IPC HOLDINGS LTD Form 425 April 16, 2009

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

FORM 8-K CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 Date of Report (Date of earliest event reported): April 16, 2009

VALIDUS HOLDINGS, LTD.

(Exact name of registrant as specified in its charter)

Bermuda 001-33606 98-0501001

(State or other jurisdiction of incorporation)

(Commission File Number)

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

19 Par-La-Ville Road, Hamilton, HM 11 Bermuda

(Address of principal executive offices)

Registrant s telephone number, including area code: (441) 278-9000 Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- b Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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EX-99.1: PRESS RELEASE

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Item 8.01 Other Events.

On April 16, 2009, Validus Holdings, Ltd. (Validus) issued a press release. The press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits. The following exhibits are filed herewith:

Exhibit No. Description

99.1 Press Release, dated April 16, 2009, entitled Validus Holdings Files Preliminary Proxy Statement in

connection with Special Meeting of its Shareholders.

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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 hereunto duly authorized.

Date: April 16, 2009

VALIDUS HOLDINGS, LTD. (Registrant)

By: /s/ Joseph E. (Jeff) Consolino Name: Joseph E. (Jeff) Consolino

Title: Executive Vice President & Chief

Financial Officer

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EXHIBIT INDEX

Exhibit Description

Exhibit 99.1 Press Release, dated April 16, 2009, entitled Validus Holdings Files Preliminary Proxy Statement in connection with Special Meeting of its Shareholders.

accounting principle (20,611,526) NET LOSS BEFORE PREFERRED STOCK DIVIDEND
(7,601,926) (23,751,328) Accretion of dividend on preferred stock (213,236)
APPLICABLE TO COMMON STOCK \$ (7,815,162) \$(23,751,328) ====================================
diluted earnings per common share: Loss before extraordinary item and cumulative effect of change in accounting
•
principle \$ (.52) \$ (.28) Extraordinary item (.02) Cumulative effect of change in accounting principle (1.80)
Net loss before preferred stock dividend (.54) (2.08) Accretion of dividend on preferred stock
(.01)
Basic and diluted weighted average common shares outstanding 14,178,105 11,439,792 ====================================
======== See notes to the consolidated financial statements. 3 4 ATRIX LABORATORIES, INC. AND
SUBSIDIARIES CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY FOR THE
THREE MONTHS ENDED MARCH 31, 2001 (Unaudited) Accumulated Additional Other Total Preferred Stock
Common Stock Paid-in Comprehensive Accumulated Shareholders' Shares Amount Shares Amount Capital Loss
Deficit Equity BALANCE, DECEMBER 31,
2000 12,015 \$ 12 13,341,681 \$ 13,342 \$ 113,763,660 \$ (471,306) \$(105,496,590) \$ 7,809,118 Comprehensive loss:
Net loss (7,815,162) (7,815,162) Other comprehensive loss: - Cumulative foreign currency translation
adjustments (22,329) (22,329) - Unrealized gain on investments 342,705 342,705
Net comprehensive loss (7,494,786) Issuance of Series A Convertible Exchangeable Preferred stock to Elan
for accrued dividends 424 Accretion on preferred stock 213,236 213,236 Issuance of
common stock to extinguish debt 1,459,672 1,460 28,099,703 28,101,163 Non-qualified stock compensation
116,524 116,524 Exercise of stock options 46,758 46 464,450 464,496 Issuance for employee
stock purchase plan 1,124 1 15,895 15,896
BALANCE, MARCH 31, 2001 12,439 \$ 12 14,849,235 \$ 14,849 \$ 142,673,468 \$ (150,930)
\$(113,311,752) \$ 29,225,647 ====== =============================
======================================
LABORATORIES, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE
THREE MONTHS ENDED MARCH 31, 2001 AND 2000 (Unaudited) 2001 2000 (RESTATED)
CASH FLOWS FROM OPERATING ACTIVITIES: Net loss applicable to common stock \$ (7,815,162)
\$(23,751,328) Adjustments to reconcile net loss to net cash provided by (used in) Operating activities: Accretion of
dividend on preferred stock 213,236 Depreciation and amortization 575,166 561,018 Equity in loss of joint venture
500,644 Loss on sale of property, plant and equipment 699 4,667 Loss on sale of marketable securities 39,288
Provision for bad debts (942) Stock compensation 116,524 75,620 Debt conversion expense 2,039,163
Extraordinary loss on extinguished of debt 281,632 Cumulative effect of change in accounting principle
20,611,526 Net changes in operating assets and liabilities: Accounts receivable (151,601) (510,635) Note receivable -
license fee 8,000,000 Interest receivable 316,300 252,589 Inventories (477,498) (318,253) Prepaid expenses and
deposits (20,042) (73,554) Accounts payable 174,938 (701,900) Interest payable 314,737 640,317 Accrued salaries
and payroll taxes 6,260 (6,652) Other accrued liabilities (171,334) (5,350) Deferred revenue 1,084,421 (515,944)
Net cash provided by (used in) operating activities 4,987,141 (3,698,591)
CASH FLOWS FROM INVESTING ACTIVITIES: Acquisition of property, plant and equipment (684,868)
(147,188) Investments in intangible assets (99,716) (81,381) Proceeds from sale of property, plant and equipment
25 Proceeds from sale of marketable securities 4,764,840 Proceeds from maturity of marketable securities
12,741,621 Investment in marketable securities (7,160,404) (98,372) Net cash provided by

