

Edgar Filing: Aeterna Zentaris Inc. - Form 6-K

Aeterna Zentaris Inc.
Form 6-K
December 07, 2004

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 December 2004

AETERNA ZENTARIS INC.

(Formerly named AEterna Laboratories Inc.)

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. AEterna Zentaris Receives Regulatory Approval for
 Impavido(R) in Germany

AEterna Zentaris Inc. 1405 du Parc-Technologique Blvd.
Quebec (Quebec) Canada G1P 4P5 T 418 652-8525 F 418 652-0881

AEterna Zentaris

Edgar Filing: Aeterna Zentaris Inc. - Form 6-K

www.aeternazentaris.com

PRESS RELEASE
For immediate release

AETERNA ZENTARIS RECEIVES REGULATORY APPROVAL FOR IMPAVIDO(R) IN GERMANY

QUEBEC CITY, CANADA, DECEMBER 6, 2004 - AETerna Zentaris Inc. (TSX: AEZ; Nasdaq: AEZS) today announced that it has received German Food and Drug Agency (BfarM) approval for miltefosine (Impavido(R)), the first-ever orally-administered, breakthrough therapy for visceral and cutaneous leishmaniasis, a parasitic disease estimated to affect millions of people worldwide. The approval enables AETerna Zentaris to market Impavido(R) in Germany, as well as to distribute it to military personnel who have become infected with leishmaniasis while serving in Afghanistan and Iraq. In addition, the German regulatory approval enables AETerna Zentaris to receive a Free Sales Certificate (FSC), which can provide the basis for registration in countries where leishmaniasis is endemic, such as Colombia and Pakistan.

Impavido(R), or miltefosine, is an alkylphospholipid that has been marketed in India since 2003 through cooperation with German Remedies (a member of Zydus Cadila). It is the first orally-administered therapy for visceral and cutaneous leishmaniasis, a parasitic infection, also known as black fever, which affects millions of people and is, according to WHO, endemic in 88 countries in the world with nearly 350 million people at risk. It is estimated that 12 million people currently suffer from this disease with 1-1.5 million new cases reported annually. Leishmaniasis is a very virulent tropical disease, second only to malaria.

The cure rate of Impavido(R) is 95%, even in patients resistant to antimony-based standard therapy. Leishmaniasis is transmitted by sand flies. The symptoms of visceral leishmaniasis include fever, spleen and liver enlargement, blood deficiencies, bleeding of mucous membranes, and severe weight loss. If left untreated, visceral leishmaniasis can lead to death within 0.5-2 years. The cutaneous form of leishmaniasis, although not deadly, is a chronic, severely disfiguring condition.

In Europe, leishmaniasis is a growing problem, especially in the southern regions where, until recently, it was not considered endemic. Immunocompromised HIV patients, in particular those with AIDS, are at an increased risk for this life-threatening disease with approximately 25%-70% of leishmaniasis cases in Southern Europe being associated with HIV infection. HIV patients are also particularly susceptible to repeated recurrences of leishmaniasis due to their immune system's inability to fight off the infection. Recently, in November 2004, AETerna Zentaris

announced a publication in the peer-reviewed CLINICAL INFECTIOUS DISEASES JOURNAL, demonstrating the therapeutic utility and favourable tolerability of oral miltefosine (Impavido(R)) as an initial and maintenance treatment of recurrent visceral leishmaniasis in immunocompromised HIV-infected patients.

"In addition to providing an orally-effective new medication with the potential to alleviate some human suffering from this horrible disease which unfortunately affects mostly the poorest people on earth, this approval represents the culmination of twenty years of Research and Development work

Edgar Filing: Aeterna Zentaris Inc. - Form 6-K

conducted by Dr. Jurgen Engel and his colleagues from the World Health Organization, the Max Planck Institute and the University of Goettingen in Germany", said Gilles Gagnon, President and Chief Executive Officer at Aeterna Zentaris. "Dr. Engel, our Executive Vice President, Global R&D and Chief Operating Officer, won the Galien Prize in 1995 in Germany for the discovery and development of this alkylphospholipid-based product, today recognized as an innovative medicine that can cure this potentially lethal disease which has now spread even to some parts of Southern Europe."

ABOUT AETERNA ZENTARIS INC.

Aeterna Zentaris Inc. is a biopharmaceutical company focused in oncology and endocrine therapy. Its extensive portfolio, from drug discovery to marketed products, includes cetrorelix and perifosine. Cetrorelix, an LHRH antagonist already marketed for IN VITRO fertilization under the brand name Cetrotide(R), is also in advanced clinical development for the treatment of uterine myoma, endometriosis and benign prostatic hyperplasia (BPH). Perifosine, an orally-active AKT inhibitor, is in several Phase II trials for multiple cancers.

Aeterna Zentaris also owns 60% of Atrium Biotechnologies Inc., which develops, manufactures and markets active ingredients, specialty fine chemicals, cosmetic and nutritional products for the cosmetics, chemical, pharmaceutical and nutritional industries.

News releases and additional information about Aeterna Zentaris are available on its new Web site www.aeternazentaris.com.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements 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 business opportunities in the pharmaceutical industry, uncertainties related to the regulatory process and general changes in economic conditions. Investors should consult the Company's 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-

CONTACTS:

MEDIA RELATIONS

Paul Burroughs
(418) 652-8525 ext. 406
paul.burroughs@aeternazentaris.com

U.S. INVESTOR RELATIONS

Lippert/Heilshorn & Associates
Kim Golodetz
(212) 838-3777
kgolodetz@lhai.com

INVESTOR RELATIONS

Jacques Raymond
(418) 652-8525 ext. 360
jacques.raymond@aeternazentaris.com

EUROPE

Dr. Mathias Pietras
+49 69 42602 3423
mathias.pietras@zentaris.de

Edgar Filing: Aeterna Zentaris 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 ZENTARIS INC.

Date: December 6, 2004

By: /s/ Mario Paradis

Mario Paradis
Senior Finance Director and
Corporate Secretary