

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

Aeterna Zentaris Inc.  
Form 6-K  
March 29, 2005

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 March 2005

AETERNA ZENTARIS 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  
-----

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

1. Press release dated March 23, 2005 - Aeterna Zentaris Receives First Regulatory Approval for Impavido(R) for Parasitic Skin Disease
- 

[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

AETERNA ZENTARIS RECEIVES FIRST REGULATORY APPROVAL FOR  
IMPAVIDO(R) FOR PARASITIC SKIN DISEASE

QUEBEC CITY, CANADA, MARCH 23, 2005 - Aeterna Zentaris Inc. (TSX: AEZ; NASDAQ: AEZS) today announced it has received Colombian Food and Drug Agency approval for Impavido(R) (miltefosine), to treat the cutaneous form of leishmaniasis, a severe parasitic skin disease estimated to affect millions of people worldwide. This is the first-ever approval of Impavido(R) for this form of leishmaniasis. The approval also applies for the visceral form (black fever) of leishmaniasis for which Impavido(R) had already received approval by the Indian and German Regulatory Authorities. Impavido(R) thus becomes the first orally-administered, breakthrough therapy for both visceral and cutaneous leishmaniasis.

Impavido(R), or miltefosine, is an alkylphospholipid that has been marketed in India since 2003 through cooperation with the Zydus Cadila Group and is available in Germany via Aeterna Zentaris' partner Paesel + Lorei. In order to optimize Latin American distribution of Impavido(R) following the approval, Aeterna Zentaris has granted distribution rights for Colombia to Tecnofarma, a leading Latin American pharmaceutical company. Tecnofarma thus holds rights to the drug for the entire Latin American territory excluding only Brazil, where Roche has been granted marketing rights. Tecnofarma is currently preparing the filing of Impavido(R) in several other Latin American countries.

"Everything is in place for a first delivery of Impavido(R) to Colombia very shortly", said Prof. Jurgen Engel, Executive Vice President Global R&D and Chief Operation Officer at Aeterna Zentaris and added, "We were hoping that German approval of Impavido(R), received only in December last year, could form the basis for registration in other countries where leishmaniasis is endemic, such as Colombia. Only three months later, we are proud to deliver on that expectation. It is our goal to place Impavido(R) as a worldwide standard therapy for both cutaneous and visceral leishmaniasis."

According to Gilles Gagnon, President and Chief Executive Officer at Aeterna Zentaris, the impact of the approval is at least twofold. "We are excited about the progress of our efforts to make this innovative drug available to patients. The approval and the subsequent roll-out of the product also has a strategic dimension in that we can further diversify the business risk of our pharmaceutical activities while optimizing return for investors. With two products on the market

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

[AETERNA ZENTARIS LOGO]

generating revenues, Cetrotide(R) and Impavido(R), we are further establishing a solid financial basis to support the development of our promising earlier pipeline projects."

### ABOUT LEISHMANIASIS

Leishmaniasis is a severe tropical disease, second only to malaria. Transmitted by sand flies, leishmaniasis affects millions of people and is, according to the World Health Organisation, endemic in 88 countries throughout 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.

The cure rate of Impavido(R) is 95%, even in patients resistant to antimony-based standard therapy. Symptoms of the visceral form of the disease 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.

### ABOUT TECNOFARMA

Technofarma is a leading Latin American company engaged in the production, promotion and marketing of pharmaceutical products. Founded in 1971, it has established branch companies in fourteen countries, including Mexico and Central America, with over 1 200 pharmaceutical sales representatives. In 2004, its annual sales were US\$159 million.

### ABOUT AETERNA ZENTARIS INC.

AEterna Zentaris Inc. is an oncology and endocrine therapy focused biopharmaceutical company with proven expertise in drug discovery, development and commercialization. The Company's broad 20 product pipeline leverages five different therapeutic approaches, including LHRH antagonists and signal transduction inhibitors. The lead LHRH antagonist compound, cetrorelix, is currently marketed for IN VITRO fertilization under the brand name Cetrotide(R). Cetrorelix is also in late-stage clinical development for endometriosis and benign prostatic hyperplasia (BPH). The lead signal transduction inhibitor compound, perifosine, is an orally-active AKT inhibitor in several Phase II trials for multiple cancers.

AEterna Zentaris owns 61.1% of Atrium Biotechnologies Inc., a leading developer, manufacturer and marketer of value-added products for the cosmetics, pharmaceutical, chemical and nutritional industries.

News releases and additional information about AEterna Zentaris are available on its Web site [www.aeternazentaris.com](http://www.aeternazentaris.com).

### FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements made pursuant to the safe

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

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

2

[AETERNA ZENTARIS LOGO]

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  
-----

INVESTOR RELATIONS

GINETTE VALLIERES  
Ginette Vallieres  
(418) 652-8525 ext. 265  
ginette.vallieres@aeternazentaris.com  
-----

EUROPE

Matthias Seeber  
+49-6942602-3425  
matthias.seeber@zentaris.com  
-----

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.

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

Date: March 25, 2005

By: /s/Mario Paradis

-----  
Mario Paradis  
Senior Finance Director and  
Corporate Secretary