

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

AETERNA LABORATORIES INC
Form 6-K
October 07, 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 September 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. Material Change Report dated October 3rd, 2003

MATERIAL CHANGE REPORT

UNDER

SECTION 75(2) OF THE SECURITIES ACT (ONTARIO),
SECTION 81(2) OF THE SECURITIES ACT (NOVA SCOTIA),
SECTION 76(2) OF THE SECURITIES ACT (NEWFOUNDLAND AND LABRADOR),
SECTION 84(1) (b) OF THE SECURITIES ACT (SASKATCHEWAN),
SECTION 112 OF THE SECURITIES ACT (MANITOBA),

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

SECTION 146(1)(b) OF THE SECURITIES ACT (ALBERTA) AND
SECTION 85(1)(b) OF THE SECURITIES ACT (BRITISH COLUMBIA)

ITEM 1. REPORTING ISSUER

AETerna Laboratories ("AETERNA" or the "CORPORATION")
1405 Parc Technologique Blvd.
Quebec City, Quebec, Canada G1P 4P5

ITEM 2. DATE OF MATERIAL CHANGE

September 24, 2003

ITEM 3. PRESS RELEASE

A press release was issued through Canada News Wire on
September 24, 2003

ITEM 4. SUMMARY OF MATERIAL CHANGE

AETerna reported the results of the Phase III trial in renal cell carcinoma evaluating Neovastat, the Corporation's antiangiogenic compound, and the results showed that the study 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).

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.

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 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 with clear cell histology showed statistically significant clinical benefit, 26.3 months for Neovastat versus 12.6 months for the placebo group.

ITEM 6. RELIANCE ON PROVISIONS APPLYING TO THE CONFIDENTIAL FILING

N/A

ITEM 7. OMITTED INFORMATION

N/A

ITEM 8. SENIOR OFFICER

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

For further information, please contact:

Claude Vadboncoeur
Vice President, Legal Affairs and Corporate Secretary

Tel.: (418) 652-8525

ITEM 9. STATEMENT OF SENIOR OFFICER

The foregoing accurately discloses the material change referred to herein.

This report is executed at Quebec City on this 3rd day of October 2003.

(SIGNED) CLAUDE VADBONCOEUR

Claude Vadboncoeur
Vice President, Legal Affairs
and Corporate Secretary

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 3rd, 2003 by:

Claude Vadboncoeur
Vice President, Legal Affairs and
Corporate Secretary