

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

Aeterna Zentaris Inc.
Form 6-K
June 10, 2009

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 June 2009

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 /X/ 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 /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. Aeterna Zentaris Discloses Preliminary Phase 2 Trial Results for
Perifosine in Combination with Radiotherapy for Non Small Cell Lung
Cancer

[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.aezsinc.com

PRESS RELEASE
For immediate release

AETERNA ZENTARIS DISCLOSES PRELIMINARY PHASE 2 TRIAL RESULTS FOR PERIFOSINE IN
COMBINATION WITH RADIOTHERAPY FOR NON-SMALL CELL LUNG CANCER

QUEBEC CITY, CANADA, JUNE 8, 2009 - Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX:

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

AEZ), a global biopharmaceutical company focused on endocrine therapy and oncology, today disclosed preliminary results for the Company's European multi-center Phase 2 trial in non-small cell lung cancer (NSCLC) with its novel, first-in-class, oral signal transduction inhibitor compound, perifosine. In 177 patients receiving radiotherapy for inoperable NSCLC, this randomized, double-blind, placebo-controlled trial assessed the radioenhancing activity and safety of perifosine co-administration.

ABOUT THE PHASE 2 TRIAL

Starting one week before the onset of a 4-week course of radiotherapy (51 Gy in 17 fractions), patients with non-metastatic but inoperable NSCLC, mainly Stage III, received a 5-week course of 150 mg perifosine daily or placebo. After end of radiotherapy, patients were followed up to determine the time to tumor recurrence or progression in the area that had been irradiated, the so called 'local control'. The primary endpoint of this trial was the extent and duration of local control, specifically the proportion of patients with absence of recurrence or progression 12 months after the end of treatment. The study was planned under the basic assumption that radiotherapy alone would result in a 35% local control rate, one year after end of therapy in the placebo group. It was hypothesized that the addition of perifosine would sensitize tumor cells to the tumor-killing effect of the radiotherapy, leading to a 15% higher rate of local control. Secondary efficacy parameters included the times to loco-regional or distant/systemic failure, the tumor response rate, and overall survival. Safety investigations included the monitoring of clinical laboratory, electrocardiograms, lung function, and adverse events.

The trial was conducted in collaboration with the Netherlands Cancer Institute. The lead investigator was Marcel Verheij, MD, Ph.D., Head of the Department of Radiation Oncology and group leader at the Division of Cell Biology of The Netherlands Cancer Institute in Amsterdam. In all, 22 study sites in The Netherlands, Bulgaria, Romania, Macedonia, and Belarus participated in this trial.

[AETERNA ZENTARIS LOGO]

RESULTS

A total of 177 patients were randomized and treated, of whom only 26 reached the milestone of one year post-treatment follow-up without disease relapse or progression, 14 of 95 patients (14.7%) in the perifosine and 12 of 82 patients (14.6%) in the placebo control group. No difference between treatment groups could be shown for local, loco-regional and overall disease control. Also the tumor response rate, as assessed after the end of the radiotherapy, was not different between the groups.

In contrast to the lack of an observed local effect, patients in the perifosine group, particularly the subgroup of patients who entered the study without prior chemotherapy, showed a trend towards longer survival than patients of the placebo control group despite the short duration of treatment (5-week course of 150 mg perifosine daily).

There were no safety signals that would lead to an amendment of the current safety data or risk benefit assessments of perifosine. The type and severity of side effects were in the expected range.

Marcel Verheij, M.D., Ph.D., lead investigator, "The neutral outcome of this study is related to the unexpectedly high number of distant failures and premature discontinuations for other reasons, which heavily compromised the power of the study to show any effect on the local control rate at one year."

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

Paul Blake, M.D., Senior Vice President and Chief Medical Officer at Aeterna Zentaris, "In light of these neutral results and an unchanged safety profile, we can concentrate our efforts on the disease targets of both multiple myeloma and metastatic colon cancer where, unlike the non-small cell lung cancer study design, perifosine is dosed 50mg or 100mg daily until progression. Recently, positive Phase 2 data for multiple myeloma and metastatic colon cancer were presented at ASH and ASCO meeting, respectively."

ABOUT PERIFOSINE

Perifosine is a novel, first-in-class, oral anti-cancer 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 1 and Phase 2 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. Most recently, positive results were reported for the single agent use of perifosine in patients with advanced metastatic renal cancer and in combination with capecitabine for advanced metastatic colon cancer (placebo-controlled), as well as for perifosine in combination with bortezomib +/- dexamethasone in relapsed and refractory myeloma.

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.aezsinc.com.

[AETERNA ZENTARIS LOGO]

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, and 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 to do so by a governmental authority or applicable law.

INVESTOR RELATIONS

Ginette Vallieres
Investor Relations Coordinator
(418) 652-8525 ext. 265
gvallieres@aezsinc.com

MEDIA RELATIONS

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

Paul Burroughs
Director of Communications
(418) 652-8525 ext. 406
pburroughs@aezsinc.com

-30-

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: June 10, 2009

By: /s/Dennis Turpin

Dennis Turpin
Senior Vice President and Chief Financial Officer