

## Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

AETERNA LABORATORIES INC

Form 6-K

June 12, 2001

### MESSAGE TO SHAREHOLDERS

Dear Shareholders,

This has been a landmark quarter in AETerna's ten-year history at the scientific, clinical and corporate levels. Recent research data and clinical results along with the signing of our first strategic alliances with pharmaceutical companies on the European market, have brought us another step closer to our ultimate goal which is to be among the first in the world to bring an angiogenesis inhibitor to market. Datamonitor, an independent market analysis company, recently ranked AETerna as the frontrunner in this new therapeutic class.

### OVERVIEW OF FIRST QUARTER ACTIVITIES

#### NEOVASTAT'S DEMONSTRATED EFFICACY IN PHASE I/II CLINICAL TRIAL

Clinical data from a Phase I/II clinical trial demonstrated a statistically significant two-fold increase ( $p < 0.01$ ) in median survival time for metastatic renal cell carcinoma (kidney cancer) patients refractory to standard treatments and who were administered a higher dose of its lead product, Neovastat. The median survival time of patients treated with a dose of 30mL twice a day was 7.1 months, compared to 16.3 months for patients who had received a dose of 120mL twice a day while expected survival time for a patient with metastatic renal cell carcinoma who does not respond to standard treatments, is approximately 8 months. These results were presented at the recent 92nd Annual Meeting of the American Association for Cancer Research (AACR), held in New Orleans.

#### NEOVASTAT: TWO ADDITIONAL MECHANISMS OF ACTION

Other new research results presented at the AACR meeting demonstrated a third mechanism of action of Neovastat which induces apoptosis (programmed cell death) of endothelial cells. New data evidencing a fourth mechanism of action was presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in San Francisco, showing that Neovastat is able to increase the level of angiostatin in mice with implanted human glioblastoma, a form of brain cancer. These results confirm Neovastat's position as a unique product with multiple mechanisms of action.

#### NEOVASTAT'S STRENGTHENED INTELLECTUAL PROPERTY

The United States Patent and Trademark Office granted AETerna another key patent that covers a new process allowing the isolation of bioactive components from cartilage, thus broadening the protection and exclusivity of Neovastat. To this day, AETerna has filed 8 patents of which 5 have already been granted.

#### EUROPEAN STRATEGIC ALLIANCES

AETerna signed its first two strategic alliances which cover 85% of the European market with Grupo Ferrer Internacional, S.A., from Spain, and Medac GmbH from Hamburg, the German oncology business unit of the multinational Schering AG. These two agreements account for more than 30% of the worldwide pharmaceutical market. Under the terms of these agreements, AETerna will secure the production of Neovastat and will receive double digit royalties on total net sales. Milestone payments to AETerna of more than \$CAN 35 million are also included in these two deals.

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### FOCUS ON ONCOLOGY AND NEW BOARD MEMBERS

AEterna appointed new members to its Scientific Advisory Board: oncologists Dr. Janice Dutcher, MD and Dr. Kenneth C. Anderson, MD, both from the United States, and Dr. Francois Berger, MD, PhD, from France.

Furthermore, Ms. Stormy Byorum from the United States and Mr. Pierre MacDonald were appointed to AEterna's Board of Directors, while Mr. Pierre Laurin was named Chairman of the Board of its subsidiary, Atrium Biotechnologies Inc. The Company also announced the appointment of Mr. Gilles Gagnon as AEterna's new Vice President and Chief Operating Officer.

### FINANCIAL RESULTS

Sales of Atrium Biotechnologies Inc. were up to 37.3% during this first quarter, reaching \$2.8 million compared to \$2 million for the same period last year. This gain is mainly due to increased sales in the United States and in Asia as well as revenues generated by the acquisition of a line of nutritional supplement products in the United States last October.

AEterna increased R&D investments to \$7.2 million in comparison to \$CAN 5.5 million during the same quarter of 2000. This increase is part of the strategic development of Neovastat through current pivotal Phase III clinical trials in lung and kidney cancers and the current pivotal Phase II trial in multiple myeloma, a form of blood cancer.

