

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

AETERNA LABORATORIES INC  
Form 6-K  
June 03, 2003

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

REPORT OF FOREIGN ISSUER

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

For the month of June 2003

AETERNA LABORATORIES INC.

-----  
(Translation of registrant's name into English)

1405, boul. du Parc-Technologique  
Quebec, Quebec  
Canada, G1P 4P5

(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  
    ---                                      ---

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 June 2, 2003: AEterna Presents Status on Neovastat

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

Phase III Trials in Kidney Cancer and Lung Cancer

-----

[LOGO]

PRESS RELEASE  
FOR IMMEDIATE RELEASE

## AETERNA PRESENTS STATUS ON NEOVASTAT PHASE III TRIALS IN KIDNEY CANCER AND LUNG CANCER

Presentations by Dr. Bernard Escudier and Dr. Charles Lu  
at the American Society of Clinical Oncology Meeting in Chicago

CHICAGO, ILLINOIS, JUNE 2, 2003 - Dr. Bernard Escudier, Head of the Immunotherapy Unit at Institut Gustave-Roussy in Paris, France and lead investigator in Europe for AEterna Laboratories (Nasdaq: AELA, TSX: AEL) Neovastat Phase III trial in renal cell carcinoma gave a status report on the trial during a presentation today at the American Society of Clinical Oncology (ASCO) Meeting in Chicago. More than 20,000 oncologists and scientists attend this meeting each year. Dr. Charles Lu of the M.D. Anderson Cancer Center in Houston, Texas and lead investigator for AEterna's Phase III trial in lung cancer also gave a status on this trial.

### CURRENT PHASE III TRIAL IN KIDNEY CANCER

AEterna is currently conducting a double-blind randomized placebo controlled Phase III trial for renal cell carcinoma with its lead antiangiogenic compound, Neovastat, involving 302 patients. Patient recruitment was completed in December 2001 and the trial is still at the patient survival monitoring stage, increased patient survival time being the primary endpoint of the study. Following discussions with the FDA (USA), Health Products and Food Branch (Canada) and Medicines Control Agency (UK), analysis of the trial's database will start when the number of deceased patients has reached 230. Furthermore, it has been agreed with these health authorities that should that number not be reached by September 30, 2003, analysis of the trial's database would begin at that time and all patients still taking part in the trial would receive Neovastat. Dr. Escudier announced that as of today, the number of deceased patients stands at 218. Trial results will be available during the current year.

"The trial is still ongoing and on three occasions, the Data Safety Monitoring Board (DSMB) stated that the study could continue without adjustments since no safety concerns have been reported," explained Dr. Escudier. The DSMB is an independent body of oncologists and statisticians responsible for evaluating patient safety and ensuring the integrity of the trial. "Confirming Neovastat's favourable safety profile in patients suffering from serious and potentially life-threatening conditions is a valuable asset in developing a new anticancer drug, especially when it has to be taken on a chronic basis," concluded Dr. Escudier.

Gilles Gagnon, President and Chief Executive Officer at AEterna added, "We are at an exciting and also important stage of Neovastat's development. Positive results from this study could allow us to reach our goal which is to bring to market a self-administered oral drug that is not only efficient in fighting cancer but also almost devoid of debilitating side effects so as to enhance patient quality of life."

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

### NEOVASTAT POSITIVE RESULTS IN PRIOR PHASE I/II TRIAL IN KIDNEY CANCER

In March, 2001, AETerna presented results of a Phase I/II kidney cancer trial with Neovastat on patients suffering from metastatic renal cell carcinoma and refractory to standard therapies at the Annual Meeting of the American Association for Cancer Research (AACR) in New Orleans. Results showed a statistically significant two-fold increase ( $p < 0.01$ ) in median survival time for patients who had received a higher dose of Neovastat. Median survival time for patients treated with a twice-daily dose of 30mL of Neovastat was 7.1 months compared to 16.3 months for patients receiving a twice-daily dose of 120mL. These results were published last year in the European scientific review ANNALS OF ONCOLOGY. "AETerna is generating highly credible data with Neovastat which seem encouraging in the development of this new approach in fighting cancer," said Dr. Gerald Batist, Director of the McGill Centre for Translational Research in Cancer and Professor at the Department of Oncology and Medicine at McGill University in Montreal, as well as lead investigator in Canada for the current Phase III trial in kidney cancer.

