

AETERNA LABORATORIES INC
Form 6-K
September 05, 2001

MESSAGE TO SHAREHOLDERS

Dear Shareholders,

During the second quarter of 2001, we witnessed the constant progression of our scientific, clinical and corporate activities, which reflects our dedication to our shareholders in making AETerna one of the first companies in the world to bring an angiogenesis inhibitor to market.

Our subsidiary, Atrium Biotechnologies Inc., enjoyed a landmark quarter by positioning itself as the largest Canadian company specializing in the development and distribution of high-end value-added products and active ingredients in cosmetics, nutrition, pharmaceuticals and fine chemicals by acquiring the French company, Unipex.

OVERVIEW OF SECOND QUARTER ACTIVITIES:

CLINICAL DATA

PROSTATE CANCER

Results from a Phase I/II clinical study in patients suffering from metastatic refractory prostate cancer were presented at the Annual Meeting of the Canadian Urological Association. The study corroborates results from prior Phase I/II clinical trials which demonstrated Neovastat's safety profile and dose-related activity. Results of the study showed no dose-limiting toxicity, excellent patient compliance while improved conditions or disease stabilization were noted in patients as indicated by Prostate Specific Antigen (PSA) levels.

PATIENT RECRUITMENT

Patient recruitment in the Phase III trial in renal cell carcinoma has surpassed the halfway point. Led by an international team of oncology experts, the trial, which involves 280 patients, is being conducted at some 50 investigative centres in Canada, the U.S., and Europe.

Patient recruitment for the pivotal Phase II trial on progressive multiple myeloma continues in some 35 investigative centres in Canada, the U.S., and Europe. The study is progressing according to schedule, and aims at evaluating the efficacy of Neovastat as a monotherapy treatment for some 120 patients who do not respond to standard therapies.

SCIENTIFIC DATA

NEW MECHANISM OF ACTION

AETerna presented new data showing that Neovastat is able to increase the level of angiostatin in mice with implanted human glioblastoma, a form of brain cancer. Data on this additional mechanism of action of Neovastat were presented in May at the Annual Meeting of the American Society of Clinical Oncology (ASCO).

NEW PATENT

AETerna discovered potent antiangiogenic activity in a class of molecules isolated from Neovastat capable of inhibiting the proliferation of

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endothelial cells. Following this discovery, the Company filed a patent application and broadened its intellectual property portfolio to 12 patents, 6 of which have already been approved by the United States Patent and Trademark Office.

CORPORATE AFFAIRS

ACQUISITION

In early July 2001, Atrium Biotechnologies Inc. acquired Unipex, a French company specializing in value-added services of importation, in supporting innovation, and in distributing raw materials and high-end brand-name additives for multinational corporations such as Bristol Myers-Squibb, Aventis, L'Oreal, Nestle, Danone and Kodak. The transaction, valued at some \$20 million, was financed from Atrium's cash surplus without any dilution. Atrium therefore acquires 70% of the Unipex shares while senior Unipex management retains control of the remaining 30%. Atrium's annual consolidated sales should exceed \$70 million for the upcoming fiscal year.

FINANCIAL RESULTS

Sales for Atrium Biotechnologies Inc. increased by 32% during this second quarter, reaching \$2.7 million compared to \$2 million for the same period last year. This increase is mainly due to sales of value-added nutritional products, which more than doubled on the Asian market as well as revenues generated by Atrium Biotech USA Inc., a subsidiary of Atrium. Established in October 2000, Atrium Biotech USA markets a line of nutrition supplement products, primarily in the United States.

AEterna's Research and Development investments reached \$6.7 million in comparison to \$4.9 million during the same quarter of 2000. This reflects the company's increased efforts in the development of its lead product, Neovastat, for current pivotal Phase III clinical trials in lung and kidney cancer and for the current pivotal Phase II trial in multiple myeloma.

During the second quarter, the Company registered net earnings of \$7.5 million, or \$0.25 per share, compared to a net loss of \$1.7 million or \$0.06 per share for the quarter ended June 30, 2000. Net earnings include a gain on dilution of \$10.2 million which was posted following an amendment to Atrium Biotechnologies Inc. Shareholders' Agreement, in May 2001.