investing activities 4,796,633 4,437,924 CASH FLOWS FROM FINANCING ACTIVITIES:
Proceeds from issuance of equity securities 480,393 262,943 Note receivable - stock subscription 15,000,000
Net cash provided by financing activities 15,480,393 262,943
NET EFFECT OF EXCHANGE RATE ON CASH (147,437) (2,818) NET
INCREASE IN CASH AND CASH EQUIVALENTS 25,116,730 999,458 CASH AND CASH
EQUIVALENTS, BEGINNING OF PERIOD 4,484,330 3,021,869 CASH AND CASH
EQUIVALENTS, END OF PERIOD \$ 29,601,060 \$ 4,021,327 ====================================
flow information: Cash paid for interest \$ \$ 4,138 ====================================
the quarter ended March 31, 2001, the Company issued common stock valued at \$28,101,163 to extinguish
\$26,062,000 of the convertible subordinated notes. See notes to the consolidated financial statements. 5 6 ATRIX
LABORATORIES, INC. AND SUBSIDIARIES NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
FOR THE THREE MONTHS ENDED MARCH 31, 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 and intercompany elimination entries) 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, Limited, with Elan
International Services, Ltd., a wholly owned subsidiary of Elan Corporation, plc to develop oncology and pain
management compounds. Drug delivery of these compounds will utilize our patented ATRIGEL and BEMA drug
delivery systems and Elan's nonoparticulate delivery technology. The Company 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. 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 an
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 represents the three months ended March 31, 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. 6 7 ATRIX LABORATORIES, INC. AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF
OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2000 AND 2000 RESTATED (Unaudited) 2000
(AS PREVIOUSLY SAB No. 101 2000 REPORTED) ADJUSTMENTS (RESTATED)
revenue 537,872 537,872 Licensing, marketing rights and milestone revenue 65,000 403,444 468,444
Total revenue 1,760,273 403,444 2,163,717 OPERATING

