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AETERNA LABORATORIES INC  
Form 6-K  
September 25, 2003

FORM 6-K  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

REPORT OF FOREIGN ISSUER  
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Pursuant to Rule 13a-16 or 15d-16 of  
the Securities Exchange Act of 1934

For the month of September 2003

AETERNA LABORATORIES INC.  
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(Translation of registrant's name into English)

1405, boul. du Parc-Technologique  
Quebec, Quebec  
Canada, G1P 4P5  
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(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports  
under cover of Form 20-F or Form 40-F.

Form 20-F                      Form 40-F    X  
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Indicate by check mark whether the registrant by furnishing the information  
contained in this Form is also thereby furnishing the information to the  
Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes                                      No    X  
-----                                      -----

If "Yes" is marked, indicate below the file number assigned to the registrant in  
connection with Rule 12g3-2(b): 82-\_\_\_\_\_.

DOCUMENTS INDEX

DOCUMENTS DESCRIPTION

- 1.            Press release dated September 24, 2003: AEterna reports  
             phase III trial results in Renal Cell Carcinoma with  
             Neovastat (R)  
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[AETERNA LABORATORIES, INC. LOGO]

PRESS RELEASE  
FOR IMMEDIATE RELEASE

## AETERNA LABORATORIES REPORTS PHASE III TRIAL RESULTS IN RENAL CELL CARCINOMA WITH NEOVASTAT

QUEBEC CITY, CANADA, SEPTEMBER 24, 2003 - AETerna Laboratories Inc. (TSX: AEL; Nasdaq: AELA) today reported results of a Phase III trial in renal cell carcinoma, a form of kidney cancer, evaluating Neovastat, the Company's antiangiogenic compound. Results showed that the study, involving 305 patients refractory to immunotherapy, did not meet its primary endpoint of improving overall median survival time. However, significant survival advantage was observed in a subgroup of healthier patients with clear cell histology and only a single metastatic site. This 38 patient subgroup showed a median survival time of 26.3 months for those treated with Neovastat compared to 12.6 months for patients receiving a placebo (p=0.0236).

Gilles Gagnon, AETerna's President and Chief Executive Officer, stated, "While this trial in refractory renal cell carcinoma did not reach its primary endpoint, the results observed for the subgroup of patients with a single metastatic site suggest Neovastat may be useful in treating specific forms of kidney cancer. Furthermore, this trial generates very useful data for our current Phase III trial in non-small cell lung cancer. The significant increase in median survival time for the renal cell carcinoma subgroup which was at an earlier disease stage compared to the overall cohort, seems to suggest that treatment with Neovastat in earlier stage cancer could be more efficacious." The Phase III trial in non-small cell lung cancer is enrolling newly diagnosed patients for front line treatment with Neovastat. "This Phase III renal cell carcinoma trial showed that Neovastat had an excellent safety profile," emphasized Dr. Pierre Champagne, Medical Director and Vice President, Clinical Affairs at AETerna.

Furthermore, patients in the non-small cell lung cancer trial are administered Neovastat in combination with chemotherapy and radiotherapy. Based on prior antiangiogenesis trials in cancer, the approach of front line therapy with best standard treatment is regarded as the strategy most likely to show clinical benefit.

"Our current Phase III trial in non-small cell lung cancer is part of our clinical program geared towards developing promising compounds from our extensive pipeline that encompasses 12 products, with two already marketed," continued Mr. Gagnon. "We presently have a solid balance sheet and our corporate objective is to accelerate the implementation of our growth strategy."

### RENAL CELL CARCINOMA PHASE III TRIAL INFORMATION

This randomized, double-blind, placebo-controlled study was conducted in approximately 50 hospitals and clinical centers throughout Canada, the United States and Europe. It was designed to evaluate the efficacy of AETerna's antiangiogenic treatment, Neovastat, in prolonging survival of patients with progressive metastatic renal cell carcinoma, refractory to immunotherapy.