AEterna maintains a solid financial position with more than \$60 million in cash and short-term investments as of June 30, 2001. Furthermore, the Company has access to \$15 million through the Technology Partnerships Canada program and has a \$5 million sponsorship from the U.S. National Cancer Institute for its pivotal Phase III clinical trial in non-small cell lung cancer.

OUTLOOK

During the next six months, our strategy will revolve mainly around the two following items: on the clinical side, all efforts will be concentrated on completing patient recruitment for our trials in kidney cancer and multiple myeloma. On the corporate side, we will pursue discussions with pharmaceutical companies in order to finalize our strategic alliances for the worldwide distribution and commercialization of Neovastat.

On a longer term basis, the acquisition of a company or of a new technology to broaden our product pipeline continues to be a main objective of our growth strategy.

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Dr. Eric Dupont, PhD
 Chairman of the Board,
 President and Chief Executive Officer

August 6, 2001

This report contains forward-looking statements, which are made pursuant to the safe harbor provisions of the U.S. Securities Litigation Reform Act of 1995. Forward-looking statements involve known and unknown risks and uncertainties which could cause the Company's actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, the ability of the Company to take advantage of the business opportunities in the pharmaceutical industry, uncertainties related to the regulatory process and general changes in economic conditions. Investors should consult the Company's ongoing quarterly and annual filings with the Canadian and U.S. securities commissions for additional information on risks and uncertainties relating to the forward-looking statements. Investors are cautioned not to rely on these forward-looking statements. The Company does not undertake to update these forward-looking statements.

AETERNA LABORATORIES INC.

CONSOLIDATED BALANCE SHEETS
 (expressed in Canadian dollars)

| | AS AT JUNE 30, 2001 | AS AT DECEMBER 2000 |
|--|---------------------------|---------------------------|
| | (UNAUDITED) | (RESTATE) |
| <hr/> | | |
| ASSETS | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | \$ 24,708,830 | \$ 7,260, |
| Short-term investments | 35,757,705 | 61,388, |
| Accounts receivable | 6,826,891 | 4,842, |
| Research and development tax credits recoverable | 1,951,892 | 1,092, |
| Inventory | 2,777,612 | 2,484, |
| Prepaid expenses | 1,102,405 | 588, |
| | <hr/> | <hr/> |
| | 73,125,335 | 77,656, |
| CAPITAL ASSETS | 14,628,661 | 14,928, |
| OTHER ASSETS | 2,975,708 | 7,347, |
| FUTURE INCOME TAX ASSETS | 855,537 | 650, |
| | <hr/> | <hr/> |
| | \$ 91,585,241 | \$100,582, |
| <hr/> | | |

LIABILITIES

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| | | |
|--|---------------|------------|
| CURRENT LIABILITIES | | |
| Accounts payable and accrued liabilities | \$ 5,957,389 | \$ 5,860, |
| Income taxes | 45,873 | 650, |
| Current portion of long-term debt | 95,000 | 313, |
| | ----- | ----- |
| | 6,098,262 | 6,824, |
| LONG-TERM DEBT | 4,753,500 | 4,753, |
| REDEEMABLE COMMON SHARES OF THE SUBSIDIARY (notes 2 and 3) | - | 24,609, |
| NON-CONTROLLING INTEREST (note 3) | 10,835,162 | |
| | ----- | ----- |
| | 21,686,924 | 36,187, |
| | ----- | ----- |
| SHAREHOLDERS' EQUITY | | |
| SHARE CAPITAL | 81,215,845 | 80,008, |
| DEFICIT | (11,317,528) | (15,613, |
| | ----- | ----- |
| | 69,898,317 | 64,394, |
| | ----- | ----- |
| | \$ 91,585,241 | \$100,582, |
| | ===== | ===== |

SUBSEQUENT EVENT (NOTE 4)

SEE ACCOMPANYING NOTES

AETERNA LABORATORIES INC.