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EXPENSES: Cost of goods sold 459,261 -- 459,261 Research and development 3,726,514 -- 3,726,514
Administrative and marketing 1,020,896 -- 1,020,896 ----- Total operating expenses
5,206,671 -- 5,206,671 ------ INCOME (LOSS) FROM OPERATIONS (3,446,398) 403,444
(3,042,954) ----- OTHER INCOME (EXPENSE): Investment income 514,287 -- 514,287
Interest expense (649,857) -- (649,857) Other 38,722 -- 38,722 -------- Net other expense
(96,848) -- (96,848) INCOME (LOSS) BEFORE CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING
PRINCIPLE (3,543,246) 403,444 (3,139,802) Cumulative effect of change in accounting principle -- (20,611,526)
(20,611,526) ------ NET LOSS APPLICABLE TO COMMON STOCK $ (3,543,246)
common share: Income (loss) before cumulative effect of change in accounting principle $ (.31) $ (.28) Cumulative
effect of change in accounting principle -- $ (1.80) ------ Net loss applicable to common stock $ (.31) $
11,439,792 ============= 7 8 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 initially owns 80.1% of Transmucosal
Technologies' outstanding common stock, Elan and its subsidiaries have retained significant minority investor rights
that are considered "participating rights" as defined in Emerging Issues Task Force 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
March 31, 2001 and December 31, 2000, are as follows: March 31, 2001 December 31, 2000 ------
------ Raw materials $1,998,293 $1,616,878 Work in process 202,746 144,723 Finished goods 200,712
179,328 ------ $2,401,751 $1,940,929 ========= NOTE 4. PROPERTY, PLANT, AND
EQUIPMENT The components of net property, plant and equipment are as follows: MARCH 31, 2001 DECEMBER
31, 2000 ------ Land $ 1,071,018 $ 1,071,018 Building 3,612,613 3,610,068 Leasehold
improvements 507,002 470,002 Furniture and fixtures 471,538 440,534 Machinery 5,440,949 5,038,815 Office
equipment 1,020,760 813,317 ----- Total property, plant and equipment 12,123,880 11,443,754
Accumulated depreciation and amortization (4,928,051) (4,625,382) ------ Property, plant and
equipment, net $7,195,829 $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 March 31, 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. The
effect of assuming conversion of the Series A convertible exchangeable convertible preferred stock is excluded from
the diluted earnings per share computations since the conversion option commences July 18, 2002. Additionally since
the Company did not draw any proceeds under the convertible promissory note agreement with Elan as of March 31,
2001, there was no effect on earnings per share computations pertaining to this convertible promissory note for the
periods presented. For the quarters ended March 31, 2001 and 2000, approximately 1.8 million and 2.0 million
equivalent dilutive securities (primarily convertible notes and common stock options), respectively, have been
excluded from the weighted-average number of common shares outstanding for the diluted net loss per share
computations as they are antidilutive. 8 9 NOTE 6. CONVERTIBLE SUBORDINATED NOTES PAYABLE In
January and February 2001, the Company completed a series of private transactions involving the exchange of
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1,459,672 newly issued common shares for \$26,062,000, or 52% of the original offering amount, of the 7% convertible subordinated notes. Of the 1,459,672 shares issued, 1,371,684 shares were valued at the conversion price of \$19.00 per share and the remaining 87,988 were valued at the closing market price as of the various exchange dates. As a result, the Company recognized an extraordinary loss of approximately \$282,000, for the write-off of approximately \$577,000 for pro rata unamortized deferred finance charges net of approximately \$295,000 interest expense eliminated as a result of these exchanges. Additionally, as part of the 87,988 shares issued to induce conversion, debt conversion expense of approximately \$2,039,000 was recognized in the quarter ended March 31, 2001. As of March 31, 2001 and December 31, 2000, the convertible notes payable balance was \$10,128,000 and \$36,190,000, respectively. NOTE 7. PENDING LEGAL ACTION Disputes exist with Block Drug Company, a wholly owned subsidiary of GlaxoSmithKline, concerning product pricing and the payments due upon achievement of milestones. 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. An arbitration hearing was set for July 25, 2001. On April 20, 2001, the Company and Block Drug reached a settlement agreement resolving the pricing dispute over Block Drug's sale of ATRIDOX. The settlement agreement provides for the payment owed to the Company for sales of the product in 1999. The parties also implemented a new pricing schedule for future purchases. 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 was due. Block has not made this payment. Pursuant to the 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 Block 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 Company has notified Block that they are in breach of the agreement for failure to commence marketing of the ATRISORB-DOXY Barrier product. The FDA approved the ATRISORB-DOXY Barrier product in September 2000. An arbitrator has been selected with respect to this dispute, but no schedule or hearing has been set. The Company intends to vigorously pursue its rights to these milestone payments. NOTE 8. SUBSEQUENT EVENTS In April 2001, the Company entered into an exclusive European marketing agreement with MediGene AG for the Leuprogel products. In the agreement, valued at approximately \$20 million, the Company 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. Additionally, MediGene purchased shares of the Company's common stock for \$4 million in April 2001 at a premium to the market as part of the agreement, and will provide all resources needed to conduct clinical research and regulatory activities associated with seeking European marketing approvals. 9 10 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 quarter ended March 31, 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 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 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, 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 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 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 \$4 million at a premium to the market in April 2001 as part of the agreement, and will provide all resources needed to conduct clinical research and regulatory activities associated with seeking European marketing approvals. In January 2001, we received an exclusive option from Tulane University Health Science Center to license human growth releasing peptide-1, or GHRP-1, a novel 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. We continued to devote significant resources during the three months ended 2001 for the research and development of our Leuprogel prostate cancer treatment products and Atrisone acne treatment product, as well as, our new GHRP-1 product. 