During the first quarter, the Company registered a net loss of \$CAN 3.2 million, or \$0.11 per share, compared to a net loss of \$CAN 2.2 million or \$0.08 per share for the quarter ended March 31, 2000. Major investments in the ongoing late-stage clinical development program account for most of the net loss increase.

AEterna maintains a solid financial position with more than \$CAN 62.2 million in cash and short-term investments as of March 31, 2001. The Company also has access to an additional \$CAN 17 million through the Technology Partnerships Canada program.

### OUTLOOK

Our sound financial position enables us to have access to sufficient funds to complete our key pivotal clinical studies in kidney cancer and multiple myeloma by the end of 2002.

Over the next few months, AEterna will pursue discussions with other pharmaceutical companies for the distribution and commercialization of Neovastat, according to our multiple partnership strategy. We will also continue to seek the acquisition of a biotech company or new technologies that will broaden our product pipeline.

Dr. Eric Dupont, PhD  
President and Chief Executive Officer

May 24, 2001

### SAFE HARBOR STATEMENT

This report contains forward-looking statements, which are made pursuant to the

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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.

### GENERAL INFORMATION

AEterna Laboratories Inc.  
1405, Parc-Technologique Blvd., Quebec, Quebec G1P 4P5 Canada  
Tel.: (418)652-8525 Fax: (418) 652-0881  
E-mail: AETERNA@AETERNA.COM Website: <http://www.aeterna.com>

### STOCK SYMBOL

TSE: AEL  
NASDAQ: AELA  
Shares outstanding: 30.2 millions

### AETERNA LABORATORIES INC.

#### CONSOLIDATED BALANCE SHEETS (expressed in Canadian dollars)

	AS AT MARCH 31, 2001	AS AT DECEMBER 31, 2000
	(UNAUDITED)	(RESTATED)
<hr/>		
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 8,613,227	\$ 7,260,582
Short-term investments	53,599,507	61,388,205
Accounts receivable	6,887,550	4,842,845
Research and development tax credits recoverable	1,370,000	1,092,000
Inventory	2,553,854	2,484,139
Prepaid expenses	1,148,836	588,442
	<hr/>	<hr/>
	74,172,974	77,656,213
CAPITAL ASSETS	14,756,302	14,928,146
OTHER ASSETS	7,113,145	7,347,884
FUTURE INCOME TAX ASSETS	717,375	650,000
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	\$ 96,759,796	\$100,582,243

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LIABILITIES

CURRENT LIABILITIES

Accounts payable and accrued liabilities	\$ 5,500,096	\$ 5,860,960
Income taxes	117,000	650,000
Current portion of long-term debt	191,000	313,953
	5,808,096	6,824,913

LONG-TERM DEBT

REDEEMABLE COMMON SHARES OF THE SUBSIDIARY (NOTES 2 AND 3)	4,753,500	4,753,500
	24,609,547	24,609,547

35,171,143 36,187,960

SHAREHOLDERS' EQUITY

SHARE CAPITAL	80,447,264	80,008,032
DEFICIT	(18,858,611)	(15,613,749)

61,588,653 64,394,283

\$ 96,759,796 \$100,582,243

SUBSEQUENT EVENT (NOTE 3)

SEE ACCOMPANYING NOTES

AETERNA LABORATORIES INC.

CONSOLIDATED STATEMENTS OF EARNINGS  
FOR THE PERIODS ENDED MARCH 31, 2001 AND 2000  
(expressed in Canadian dollars)

UNAUDITED	2001	2000
		(RESTATED)
REVENUES	\$ 2,766,625	\$ 2,015,053
OPERATING EXPENSES		
Cost of goods sold	443,653	297,091
Selling and administrative	833,648	456,244
Research and development	7,214,218	5,475,258
Research and development tax credits and grants	(2,042,000)	(1,638,483)
Depreciation and amortization		
Capital assets	291,816	281,446
Other assets	83,651	37,863
	6,824,986	4,909,419
OPERATING LOSS	(4,058,361)	(2,894,366)

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INTEREST INCOME	1,075,599	746,409
INTEREST EXPENSE	(262,100)	(8,900)
-----		
NET LOSS FOR THE PERIOD	\$ (3,244,862)	\$ (2,156,857)
=====		

