

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

Aeterna Zentaris Inc.  
Form 6-K  
May 20, 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 May 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  \_\_\_\_\_

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  \_\_\_\_\_

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 May 16, 2005 - AEterna Zentaris' North

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

American Partner Announces Disclosure of Phase II results with Perifosine in prostate cancer at the American Society of Clinical Oncology Annual (ASCO) Meeting

[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' NORTH AMERICAN PARTNER ANNOUNCES DISCLOSURE OF PHASE II RESULTS WITH PERIFOSINE IN PROSTATE CANCER AT THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY ANNUAL (ASCO) MEETING

### FURTHER EVIDENCE OF SINGLE AGENT ACTIVITY OBSERVED

QUEBEC CITY, CANADA, MAY 16, 2005 - Aeterna Zentaris Inc. (TSX: AEZ; NASDAQ: AEZS) announced that its North American partner for perifosine, Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX) disclosed earlier today that data presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in Orlando, Florida, demonstrated the tolerability and potential efficacy of perifosine in the treatment of patients with biochemically recurrent hormone-sensitive prostate cancer (HSPC). This study was conducted by a consortium of cancer centers under the leadership of the University of California, Davis pursuant to a Collaborative Research and Development Agreement (CRADA) between Keryx and the National Cancer Institute. Perifosine is a novel, oral, anticancer agent that modulates AKT and several other important signal transduction pathways, including MAP kinase and JNK.

This single-agent Phase II multi-center study of perifosine enrolled 25 patients with HSPC who had received prior prostatectomy and/or radiation treatment and had a rising PSA without radiographic metastasis. In the study, the patients received a loading dose of perifosine of 900mg on day one, in divided doses of at least six hours apart, then 100mg daily. Of the 25 patients enrolled, 22 were evaluable for response. Of the evaluable patients, 18 patients (82%) had stable disease and 3 (14%) had PSA progression. While no patients had a >50% reduction in PSA, 3 patients (14%) had a minor response demonstrated by a PSA reduction of less than 50%. Grade 3-4 toxicities included grade 3 hyponatremia, arthritis, hyperuricemia and vision change.

The authors concluded that perifosine in HSPC patients is feasible, well-tolerated and can reduce PSA by less than 50% in some patients. Because of its inhibitory effects on the P13K/AKT pathway, further studies of perifosine in combination with androgen ablation and chemotherapy are

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

warranted.

[AETERNA ZENTARIS LOGO]

Michael S. Weiss, Chairman and Chief Executive Officer of Keryx, stated, "We are very pleased with the results of this study. These data provide additional evidence of perifosine's potential anti-cancer activity and provide a strong basis for further studies in prostate cancer, which we plan to initiate this year. Our goal remains to provide data from our corporate sponsored clinical program later this year or early next year that will lead us to one or more regulatory approval pathways."

"We are appreciative of Keryx's strong commitment to pursue further clinical trials with perifosine following these encouraging data. Later this year, we will initiate our own Phase II clinical trials of perifosine in combination with radiotherapy, as part of our comprehensive development program for this product," said Prof. Jurgen Engel, Executive Vice President, Global R&D and Chief Operating Officer at AETerna Zentaris.

To access the abstract, entitled "The AKT Inhibitor Perifosine in Biochemically Recurrent Prostate Cancer (HSPC): A Phase 2 California Cancer Consortium Trial" please click on [www.keryx.com/pr/0401abstract.pdf](http://www.keryx.com/pr/0401abstract.pdf).

-----

Perifosine is out-licensed by AETerna Zentaris to Keryx, which holds North American rights to the drug. AETerna Zentaris holds the rest of the world rights.

### ABOUT PERIFOSINE

Perifosine, a novel, first-in-class, oral anticancer agent that modulates several key signal transduction pathways, including AKT, MAPK, and JNK that have been shown to be critical for the survival of cancer cells. Perifosine has demonstrated single agent anti-tumor activity in Phase I and Phase II studies and is currently being studied as a single agent and in combination with several forms of anti-cancer treatments for various forms of cancer, including non-small cell lung cancer and breast cancer.

### ABOUT AETERNA ZENTARIS INC.

AETerna Zentaris Inc. is an oncology and endocrine therapy focused biopharmaceutical company with proven expertise in drug discovery, development and marketing. The Company's broad 20 product pipeline leverages six 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 a novel, first-in-class, oral anticancer agent that modulates several key signal transduction pathways, including AKT, MAPK, and JNK that have been shown to be critical for the survival of cancer cells. Perifosine has demonstrated single agent anti-tumor activity in Phase I and Phase II studies and is currently being studied as a single agent and in combination with several forms of anti-cancer treatments for various forms of cancer, including non-small cell lung cancer and breast cancer.

AETerna Zentaris also owns 50.3% of Atrium Biotechnologies Inc. (TSX: ATB.sv), a leading developer, manufacturer and marketer of value-added products for the

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

cosmetics, pharmaceutical, chemical and nutritional industries.

2

[AETERNA ZENTARIS LOGO]

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 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

Ginette Vallieres  
(418) 652-8525 ext. 265  
[ginette.vallieres@aeternazentaris.com](mailto:ginette.vallieres@aeternazentaris.com)

EUROPE

Matthias Seeber  
+49 69 42602 3425  
[matthias.seeber@aeternazentaris.com](mailto:matthias.seeber@aeternazentaris.com)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of

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

1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AETERNA ZENTARIS INC.

Date: May 17, 2005  
-----

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

Mario Paradis  
Senior Finance Director and  
Corporate Secretary