

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

Aeterna Zentaris Inc.  
Form 6-K  
February 13, 2008

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 February 2008

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 February 12, 2008: AETerna Zentaris Reports First  
Patients Treated with Anti-Cancer Compound AEZS-108 in Phase 2 Trial in  
Ovarian and Endometrial Cancers

[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

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

PRESS RELEASE  
For immediate release

### AETERNA ZENTARIS REPORTS FIRST PATIENTS TREATED WITH ANTI-CANCER COMPOUND AEZS-108 IN PHASE 2 TRIAL IN OVARIAN AND ENDOMETRIAL CANCERS

QUEBEC CITY, CANADA, FEBRUARY 12, 2008 - Aeterna Zentaris Inc. (NASDAQ: AEZS; TSX: AEZ), a global biopharmaceutical company focused on endocrine therapy and oncology, today reported that dosing of AEZS-108, a luteinizing hormone-releasing hormone (LHRH) agonist linked to doxorubicin, has commenced in its Phase 2 trial in gynaecological cancers for which patient enrolment had begun in December 2007. This open-label, non-comparative multi-center Phase 2 trial will treat up to 82 women with LHRH-receptor positive ovarian and endometrial cancerous tumors. The primary endpoint for the trial will be the partial or complete tumor response rate according to Response Evaluation Criteria in Solid Tumors (RECIST) and/or Gynaecologic Cancer Intergroup (GCIG) guidelines. The trial is being conducted in 15 centers in Europe under the supervision of lead investigator, Prof. Gunter Emons, M.D., of the Georg-August-University, Gottingen Institute of Gynaecology and Obstetrics in Gottingen, Germany.

David J. Mazzo, Ph.D., President and CEO of Aeterna Zentaris commented, "We are excited to have started dosing patients in our Phase 2 trial with AEZS-108, our highest priority oncology compound. We believe that our approach targeting only patients with LHRH-receptor expressing tumors using doxorubicin is key to both potential increased individual patient safety and potential augmented clinical benefit, while ultimately providing us results that will be pivotal in formulating the next steps in the clinical development of this novel agent."

#### ABOUT THE PHASE 2 TRIAL

Entitled, "THE ANTITUMORAL ACTIVITY AND SAFETY OF AEZS-108 (AN-152), A LHRH AGONIST LINKED DOXORUBICIN IN WOMEN WITH LHRH-RECEPTOR POSITIVE GYNAECOLOGICAL TUMORS", this European open-label, non-comparative multi-center Phase 2 trial will have as its primary endpoint the partial or complete tumor response rate according to RECIST and/or GCIG guidelines. Secondary endpoints will include time to progression, survival, toxicity as well as adverse effects. The trial will include up to 82 patients (up to 41 with a diagnosis of platinum-resistant ovarian cancer and up to 41 with disseminated endometrial cancer). Patients will be administered an intravenous infusion of 267 mg/m (TO THE POWE OF 2) of AEZS-108 over a period of 2 hours at a constant rate, every Day 1 of a 21-day (3-week) cycle. The proposed duration of the study

treatment is six, three-week cycles. The planned study period is approximately 24 months. Further information on the trial is available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

#### PRIOR PHASE 1 TRIAL RESULTS

On June 3, 2007 positive results of an open, multi-center, sequential group, dose-escalation Phase 1 study in various gynaecological cancers were presented at the American Society of Clinical Oncology's (ASCO) Annual Meeting in Chicago, Illinois. 17 patients with LHRH-receptor positive gynaecological cancers were recruited. AEZS-108 was administered by intravenous infusion over two hours at dosages of 10, 20, 40, 80, 160 and 267 mg/m (TO THE POWE OF 2). At 160 mg/m (TO THE POWE OF 2), six patients had a total of 32 cycles and at 267 mg/m (TO THE POWE OF 2), seven patients had a total of 27 cycles. Most of the patients had been pretreated with various chemotherapies.

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

The study showed that AEZS-108 was well tolerated by patients with gynaecological tumors. Furthermore, AEZS-108 is the first drug in a clinical study that targets the cytotoxic activity of doxorubicin specifically to LHRH-receptor expressing tumors. Finally, signs of anti-tumor activity were observed in three out of 13 patients treated with 160 or 267 mg/m (TO THE POWE OF 2) of AEZS-108, including three patients with complete or partial response.

### ABOUT AEZS-108

AEZS-108 is a targeted cytotoxic peptide conjugate which is a hybrid molecule composed of a synthetic peptide carrier and a well-known cytotoxic agent, doxorubicin. The design of this product allows for the specific binding and selective uptake of the cytotoxic conjugate by LHRH-receptor-positive tumors. The binding of AEZS-108 to cancerous cells that express these receptors results in its accumulation in the malignant tissue. This binding is followed by internalization and retention of the cytotoxic drug, doxorubicin, in the cells. Therefore, since they target specific cells, cytotoxic conjugates are postulated to be less toxic, have less side-effects and are more effective IN VIVO than the respective non-conjugated/non-linked cytotoxic agents in inhibiting tumor growth.

### ABOUT OVARIAN AND ENDOMETRIAL CANCER

Ovarian cancer is one of the most common gynaecologic malignancies and the fifth most frequent cause of cancer death in women, with most of the cases occurring in women between 50 and 75 years of age. Overall, ovarian cancer accounts for 4% of all cancer diagnosis in women and 5% of all cancer deaths. Approximately 26,000 new cases and 17,000 deaths from this disease are estimated in the European community every year.

(Source: GYNECOLOGIC ONCOLOGY, VOLUME 92, ISSUE 3, MARCH 2004, PAGES 819-826)

Cancer of the endometrium is the most common gynaecologic malignancy and accounts for 6% of all cancers in women. The majority of the cases occur in postmenopausal women, with the largest number of women developing their cancers during the sixth decade. Approximately 38,000 new cases and 9,000 deaths from this disease are estimated annually in Europe.

(Source: ANNALS OF ONCOLOGY 15:1149-1150, 2004)

### ABOUT AETERNA ZENTARIS INC.

Aeterna Zentaris Inc. is a global biopharmaceutical company focused on endocrine therapy and oncology with proven expertise in drug discovery, development and commercialization.

News releases and additional information are available at [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

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

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. We disclaim any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements contained herein to reflect future results, events or developments except if we are requested by a governmental authority or applicable law.

-30-

CONTACTS

Jenene Thomas  
Senior Director, Investor Relations & Corporate Communications  
(908) 626-5509  
jthomas@aezsinc.com

Paul Burroughs  
Media Relations  
(418) 652-8525 ext. 406  
pburroughs@aezsinc.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.

Date: February 12, 2008  
-----

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

Mario Paradis  
Senior Vice President, Administrative and  
Legal Affairs and Corporate Secretary