NET LOSS PER SHARE		
Basic and fully diluted	\$ (0.11)	\$ (0.08)
WEIGHTED AVERAGE NUMBER OF SHARES USED TO CALCULATE LOSS PER SHARE	30,114,062	28,502,994
=====		

CONSOLIDATED STATEMENTS OF DEFICIT  
FOR THE PERIODS ENDED MARCH 31, 2001 AND 2000  
(expressed in Canadian dollars)

UNAUDITED	2001	2000
		(RESTATED)
-----		
BALANCE - BEGINNING OF PERIOD	\$ (15,613,749)	\$ (5,955,956)
Net loss for the period	(3,244,862)	(2,156,857)
-----		
BALANCE - END OF PERIOD	\$ (18,858,611)	\$ (8,112,813)
=====		
SEE ACCOMPANYING NOTES		

AETERNA LABORATORIES INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE PERIODS ENDED MARCH 31, 2001 AND 2000  
(expressed in Canadian dollars)

UNAUDITED	2001	2000
		(RESTATED)
-----		
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	\$ (3,244,862)	\$ (2,156,857)
Items not affecting cash		
Depreciation and amortization	375,467	319,309
Future income taxes	(67,375)	--
Interest expense	262,100	8,900
Change in non-cash operating working capital items		
Accounts receivable	(2,044,705)	(1,268,834)
Research and development tax credits recoverable	(278,000)	(262,443)
Inventory	(69,715)	(395,063)
Prepaid expenses	(560,394)	(249,148)
Accounts payable and accrued liabilities	(360,864)	1,694,825
Income taxes	(533,000)	--
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	(6,521,348)	(2,309,311)
-----		

CASH FLOWS FROM FINANCING ACTIVITIES

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Issuance of share capital, net of related expenses	439,232	4,149,104
Payments of long-term debt	(122,953)	--
Redeemable common shares of the subsidiary (notes 2 and 3)	--	10,000,000
Deferred interest expense paid in cash	--	(235,721)
	316,279	13,913,383

CASH FLOWS FROM INVESTING ACTIVITIES

Change in short-term investments	7,788,698	(907,656)
Purchase of capital assets	(119,972)	(209,812)
Additions to other assets	(111,012)	(31,126)
	7,557,714	(1,148,594)

NET CHANGE IN CASH AND CASH EQUIVALENTS 1,352,645 10,455,478

CASH AND CASH EQUIVALENTS - BEGINNING  
OF PERIOD 7,260,582 6,025,733

CASH AND CASH EQUIVALENTS - END OF PERIOD \$ 8,613,227 \$ 16,481,211

ADDITIONAL INFORMATION

Interest paid -- --

Income taxes paid \$ 600,375 \$ --

SEE ACCOMPANYING NOTES

AETERNA LABORATORIES INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE PERIODS ENDED MARCH 31, 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 March 31, 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

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statements. The results of operations for the three-month period ended March 31, 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 SUBSEQUENT EVENT

In May 2001, Atrium and all its shareholders amended certain terms of the shareholders' agreement. As a result of the amendment, the Company will reclassify 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 of the financial year ending December 31, 2001, the Company will recognize a dilution gain and a minority interest in Atrium.

On a pro-forma basis, the impact of these amendments as at December 31, 2000 and for the year ended December 31, 2000 will be to bring the Company back to the situation it was before the restatements as described in note 2.

### 4 SEGMENT INFORMATION

	THREE MONTHS ENDED MARCH 31	
	2001	2000
	(RESTATED)	
<b>REVENUES</b>		
Cosmetics and nutrition	\$ 2,766,625	\$ 2,015,053
Biopharmaceutical	--	--
	\$ 2,766,625	\$ 2,015,053
<b>NET EARNINGS (LOSS) FOR THE PERIOD</b>		
Cosmetics and nutrition	\$ 1,418,056	\$ 1,216,803
Biopharmaceutical	(4,662,918)	(3,373,660)
	\$ (3,244,862)	\$ (2,156,857)