CONSOLIDATED STATEMENTS OF EARNINGS
FOR THE PERIODS ENDED JUNE 30, 2001 AND 2000
(expressed in Canadian dollars)

| UNAUDITED | QUARTERS ENDED JUNE 30, | |
|---|-------------------------|--------------|
| | 2001 | 2000 |
| | | (RESTATED) |
| REVENUES | \$ 2,668,278 | \$ 2,022,619 |
| | ----- | ----- |
| OPERATING EXPENSES | | |
| Cost of goods sold | 411,613 | 221,837 |
| Selling and administrative | 861,010 | 496,663 |
| Research and development | 6,675,681 | 4,857,974 |
| Research and development tax credits and grants | (2,528,560) | (1,508,200) |
| Depreciation and amortization | | |
| Capital assets | 305,897 | 288,101 |
| Other assets | 80,717 | 38,261 |
| | ----- | ----- |
| | 5,806,358 | 4,394,636 |
| | ----- | ----- |
| OPERATING LOSS | (3,138,080) | (2,372,017) |

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| | | | |
|---|--------------|----------------|----|
| INTEREST INCOME | 980,562 | 723,407 | |
| INTEREST EXPENSE | (174,733) | (11,737) | |
| ----- | | | |
| LOSS BEFORE THE FOLLOWING | (2,332,251) | (1,660,347) | |
| GAIN ON DILUTION (note 3) | 10,223,567 | - | 1 |
| NON-CONTROLLING INTEREST | (350,233) | - | |
| ----- | | | |
| NET EARNINGS (LOSS) FOR THE PERIOD | \$ 7,541,083 | \$ (1,660,347) | \$ |
| ===== | | | |
| NET EARNINGS (LOSS) PER SHARE | | | |
| Basic | \$ 0.25 | \$ (0.06) | \$ |
| ===== | | | |
| Fully diluted | \$ 0.24 | \$ (0.06) | \$ |
| ===== | | | |
| WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING | | | |
| Basic | | | 3 |
| ===== | | | |
| Fully diluted | | | 3 |
| ===== | | | |

CONSOLIDATED STATEMENTS OF DEFICIT
FOR THE PERIODS ENDED JUNE 30, 2001 AND 2000
(expressed in Canadian dollars)

UNAUDITED

| | | |
|------------------------------------|--|--------|
| BALANCE - BEGINNING OF PERIOD | | \$ (15 |
| Net earnings (loss) for the period | | 4 |
| ----- | | |
| BALANCE - END OF PERIOD | | \$ (11 |
| ===== | | |

SEE ACCOMPANYING NOTES

AETERNA LABORATORIES INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE PERIODS ENDED JUNE 30, 2001 AND 2000
(expressed in Canadian dollars)

| UNAUDITED | QUARTERS ENDED JUNE 30, | |
|-----------|-------------------------|------|
| | 2001 | 2000 |
| ----- | | |

(RESTATED)

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CASH FLOWS FROM OPERATING ACTIVITIES

| | | | |
|--|--------------|----------------|----|
| Net earnings (loss) for the period | \$ 7,541,083 | \$ (1,660,347) | \$ |
| Items not affecting cash | | | |
| Depreciation and amortization | 386,614 | 326,362 | |
| Interest expense | 174,733 | 11,737 | |
| Gain on dilution | (10,223,567) | - | (1 |
| Non-controlling interest | 350,233 | - | |
| Future income taxes | (138,162) | - | |
| Change in non-cash operating working capital items | | | |
| Accounts receivable | 60,659 | (522,219) | (|
| Research and development tax credits recoverable | (581,892) | (325,963) | |
| Inventory | (223,758) | 74,924 | |
| Prepaid expenses | 46,431 | (173,202) | |
| Accounts payable and accrued liabilities | 457,293 | (72,524) | |
| Income taxes | (71,127) | - | |
| | (2,221,460) | (2,341,232) | (|

CASH FLOWS FROM FINANCING ACTIVITIES

| | | | |
|---|----------|------------|--|
| Issuance of share capital , net of related expenses | 768,581 | 13,256,216 | |
| Increase (payments) of long-term debt | (96,000) | 95,186 | |
| Redeemable common shares of the subsidiary | - | - | |
| Deferred interest expense paid in cash | - | - | |
| | 672,581 | 13,351,402 | |

