,194,906	621,532	--	--	--

The other directors whose term continues after the meeting are John E. Urheim, Sander A. Flaum, Dr. D. Walter Cohen, C. Rodney O'Connor, H. Stuart Campbell.

The following votes were cast by the stockholders with respect to the amendment to the 2000 Stock Incentive Plan.

	Shares Voted For -----	Shares Voted Against -----	Shares Voted Withhold -----	Shares Voted Abstained -----	Broker Non-Vote -----
	6,779,223	1,954,619	--	70,142	--

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The following votes were cast by the stockholders with respect to the amendment to the Company's Amended and Restated Certificate of Incorporation:

Shares Voted For -----	Shares Voted Against -----	Shares Voted Withhold -----	Shares Voted Abstained -----	Broken Non-Vote -----
7,766,664	969,846	--	67,474	--

The following votes were cast by the stockholders with respect to the resolution to ratify the Board of Directors' selection of Deloitte & Touche LLP as the Company's independent auditors for the fiscal year ending December 31, 2001:

Shares Voted For -----	Shares Voted Against -----	Shares Voted Withhold -----	Shares Voted Abstained -----	Broken Non-Vote -----
13,483,954	287,870	--	44,614	--

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:

3.1 Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to the Company's Registration Statement on Form S-3, file number 333-55634).

(b) Reports on Form 8-K. We filed the following Current Reports on Form 8-K during the quarter ended June 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 April 20, 2001, filed with the Securities and Exchange Commission on April 24, 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.

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(Registrant)

July 24, 2001

By: /s/ David R. Bethune

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David R. Bethune  
Chairman of the Board of Directors and Chief  
Executive Officer

July 24, 2001

By: /s/ Brian G. Richmond

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Brian G. Richmond  
Chief Financial Officer and Assistant Secretary

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EXHIBIT INDEX

EXHIBIT  
NO.  
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DESCRIPTION  
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3.1	Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to the Company's Registration Statement on Form S-3, file number 333-55634).
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