

Edgar Filing: AETERNA LABORATORIES INC - Form 6-K

AETERNA LABORATORIES INC  
Form 6-K  
July 30, 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 July 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 July 29, 2003: AETERNA reports positive Phase III  
trial results with Impavido(R) (miltefosine)

[AETERNA LABORATORIES LOGO]

PRESS RELEASE  
FOR IMMEDIATE RELEASE

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

### AETERNA REPORTS POSITIVE PHASE III TRIAL RESULTS WITH IMPAVIDO(R) (MILTEFOSINE)

QUEBEC CITY, CANADA / FRANKFURT/MAIN, GERMANY JULY 29, 2003. - AETerna Laboratories Inc. (NASDAQ: AELA, TSX: AEL) reported today that results of a Phase III trial evaluating its drug Impavido(R) (miltefosine) for the treatment of cutaneous Leishmaniasis, a severe skin disease, showed that patients taking Impavido(R) had a 220% better cure rate compared with those in the placebo group. The average cure rate after treatment with Impavido(R) was 70%. This favourable data enables AETerna's subsidiary, Zentaris, which develops the drug, to immediately apply for a marketing authorization in South American countries where the cutaneous form of the disease is predominant.

"Impavido(R) is a breakthrough drug for the treatment of Leishmaniasis," said Prof. Jurgen Engel, Managing Director of Zentaris GmbH, Executive Vice President R&D and Chief Operating Officer at AETerna. "It has recently been approved in India as the first effective oral treatment for the life-threatening visceral form of Leishmaniasis. An even larger number of patients worldwide suffer from the cutaneous form of Leishmaniasis which can become a chronic, severely disfiguring condition. These patients are currently treated with toxic drugs that require hospitalization and intravenous administration which is often the source of new infections, like HIV. For that reason an effective orally administered drug is eagerly awaited."

Gilles Gagnon, President and Chief Executive Officer at AETerna added, "These results are another example of the depth and potential of our 12 product pipeline. Within the last three years, this pipeline has yielded three successful Phase III trials with Cetrotide(R) and Impavido(R), products which are already generating significant revenues."

#### ABOUT THE PHASE III TRIAL

Impavido(R) was tested in a randomized, double-blind, placebo-controlled study in Colombia and Guatemala, involving 133 patients suffering from cutaneous Leishmaniasis. Of these patients, 89 were treated with Impavido(R), at a dosage of 150 mg/day for four weeks, while 44 received placebo. Cure from the disease was assessed six months after the end of treatment; all skin lesions had to be healed at that time and no new skin lesions were allowed to appear. Importantly, patients with newly diagnosed cutaneous Leishmaniasis responded to treatment equally well as patients who were not cured by prior therapy. The new treatment was well tolerated; side effects of Impavido(R) were limited to short episodes of vomiting or diarrhea, similar to earlier findings in patients with visceral Leishmaniasis.

#### ABOUT LEISHMANIASIS

Leishmaniasis is a tropical disease caused by the Leishmania parasite. According to the World Health Organization (WHO), more than 12 million people are affected worldwide, with an infection rate of 2 million new cases per year. Impavido(R) has recently been approved in India for the treatment of the visceral form of this disease.

#### ABOUT AETERNA LABORATORIES INC.

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

AEterna Laboratories has an extensive portfolio of marketed and development-stage biopharmaceutical products focused in oncology and endocrinology. Its lead oncology compound is Neovastat(R), a proprietary angiogenesis inhibitor with multiple mechanisms of action in a Phase III clinical trial for renal cell carcinoma (data available by year-end 2003) and in a Phase III trial for non-small cell lung cancer. Cetrotide(R), its lead compound in endocrinology is sold in the U.S. and Europe to the IN 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 \$Cdn 100 million in 2002.

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). To find out more about the current 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) 577-7671  
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) 577-7671  
E-mail: [jacques.raymond@aeterna.com](mailto:jacques.raymond@aeterna.com)

### USA

#### INVESTOR RELATIONS

Lippert/Heilshorn & Associates  
Kim Sutton Golodetz  
Tel: (212) 838-3777  
E-mail: [kgolodetz@lhai.com](mailto:kgolodetz@lhai.com)

### GERMANY

#### SALES & MARKETING

Dr.Mathias Pietras  
Tel.: +49 69 426023423  
Fax: +49 69 426023444  
E-mail: [mathias.pietras@zentaris.de](mailto:mathias.pietras@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: July 29, 2003  
-----

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

Claude Vadboncoeur  
Vice President, Legal Affairs and  
Corporate Secretary