Aeterna Zentaris Inc.
Form 6-K
September 23, 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 September 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 September 22, 2005 - AEterna Zentaris Initiates Multi-Center Phase II Trial of Perifosine in Combination with Radiotherapy in Non-Small Cell Lung Cancer

AETERNA ZENTARIS LOGO

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PRESS RELEASE
For immediate release

AETERNA ZENTARIS INITIATES MULTI-CENTER PHASE II TRIAL OF PERIFOSINE IN COMBINATION WITH RADIOTHERAPY IN NON-SMALL CELL LUNG CANCER

QUEBEC CITY, CANADA, SEPTEMBER 22, 2005 - AEterna Zentaris Inc. (TSX: AEZ; Nasdaq: AEZS) today announced the initiation of a European multi-center Phase II trial of perifosine, a novel, first-in-class, oral signal transduction inhibitor, in combination with radiotherapy, in non-small cell lung cancer (NSCLC). This exploratory randomized, double-blind, placebo-controlled trial will assess the efficacy and safety of a 150 mg daily dose of perifosine when combined with radiotherapy in 160 patients with inoperable Stage III NSCLC.

Patients will receive perifosine daily for 5 to 6 weeks, starting 7 days prior to radiotherapy, and will be followed up for at least 12 months. The primary endpoint of this trial will be the extent and duration of local control, i.e. the absence of tumor recurrence or progression in the area that has been irradiated.

The trial is being conducted in collaboration with the Netherlands Cancer Institute. The lead investigator is Marcel Verheij, MD PhD, of the Department of Radiation Oncology / Division of Cellular Biochemistry, at The Netherlands Cancer Institute in Amsterdam.

Dr. Verheij was the lead investigator in a prior Phase I trial with perifosine in combination with radiotherapy. Results of that trial were presented at the

American Society of Clinical Oncology (ASCO) annual meeting in June 2004. A total of 21 radiotherapy-naive patients, of whom 17 had advanced non-small cell lung cancer (1 Stage IIIA, 15 Stage IIIB, 1 Stage IV) and 14 had become refractory to prior chemotherapy, received oral perifosine doses ranging from 50 mg to 200 mg/day concurrently with standard doses of radiotherapy. The trial data demonstrated the following: (i) acceptable safety and tolerability, with 150 mg/day established as the dose recommended for use in subsequent clinical trials; (ii) dose limiting toxicity (nausea/vomiting) at 200 mg/day; (iii) no bone marrow toxicity; and (iv) preliminary evidence of anti-tumor activity at all dosage levels, including complete or partial responses (complete disappearance and decreased tumor size, respectively), or stable disease, with a median follow-up for responders of 8 months.

Importantly, in the cohort of 10 patients who were treated with 150 mg/day established as the dose recommended for and now used in this Phase II trial, there were 3 complete responses (2 NSCLC and 1 esophageal cancer), 3 partial responses (2 NSCLC and 1 prostate cancer), and

4 patients with stable disease. In addition, a patient with bladder cancer who received 50 mg/day perifosine had an unexpected finding, namely a long-lasting complete response.

"There is sound scientific, preclinical and early clinical rationale for using perifosine to increase the efficacy of radiotherapy while maintaining favourable tolerability and avoiding overlapping toxicity", said Dr. Jurgen Engel, Executive Vice President, Global R&D and Chief Operating Officer at AEterna Zentaris. "The initiation of this trial is a significant step in further exploring the potential of perifosine as an important therapeutic approach that can improve the outcomes of advanced NSCLC patients treated with radiotherapy."

Gilles Gagnon, President and Chief Executive Officer at AEterna Zentaris added, "This large Phase II trial assessing perifosine in combination with radiotherapy, in addition to ongoing studies by our North American partner Keryx Biopharmaceuticals with perifosine in monotherapy and in combination with chemotherapy, are all aimed at establishing perifosine as a potential breakthrough cancer drug and reflect our commitment in building a solid oncology franchise at AEterna Zentaris."

ABOUT PERIFOSINE

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. To date, approximately 350 patients have been treated with perifosine at various doses and schedules. From a clinical safety perspective, no dose-limiting toxicity, other than gastro-intestinal toxicity, has been observed.

Perifosine has demonstrated single agent anti-tumor activity in Phase I and Phase II studies. As a single agent, perifosine was the object of a large screening Phase II program funded by the U.S. National Cancer Institute in collaboration with AEterna Zentaris' North American partner, Keryx Biopharmaceuticals (Nasdaq: KERX). Finding from these screening studies led investigators to conclude that perifosine in monotherapy could be further investigated in soft tissue sarcoma, melanoma as well as breast, prostate and non-small cell lung cancer, while it was advised not to pursue studies with

perifosine in monotherapy in head and neck and pancreatic cancer.

Keryx has initiated a large Phase II trial program with perifosine. In monotherapy, foreseen indications are non-small cell lung cancer, prostate cancer and soft tissue sarcoma. In combination therapy, studies have been or will soon be initiated with agents such as Gemcitabine (pancreatic cancer), Paclitaxel/Taxol, Docetaxel/Taxotere, as well as with biologic agents such as Herceptin in breast cancer.

ABOUT NON-SMALL CELL LUNG CANCER

Non-small cell lung cancer is the most common form of the disease and accounts for almost 80 percent of all lung cancers. According to the World Health Organization, there are more than 1.2 million cases of lung and bronchial cancer worldwide each year. It is estimated that more than 173,000 people will be diagnosed with lung cancer in the United States in 2005. According to the National Cancer Institute, lung cancer is the leading cause of cancer deaths in the United States and is responsible for nearly 30 percent of cancer deaths in this country.

ABOUT AETERNA ZENTARIS INC.

AEterna Zentaris Inc. is a growing global biopharmaceutical company engaged in the discovery, development and marketing of therapies for cancer and endocrine disorders.

AEterna Zentaris also owns 50.03% of Atrium Biotechnologies Inc. (TSX: ATB.sv), a developer, manufacturer and marketer of science-based products for the cosmetics, pharmaceutical, chemical and nutritional industries.

News releases and additional information are available at 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.

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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: September 22, 2005

By: /s/ Mario Paradis
Mario Paradis

Senior Finance Director and Corporate Secretary