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Patient recruitment opened in May 2000 and was completed in December 2001. The trial involved 305 patients who had failed to respond to immunotherapy. From this number, 153 patients were administered Neovastat, while 152 patients were given a placebo. Overall median survival time for the Neovastat group was 12.4 months compared to 12.3 months for the placebo group. Analysis of a pre-planned stratification showed that healthier patients (ECOG performance=0, metastatic site=1) with clear cell histology showed statistically significant clinical benefit, 26.3 months for Neovastat (n=20) versus 12.6 months for the placebo group (n=18) (p=0.0236).

Renal cell carcinoma represents approximately 85% of all cases of kidney cancer in the U.S. and accounts for about 32,000 new cases in North America and about 38,000 new cases in Europe, with a five-year mortality rate of approximately 90%.

The principal investigators for this trial were Dr. Peter Venner, Director of Medical Oncology at the Cross Center Institute in Edmonton, Alberta for the Canadian portion, Dr. Ronald Bukowski, Director of the Experimental Therapeutics Program of the Cleveland Clinic Cancer Center, in Cleveland, Ohio for the U.S. portion and Dr. Bernard Escudier, Head of Immunotherapy and Innovative Therapy Unit, Institut Gustave Roussy, Villejuif, France for the European portion of the trial.

"We would like to acknowledge the dedicated efforts of all our investigators and thank the 305 patients who took part in this study which was conducted according to the industry's highest standards," concluded Gilles Gagnon.

### CONFERENCE CALL INFORMATION

Management will be hosting an investment community conference call beginning at 9:45 a.m. Eastern Time today, Wednesday, September 24, to discuss this announcement and to answer questions.

To participate in the live call by telephone, please dial 514-807-8791, 416-640-4127 from Canada or 1-800-814-4890 from outside Canada. A telephone replay will be available from 12:00 noon eastern on September 24 until 11:59 p.m. Eastern on September 26, by dialing 416-640-1917 and entering passcode 21018858#. Individuals interested in listening to the conference call via the Internet may do so by visiting [WWW.AETERNA.COM](http://WWW.AETERNA.COM). A replay will be available on the Company's Web site for 30 days.

### PRESS MEETING INFORMATION

Management will be holding a press meeting to discuss the Renal Cell Carcinoma Phase III trial results at 11:00 a.m. Eastern Time today, Wednesday, September 24 in the Fortin-Leduc room at the Loew's - Le Concorde Hotel, 1225 Cours du General Montcalm in Quebec City.

### ABOUT AETERNA LABORATORIES

AETerna Laboratories is a biopharmaceutical company with an extensive portfolio of marketed and development-stage biopharmaceutical products focused in oncology and endocrinology. Its lead oncology compound Neovastat(R), a proprietary angiogenesis inhibitor with multiple mechanisms of action, is currently in a Phase III clinical trial for non-small cell lung cancer. A Phase III trial in renal cell carcinoma with Neovastat was recently completed. Neovastat was granted Orphan Drug Status for renal cell carcinoma, by the FDA. Cetrotide(R), its lead compound in endocrinology, is sold in the U.S. and Europe to the IN

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VITRO fertilization market, and is in clinical testing for endometriosis, uterus myoma and enlarged prostate (BPH). A further seven clinical programs are underway with various compounds. In addition, AETerna owns 62% of Atrium Biotechnologies, a profitable and growing developer, distributor and marketer of active ingredients, fine chemicals, cosmetic and nutritional products with sales exceeding \$100 million in 2002.

AETerna and its entities have 300 employees in Canada and Europe, and its shares are listed on the Toronto Stock Exchange (AEL) and the NASDAQ National Market (AELA). News releases and additional information about AETerna are available on its Web site at WWW.AETERNA.COM. To find out more about the current Phase III trial in non-small cell lung cancer, call 1-888-349-3232.

### FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements 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 business opportunities in the pharmaceutical industry, uncertainties related to the regulatory process and general changes in economic conditions. Investors should consult the Company's 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.

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### SIGNATURE

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.

AETERNA LABORATORIES INC.

Date: July 29, 2003  
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By: /s/ Claude Vadboncoeur  
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Claude Vadboncoeur

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Vice President, Legal Affairs and  
Corporate Secretary