Renal cell carcinoma is the most common type of kidney cancer in adults. There are about 34,000 new cases of renal cell carcinoma in North America each year and about 38,000 new cases in Europe. The five-year mortality rate for this disease is approximately 90%. The therapies currently available are effective in less than 20% of cases and are associated with a large number of serious side effects.

### CURRENT PHASE III TRIAL IN LUNG CANCER

AETerna is also conducting a Phase III trial with Neovastat in non-small cell lung cancer. Sponsored by the U.S. National Cancer Institute (NCI), the study is being held in approximately 40 hospital centers in the United States and Canada. Patients are receiving chemotherapy and radiotherapy treatments in combination with a placebo or Neovastat and the main endpoint is an increase in median survival time. At the current ASCO meeting, Dr. Charles Lu of the M.D. Anderson Cancer Center in Houston, Texas and lead investigator of this study for the United States, announced that as of today, 240 patients have been enrolled out of a total of 760. He also outlined Neovastat's excellent safety profile following recently obtained data.

### NEOVASTAT POSITIVE RESULTS IN PRIOR PHASE I/II TRIAL IN LUNG CANCER

Back in September 1999, at the 10th European Cancer Conference in Vienna (ECCO 10), AETerna had divulged results of an open-label, non-small cell lung cancer Phase I/II study. Results showed that higher doses (240 mL per day) of Neovastat significantly increased ( $p < 0.02$ ) the median survival time by 33% as compared to patients receiving lower doses. Results were published in early 2003 in CLINICAL LUNG CANCER.

### ABOUT AETERNA LABORATORIES INC.

AETerna is a biopharmaceutical company focused on the development of novel therapeutic treatments, mainly in oncology and endocrinology. The product pipeline includes 12 products ranging from preclinical stage up to marketing. AETerna has strategic worldwide partners such as Access Oncology, Ardana Bioscience, Baxter Healthcare S.A., German Remedies Ltd., Grupo Ferrer Internacional, Hainan Chang An Pharmaceutical ltd, LG Life Sciences Ltd., Mayne Group, Medac GmbH, Nippon Kayaku, Serono International S.A., Shionogi & Co. Ltd, Solvay Pharmaceuticals B.V. and Teikoku Hormone Mfg. Co. Ltd.

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

AEterna owns 100% of the biopharmaceutical company, Zentaris GmbH, based in Frankfurt, Germany.

AEterna also owns 61.8% of Atrium Biotechnologies Inc., which develops and markets nutritional supplements, as well as active ingredients and fine chemicals intended for the cosmetics, nutrition, fine chemicals and pharmaceuticals industries. Atrium markets over 500 products in 20 countries to industry leaders such as Estee Lauder, L'Oreal, Clarins, Chanel, Avnetis, SanofiSynthelabo and Nestle.

AEterna and its entities have 270 employees in Canada and Europe.

AEterna 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](http://www.aeterna.com).

PS. FOR MORE INFORMATION ON THE PHASE III TRIAL IN NON-SMALL CELL LUNG CANCER, CALL 1-888-349-3232.

### SAFE HARBOR STATEMENT

This press release 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.

- 30 -

### CANADA

#### MEDIA RELATIONS:

Paul Burroughs  
Tel.: (418) 652-8525 ext. 406  
Cell.: (418) 573-8982  
Fax: (418) 577-7700  
E-mail: [paul.burroughs@aeterna.com](mailto:paul.burroughs@aeterna.com)

#### INVESTOR RELATIONS:

Jacques Raymond  
Tel.: (418) 652-8525 ext 360  
Cell.: (514) 703-5654  
Fax: (418) 577-7700  
E-mail: [jacques.raymond@aeterna.com](mailto:jacques.raymond@aeterna.com)

### USA

#### THE INVESTOR RELATIONS GROUP

Lisa Lindberg  
Tel.: (212) 825-3210  
Fax: (212) 825-3229  
E-mail: [TheProTeam@aol.com](mailto:TheProTeam@aol.com)

### EUROPE

#### INVESTOR RELATIONS

Matthias Seeber  
Tel.: 011 49 69 4 26 02 34 25  
Fax: 011 49 69 4 26 02 34 44  
E-mail: [matthias.seeber@zentaris.de](mailto:matthias.seeber@zentaris.de)

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

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: June 2, 2003  
-----

By: /s/ Claude Vadboncoeur  
-----

Claude Vadboncoeur  
Vice President, Legal Affairs and  
Corporate Secretary