CASH FLOWS FROM INVESTING ACTIVITIES

| | | | |
|----------------------------------|------------|-----------|---|
| Change in short-term investments | 17,841,802 | 5,663,671 | 2 |
| Purchase of capital assets | (178,256) | (191,509) | |
| Additions to other assets | (19,064) | (39,189) | |
| | 17,644,482 | 5,432,973 | 2 |

NET CHANGE IN CASH AND CASH EQUIVALENTS 16,095,603 16,443,143 1

CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD 8,613,227 16,481,211

CASH AND CASH EQUIVALENTS - END OF PERIOD \$ 24,708,830 \$32,924,354 \$ 2

ADDITIONAL INFORMATION

| | | | |
|-------------------|------------|------|----|
| Interest paid | - | - | |
| Income taxes paid | \$ 122,125 | \$ - | \$ |

SEE ACCOMPANYING NOTES

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AETERNA LABORATORIES INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
FOR THE PERIODS ENDED JUNE 30, 2001 AND 2000
(expressed in Canadian dollars)

UNAUDITED

1 BASIS OF PRESENTATION

These unaudited quarterly financial statements have been prepared by the Company in accordance with Canadian generally accepted accounting principles for quarterly financial information and reflect, in the opinion of management, all adjustments necessary to present fairly the financial position, results of operations and cash flows as at June 30, 2001, and for all periods presented.

The accounting policies and methods of computation adopted in these financial statements are the same as those used in the preparation of the Company's most recent annual consolidated financial statements. All disclosures required for annual financial statements have not been included in these financial statements. These consolidated financial statements should be read in conjunction with the Company's most recent annual consolidated financial statements. The results of operations for the six-month period ended June 30, 2001, are not necessarily indicative of the results for the full year.

2 RESTATEMENTS

The Company has restated its financial statements to reflect a change in the method of accounting for the issuance of redeemable common shares by its subsidiary, Atrium Biotechnologies Inc. (Atrium), to its minority shareholders. The financial statements have been restated to eliminate the recognition of a minority interest and the previously recognized dilution gain recorded on the issuance of the subsidiary's redeemable common shares. The redeemable common shares of the subsidiary are classified as a liability in accordance with the substance of the shareholders' agreement and the definition of a financial liability.

3 AMENDMENT OF ATRIUM SHAREHOLDERS' AGREEMENT

In May 2001, Atrium and all its shareholders amended certain terms of the shareholders' agreement. As a result of the amendment, the Company reclassified the common shares issued by Atrium to the minority shareholders from a liability to equity. In addition, the Company will no longer have an obligation to deliver cash or another financial amount to the minority shareholders of Atrium. Accordingly, in the second quarter ended June 30, 2001, the Company recognized a dilution gain and a minority interest in Atrium.

4 SUBSEQUENT EVENT

On July 2, 2001, Atrium acquired 70% of the issued and outstanding common shares of Unipex Finance S.A. for a total cash consideration of \$21 M. Unipex Finance S.A. is specialized in value-added services of importation, in supporting innovation, and in distributing raw materials and high-end brand-name additives for multinational corporations. The amount by which Atrium's purchase price will exceed the underlying net book value of the assets and liabilities will be approximately \$12.9 M. The results of the company acquired will be included in the consolidated statement of earnings of the Company from the date of the acquisition, July 2, 2001.

5 SEGMENT INFORMATION

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| | QUARTERS ENDED JUNE 30, | | |
|------------------------------------|-------------------------|----------------|------------|
| | 2001 | 2000 | |
| | | | |
| | | | \$ |
| | | | (RESTATED) |
| REVENUES | | | |
| Cosmetics and nutrition | \$2,668,278 | \$ 2,022,619 | \$5, |
| Biopharmaceutical | - | - | |
| | \$2,668,278 | \$ 2,022,619 | \$5, |
| NET EARNINGS (LOSS) FOR THE PERIOD | | | |
| Cosmetics and nutrition | \$1,134,022 | \$ 1,363,917 | \$2, |
| Biopharmaceutical | 6,407,061 | (3,024,264) | 1, |
| | \$7,541,083 | \$ (1,660,347) | \$4, |