

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

Aeterna Zentaris Inc.  
Form 6-K  
November 17, 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 November 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.	Press release dated November 15, 2004 -- Clinical Experience on Aeterna Zentaris' Impavido(R) Published in CLINICAL INFECTIOUS DISEASES

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

[AETERNA ZENTARIS LOGO]

AETERNA ZENTARIS INC. 1405 du Parc-Technologique Blvd.  
Quebec (Quebec) Canada G1P 4P5 T 418 652-8525 F 418 652-0881  
www.aeternazentaris.com

PRESS RELEASE  
For immediate release

## CLINICAL EXPERIENCE ON AETERNA ZENTARIS' IMPAVIDO(R) PUBLISHED IN CLINICAL INFECTIOUS DISEASES

Results support the therapeutic utility of Impavido(R) in immunocompromised HIV-infected patients with recurrent leishmaniasis

QUEBEC CITY, CANADA, NOVEMBER 15, 2004 - AETerna Zentaris Inc. (TSX: AEZ; Nasdaq: AEZS) today announced a publication in the peer-reviewed CLINICAL INFECTIOUS DISEASES Journal demonstrating the therapeutic utility and favourable tolerability of oral miltefosine (Impavido(R)) as initial and maintenance treatment of recurrent visceral leishmaniasis, an opportunistic life-threatening infection also known as black fever, in immunocompromised HIV-infected patients. The results come from a compassionate use program of oral miltefosine in 39 HIV-infected patients, all with parasitologically verified leishmaniasis, who had failed at least one and as many as nine prior courses of standard therapy for leishmaniasis and were receiving antiviral combination therapy for HIV. The initial response and initial cure rates for miltefosine were shown to be 64% and 41%, respectively, a significant positive finding in this tough-to-treat patient population that currently lacks treatment alternatives. All currently existing drug treatments for leishmaniasis have a high rate of relapse and, unlike miltefosine, are for parenteral (injection) use. Miltefosine was generally well-tolerated, with no dose-limiting side effects or adverse interactions with antiviral therapy, even when used for extended periods of maintenance treatment for up to two years. The most frequently observed side effects in this study were gastrointestinal and included vomiting, nausea and diarrhea. Miltefosine's safety and tolerability profile compares favourably to that of other treatment modalities, which can be associated with treatment-limiting side effects such as kidney toxicity.

"The results of this study continue to support the use of Impavido(R) as a much-needed treatment alternative that combines the convenience of oral use with favourable efficacy and tolerability for patients with leishmaniasis," said Prof. Jurgen Engel, Executive Vice President, Global R&D and Chief Operating Officer at AETerna Zentaris. "Leishmaniasis is becoming a growing problem in countries in Southern Europe where, until recently, it was not considered endemic. Immunocompromised patients, in particular, 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."

[AETERNA ZENTARIS LOGO]

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

Impavido(R) is currently marketed in India through cooperation with German Remedies (a member of Zydus Cadila) and has been submitted for registration in Germany, Pakistan and Colombia. It is the first orally-administered therapy for visceral and cutaneous leishmaniasis, a parasitic infection which affects millions of people and is, according to WHO, endemic in 88 countries in the world. It is estimated that annually 1-1.5 million people are newly infected and a total of 12 million people are infected. 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.

### 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](http://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](mailto:paul.burroughs@aeternazentaris.com)

#### INVESTOR RELATIONS

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

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

[AETERNA ZENTARIS LOGO]

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

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

3

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: November 16, 2004  
-----

By: /s/ Mario Paradis  
-----

Mario Paradis  
Senior Finance Director and  
Corporate Secretary