AETERNA LABORATORIES INC
Form 6-K
October 30, 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 October 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

Exhibit Description

1. Press Release of October 29, 2002 - FDA Grants Orphan-Drug Status to AEterna's Neovastat(R) for Kidney Cancer.

[AETERNA LOGO HERE]

PRESS RELEASE
FOR IMMEDIATE RELEASE

# FDA GRANTS ORPHAN-DRUG STATUS TO AETERNA'S NEOVASTAT(R) FOR KIDNEY CANCER

QUEBEC CITY, QUEBEC, OCTOBER 29, 2002 - AEterna Laboratories Inc. (Nasdaq: AELA; TSX: AEL) announced that the U.S. Food and Drug Administration (FDA) has granted its lead product, Neovastat(R), antiangiogenic components extracted from marine cartilage, orphan-drug status for the treatment of renal cell carcinoma, a form of kidney cancer.

"We are pleased with this designation from the FDA which acknowledges the potential clinical benefit of Neovastat in renal cell carcinoma. This orphan-drug status together with the invaluable commitment from investigators in the current international Phase III clinical trials in renal cell carcinoma and non-small cell lung cancer are very encouraging, as we are completing late-stage development of this unique oral multifunctional antiangiogenic drug", said Dr. Claude Hariton, AEterna's Vice President and Chief Medical Officer.

Gilles Gagnon, President and COO at AEterna Laboratories, added, "It illustrates to our stakeholders that we continue to put in place all processes to insure the success of Neovastat's registration according to our time-to-market strategy which could enable AEterna to open a new anti-cancer therapy class."

## ORPHAN DRUG STATUS

The Orphan Drug status entitles a product to seven-year exclusive marketing rights upon receiving approval in this indication. The status further allows a company to apply for clinical research funding, tax credits on clinical research and development expenses, potential waiver of fees associated with the filing of marketing application, and assistance from the FDA Office of Orphan Products Development in guiding the drug through the regulatory approval process.

## NEOVASTAT'S FAVORABLE SAFETY PROFILE CONFIRMED

Dr. Hariton also presented the conclusions of the third meeting of the Data Safety Monitoring Board, an independent body of oncologists, responsible for evaluating patient safety and ensuring the integrity of this international Phase III trial in renal cell carcinoma. The Board stated that the safety profile of the study drug is acceptable to allow the trial to continue without adjustment. The same conclusions were conveyed by the Board during the two first meetings held in November 2001 and April 2002.

## ABOUT NEOVASTAT RCC PHASE III TRIAL

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. It is currently being conducted in nine countries on the American and European continents. The lead investigators for this study are 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, Montreal, in Canada, Dr. Ronald Bukowski, Director of Experimental Therapeutics Program at the Cleveland Clinic Cancer Center in the United States, and Dr. Bernard Escudier, Head of Immunotherapy and Innovative Therapy Unit at the Institut Gustave Roussy in Villejuif, France, in Europe.

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 ($p<0.01$) two-fold increase 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 was published in the August issue of ANNALS OF ONCOLOGY.

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.

ABOUT AETERNA AND NEOVASTAT

AEterna is a Canadian biopharmaceutical company and a frontrunner in the development of an angiogenesis inhibitor, primarily in oncology.

Neovastat, antiangiogenic components extracted from marine cartilage, is currently undergoing two Phase III clinical trials for the treatment of lung and kidney cancer and one Phase II trial for the treatment of multiple myeloma, a form of blood cancer. These trials are currently being held in more than 120 clinical institutions in Canada, the United States and several European countries.

Atrium Biotechnologies Inc., a 61.8% owned subsidiary of AEterna Laboratories, develops and markets nutritional supplements, as well as active ingredients and fine chemicals intended for the cosmetics, nutritional, fine chemicals and pharmaceutical industries. The Company markets over 500 products in 20 countries to industry leaders such as Estee Lauder, L'Oreal, Clarins, Chanel, Aventis, SanofiSynthelabo and Nestle.

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.

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: October 29, 2002

By: /s/Claude Vadboncoeur
Claude Vadboncoeur
Vice President, Legal Affairs and
Corporate Secretary