AETERNA LABORATORIES INC
Form 6-K
May 21, 2002

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 May 2002

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-__

EXHIBIT INDEX

[GRAPHIC OMITTED]

PRESS RELEASE

FOR IMMEDIATE RELEASE

AEterna: Neovastat's Favorable Safety Profile in Phase III Trials Confirmed by Independent Safety Monitoring Boards

ORLANDO, FLORIDA, MAY 21, 2002 - AEterna Laboratories Inc. (NASDAQ: AELA; TSX: AEL) announced today that the planned safety analysis of its two Phase III trials in renal cell carcinoma, a form of kidney cancer and non-small cell lung cancer conducted with Neovastat, have been positively completed.

"The Data Safety Monitoring Board (DSMB) involved in each trial stated that both studies can continue without adjustment since the safety profile of the study drug is acceptable and no safety concerns have been reported", said Dr. Claude Hariton, AEterna's Vice President and Chief Medical Officer, at a meeting on the current status of the ongoing Phase III trials, during the American Society of Clinical Oncology (ASCO) Annual Meeting in Orlando, Florida. "Last December, a first safety analysis on the Phase III renal cell carcinoma trial was also favorable." The DSMBs are independent bodies of oncologists and statisticians responsible for evaluating patient safety and ensuring the integrity of the trials.

AEterna's current international Phase III trial in renal cell carcinoma aims to increase survival time in patients who have failed to respond to standard immunotherapy treatment. Recruitment of all 302 patients for the trial has been completed and results are expected in the first quarter of 2003. The outcome of a prior Phase I/II clinical trial in renal cell carcinoma had demonstrated a statistically significant two-fold increase (p0.01) in median survival time for patients who were administered an optimal dose of Neovastat. A peer-review on the results of this Phase I/II trial will appear in an upcoming issue of ANNALS OF ONCOLOGY.

Lead investigators for the renal cell carcinoma Phase III trial expressed satisfaction regarding the conclusions of the second DSMB report on this trial. In a joint statement, Dr. Ronald Bukowski, Director of Experimental Therapeutics Program at the Cleveland Clinic Cancer Center in the United States, Dr. Gerald Batist, Director of the McGill Centre for Translational Research in Cancer and Professor in the Department of Oncology and Medicine at McGill University in Montreal, Canada, as well as Dr. Bernard Escudier, Head of Immunotherapy and Innovative Therapy Unit at the Gustave-Roussy Institute in Villejuif, France, said, "Confirming Neovastat's favorable safety profile in patients suffering from serious and potentially life-threatening conditions is a valuable asset in its development as a new anticancer drug, especially when it has to be taken on a chronic basis."

Gilles Gagnon, President and COO at AEterna Laboratories, added, "We are very pleased with the DSMB conclusions about Neovastat's safety profile. They are in line with our clinical strategy to develop a self-administered oral drug that is not only efficient in fighting cancer but also devoid of debilitating side effects so as to enhance patient quality of life when taking Neovastat alone or in combination with other therapies."

ABOUT PHASE III RENAL CELL CARCINOMA TRIAL

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.

AEterna's Phase III renal cell carcinoma cancer trial involves 302 patients who have failed to respond to standard immunotherapy treatment and aims at increasing patient survival time. It is currently being conducted in nine (9) countries on the American and European continents. Recruitment of patients for the trial has been completed and results are expected in the first quarter of 2003.

ABOUT PHASE III NON-SMALL CELL LUNG CANCER TRIAL

Lung cancer is the most prevalent form of cancer in men and women. The American Cancer Society estimates that over 170,000 new cases will be diagnosed this year, accounting for 14% of cancer diagnoses. Lung cancer is responsible for an estimated 157,000 deaths in the U.S. in 2001, accounting for 28% of all cancer deaths.

This Phase III clinical trial involving over 760 patients in approximately 50 sites across North America, strives to increase survival time of patients receiving Neovastat in combination with chemotherapy and radiotherapy. Currently, 160 patients have been enrolled in this trial which should be completed in 2005.

The trial is sponsored by the U.S. National Institutes of Health in Bethesda, Maryland. The lead investigators are Dr. Charles Lu, University of Texas M. D. Anderson Cancer Center in Houston and Dr. William K. Evans, Cancer Care Ontario, Toronto, Canada.

ABOUT AETERNA AND NEOVASTAT

AEterna Laboratories Inc. is a Canadian biopharmaceutical company and a frontrunner in the field of angiogenesis inhibitors. The Company's efforts are mainly focused on developing new cancer therapies.

AEterna's lead compound, Neovastat, is currently undergoing two Phase III clinical trials for the treatment of lung and kidney cancer, and one Phase II trial for treatment of multiple myeloma, a form of blood cancer. These clinical trials are currently being conducted in more than 140 clinical institutions in America and Europe.

AEterna shares are listed on the Toronto Stock Exchange (AEL) and the Nasdaq (AELA).

News releases and additional information about AEterna are available on its Web site at www.aeterna.com.

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.

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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: May 21, 2000

By: /s/ Claude Vadboncoeur

Claude Vadboncoeur
Vice President, Legal Affairs and
Corporate Secretary