

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      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 May 17, 2005 - AEterna Zentaris: An Interim Report of Toxicity and Response From a US National Cancer Institute Phase III Trial in Lung Cancer with Neovastat

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

AETERNA ZENTARIS

AETERNA ZENTARIS INC.: 1405 du Parc-Technologique Blvd.  
Quebec (Quebec) Canada G1P 4P5 T 418 652-8525 F 416 652-0881  
www.aeternazentaris.com

PRESS RELEASE  
For immediate release

AETERNA ZENTARIS: AN INTERIM REPORT OF TOXICITY AND RESPONSE FROM A US NATIONAL  
CANCER INSTITUTE PHASE III TRIAL IN LUNG CANCER WITH NEOVASTAT

RESULTS PRESENTED AT THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) ANNUAL  
MEETING

QUEBEC CITY, CANADA, MAY 17, 2005 - Aeterna Zentaris Inc. (TSX: AEZ; NASDAQ: AEZS) announced that an interim report of toxicity and response from the ongoing US National Cancer Institute (NCI) Phase III trial in unresectable stage III non-small cell lung cancer with Neovastat, was presented earlier today by Dr. Charles Lu, of the M.D. Anderson Cancer Center, in Houston, Texas and one of the lead investigators of the trial, at the annual meeting of the American Society of Clinical Oncology (ASCO) in Orlando, Florida. Data from 341 patients as of November 2004, demonstrated that blinded overall toxicity observed in this trial appears acceptable. Blinded response data after induction chemotherapy (IC) and concomitant chemoradiotherapy (CRT) are available for 233 and 214 subjects, respectively IC and CRT: partial response and complete response combined was shown in 35% of IC patients and in 39% of CRT patients. Stabilization of the disease was observed in 57% of IC patients and in 48% of CRT patients. Progressive disease was shown in 8% of IC patients and in 13% of CRT patients.

Patients registered in the trial receive one of two treatment regimens: carboplatin (C) and paclitaxel (P), followed by concomitant chemoradiotherapy (CRT) with weekly C and P or cisplatin (CDDP) and vinorelbine (V) followed by CRT with CDDP and V. Neovastat or placebo (120ml orally twice daily) is started with induction chemotherapy (IC) and continued after CRT as maintenance therapy.

The study is being conducted in multiple centers in the United States and Canada. The planned total number of patients to be recruited is 756. Accrual to this NCI-sponsored intergroup study continues and so far, 355 patients have been randomized.

The complete data of the trial is available in the abstract, entitled "A Phase III study of AE-941 with induction chemotherapy (IC) and concomitant chemoradiotherapy (CRT) for stage III non-small cell lung cancer (NSCLC) (NCI T99-0046, RTOG 02-70, MDA 99-303): An interim report of toxicity and response."

AETERNA ZENTARIS

ABOUT NEOVASTAT

Neovastat is an antiangiogenic inhibitor with multiple mechanisms of action: inhibition of VEGF signalling, MMP activity, and induction of endothelial cell apoptosis.

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 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 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.

AETERNA ZENTARIS

-30-

CONTACTS

MEDIA RELATIONS

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

INVESTOR RELATIONS

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

EUROPE

Matthias Seeber  
+49 69 42602 3425  
matthias.seeber@aeternazentaris.com  
-----

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: May 18, 2005  
-----

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

Mario Paradis  
Senior Finance Director and Corporate Secretary