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. Research and development costs for third-party partnerships, such as Pfizer, Geneva Pharmaceuticals, and our joint venture with Elan will continue as well. RESULTS OF OPERATIONS THREE MONTHS ENDED MARCH 31, 2001 COMPARED TO THREE MONTHS ENDED MARCH 31, 2000 (RESTATED) Total revenues for the three months ended March 31, 2001 were approximately \$3,255,000 compared to approximately \$2,164,000 for the three months ended March 31, 2000, representing a 50% increase. Product net sales and royalty revenue were approximately \$1,234,000 during the three months ended March 31, 2001 compared to approximately \$1,157,000 for the three months ended March 31, 2000. This 7% increase was primarily related to the launch of ATRIDOX international sales by our German subsidiary in the first quarter of 2001. 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 \$1,304,000 for the three months ended March 31, 2001 compared to 10 11 approximately \$538,000 for the three months ended March 31, 2000, representing a 142% increase. This increase is primarily related to revenue recognition of approximately \$625,000 for oncology and pain management research activities with our joint venture, Transmucosal Technologies, Ltd., which commenced in October 2000 and approximately \$215,000 for dermatology research activities with Geneva Pharmaceuticals, which commenced in August 2000. Licensing fees, marketing rights and milestone revenue in accordance with SAB No. 101 for the three months ended March 31, 2001 was approximately \$717,000 compared to approximately \$468,000 for the three months ended March 31, 2000, representing a 53% increase. This increase is primarily related to the recognition of approximately \$200,000 in license fee revenue in accordance with SAB No. 101 for our Leuprogel products under the Sanofi-Synthelabo December 2000 agreement. 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. This sales milestone payment will be recognized as revenue over a ten-year period using the straight-line method in accordance with SAB No. 101 - Revenue Recognition in Financial Statements. We are currently in dispute with Block pertaining to two ATRISORB-DOXY milestone payments. See Note 7. Pending Legal Action. Cost of goods sold recorded for the three months ended March 31, 2001 was approximately \$436,000 compared to approximately \$459,000 for the three months ended March 31, 2000, representing a 5% decrease. This decrease in cost of sales reflects improved margins on our ATRIDOX product. Research and development expenses for the three months ended March 31, 2001 were approximately \$6,765,000 compared to approximately \$3,727,000 for the three months ended March 31, 2000, representing an 82% increase. Approximately \$1,667,000 of this expected increase was due to the rapid progress in our Leuprogel for prostate cancer treatment products. This included our March 2001 filing of the NDA to the FDA for the Leuprogel One-month product, near completion of the Leuprogel Three-month product, and completion of patient enrollment for the Leuprogel Four-month product. In January 2001, we received an exclusive option from Tulane University Health Science Center to license human growth releasing peptide-1, or GHRP-1, a novel patented growth-promoting compound. Research and development activities for the GHRP-1 were approximately \$684,000 for the first quarter 2001. Dermatology research and development activities for Geneva Pharmaceuticals' related projects increased approximately \$425,000 for the first quarter of 2001. Additionally, Atrisone research and development expenditures increased approximately \$222,000 for the three months ending March 31, 2001. Atrisone Phase III patient enrollment commenced in April 2001. Administrative and marketing expenses for the three months ended March 31, 2001 were approximately \$1,269,000 compared to approximately \$1,021,000 for the three months ended March 31, 2000, representing a 24% increase. The increase was primarily related to the recognition of compensation expense for the issuance of non-qualified stock options and an increase in legal fees associated with the Block arbitration. See Note 7. Pending Legal Action. We recognized a loss of approximately \$501,000 for the three months ended March 31, 2001 for our 80.1% equity share in the loss of Transmucosal Technologies, our joint venture with Elan. We expect to record additional equity losses for Transmucosal Technologies in the foreseeable future. Investment income for the three months ended March 31, 2001 was approximately \$749,000 compared to approximately \$514,000 for the three months ended March 31, 2000, representing a 46% increase. The increase was primarily the result of a net increase in our cash and cash equivalents and our marketable securities of approximately \$19,134,000 for the first quarter of 2001 in comparison to the first quarter 2000 cash and investment balances. 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. Interest expense for the three months ended March 31, 2001 was approximately \$315,000 compared to approximately \$650,000 for the three months ended March 31, 2000, representing a 52% decrease. The reduction in interest expense was primarily the result of our repurchase and retirement of \$26,562,000 of our 7% convertible subordinated notes since the period ended March 31, 2000. In January and February 2001, we completed a series of private transactions involving the exchange of 1,459,672 newly issued common shares for \$26,062,000, or 52% of the original offering amount, of the 7% convertible subordinated notes. Of the 1,459,672 shares issued, 1,371,684 shares were valued at the conversion price of \$19.00 per share and the remaining 87,988 were valued at the closing market price as of the various exchange dates. As a result, we recognized an extraordinary loss of approximately \$282,000, for the write-off of approximately \$577,000 for pro rata unamortized deferred finance charges net of approximately \$295,000 interest expense eliminated as a result of these exchanges. Additionally, as part of the 87,988 shares issued to induce conversion, a debt conversion expense of approximately \$2,039,000 was also recognized in the first quarter ended March 31, 2001. The convertible notes payable balance was reduced to \$10,128,000 as a result of these exchanges. 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 an 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 Elan. Related to this issuance, we recognized approximately \$213,000 for accretion of dividend on preferred stock for the three months ended March 31, 2001. 11 12 For the reasons described above, we recorded a net loss applicable to common stock of approximately \$7,815,000, or \$.55 per share, for the three months ended March 31, 2001 compared to a net loss applicable to common stock of approximately \$23,751,000, or \$2.08 per share, for the three months ended March 31, 2000. LIQUIDITY AND CAPITAL RESOURCES As of March 31, 2001, we had cash and cash equivalents of approximately \$29,601,000, marketable securities (at fair market value) of approximately \$23,671,000 and other current assets of approximately \$6,383,000 for total current assets of approximately \$59,655,000. Current liabilities totaled approximately \$7,147,000, which resulted in working capital of approximately \$52,508,000. 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 March 31, 2001, we had no outstanding balance under this line of 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 March 31, 2001, we had not drawn any amounts under the note. During the three months ended March 31, 2001, net cash provided by operating activities was approximately \$4,987,000. This was primarily the result of the net loss for the period of approximately \$7,815,000, 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 a non-cash charge for debt conversion expense of \$2,039,000 during the three months ended March 31, 2001 for the exchange of 1,459,672 shares of our common stock to extinguish approximately \$26,062,000 our convertible subordinated notes. Net cash provided by investing activities was approximately \$4,797,000 during the three months ended March 31, 2001, primarily as a result of proceeds of approximately \$12,742,000 for three called bond investments. This was offset by approximately \$7,160,000 for the purchase of three bond investments. Net cash provided by financing activities was approximately \$15,480,000 during the three months ended March 31, 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. Additionally, approximately \$480,000 was for the issuance of our common stock related to employee stock options and the employee stock purchase plan. 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, 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 an 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. 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. 12 13 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. 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. 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. 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. 13 14 o Our ability to successfully acquire and integrating 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. Interest Rate Risk. Our investment portfolio includes fixed rate debt instruments that are primarily United States government and agency bonds with maturity dates ranging from one to nine 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 the highest rated commercial paper (A1P1) only. As a result, we do not anticipate any material 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 long-term and short-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 March 31, 2001. The fair values that result from these computations are compared with the fair values of these financial instruments at March 31, 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 March 31, 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 \$286,000 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 \$286,000 per year. We maintain a portion of our financial instruments, including long-term debt instruments of approximately \$7,813,000 at March 31, 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 \$8,482,000 at March 31, 2001 and is lower than the carrying value by approximately \$1,646,000. 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 \$203,000. 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 March 31, 2001 was not material. Based on our overall foreign currency rate exposure at March 31, 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 With respect to our product pricing dispute with Block Drug Company, arbitration began in December 2000 to resolve the issue as to the minimum price Block must pay for products under the agreement. An arbitration hearing was set for July 25, 2001. On April 20, 2001, we entered into a settlement agreement with Block resolving the pricing dispute over Block's sale of our ATRIDOX product. The settlement agreement provides for the payment owed to us for sales of the product in 1999. We also implemented a new pricing schedule for future purchases. 14 15 ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS In January and February 2001, we completed a series of private transactions involving the exchange of 1,459,672 newly issued shares of common stock for \$26,062,000, or 52% of the original offering amount, of our

7% convertible subordinated notes. Of the 1,459,672 shares issued, 1,371,684 shares were valued at the conversion price of \$19.00 per share and the remaining 87,988 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 - None (b) Reports on Form 8-K. We filed the following Current Reports on Form 8-K during the quarter ended March 31, 2001; o Current Report on Form 8-K dated December 29, 2000 filed with the SEC on January 9, 2001, reporting an agreement with Sanofi-Synthelabo Inc. granting Sanofi-Synthelabo exclusive North American marketing rights to our Leuprogel One-, Three-, and Four-month products, and an investment by Sanofi-Synthelabo in our common stock, under Item 5. Other Events, and Item 7. Exhibits. o Current Report on Form 8-K dated December 29, 2000 filed with the SEC on January 9, 2001 reporting the execution of a collaboration, license and supply agreement with Sanofi-Synthelabo and an investment by Sanofi-Synthelabo in our common stock, 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) April 26, 2001 By: /s/ David R. Bethune ----- David R. Bethune Chairman of the Board of Directors and Chief Executive Officer April 26, 2001 By: /s/ Brian G. Richmond ------- Brian G. Richmond Chief Financial Officer and Assistant Secretary 15