

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

Aeterna Zentaris Inc.
Form 6-K
October 01, 2004

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 2004

AETERNA ZENTARIS INC.
(Formerly named AEterna Laboratories 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 30, 2004 - Data from Perifosine Phase II
 Single-Agent Soft Tissue Sarcoma Study Presented at the 16th Annual
 EORTC-NCI-AACR Conference

Aeterna Zentaris

Aeterna Zentaris Inc. 1405 du Parc-Technologique Blvd.
Quebec (Quebec) Canada G1P 4P5 T 418 652-8525 F 418 577-7697
www.aeternazentaris.com

PRESS RELEASE
For immediate release

DATA FROM PERIFOSINE PHASE II SINGLE-AGENT SOFT TISSUE SARCOMA STUDY PRESENTED
AT THE 16TH ANNUAL EORTC-NCI-AACR CONFERENCE

QUEBEC CITY, CANADA, SEPTEMBER 30, 2004 - Aeterna Zentaris Inc. (TSX: AEZ; NASDAQ: AEZS) through its North American partner, Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX), announced today that Phase II data presented at the 16th Annual EORTC-NCI-AACR symposium on "Molecular Targets and Cancer Therapeutics" demonstrated the tolerability and potential efficacy of perifosine in the treatment of patients with advanced soft tissue sarcoma. This study was conducted by the National Cancer Institute (NCI) pursuant to a Collaborative Research and Development Agreement (CRADA) between Keryx and the NCI.

In this single-agent Phase II multi-center study of perifosine, 23 patients with advanced soft-tissue sarcoma received a loading dose of 150 mg, every six hours starting on day one, followed by 100 mg daily thereafter. The patients enrolled in this study had prior treatment, including 1-2 chemotherapy regimens, surgery and/or radiotherapy. Nineteen patients received more than one course of treatment. There was one confirmed partial response lasting more than five months and two patients that remained progression-free at six months.

Perifosine was also shown to be well tolerated at the doses used. All 23 patients were evaluable for toxicity and notable toxicities seen included Grade 4 ileus (one patient), Grade 3 toxicity (six patients) including fatigue (two patients) and one patient each of anemia, infection, muscle weakness, pain, rash, anorexia, dehydration, and diarrhea. Of the Grade 3 and 4 toxicities seen, it is unclear which ones were related to the disease or the drug. There was no Grade 3 or 4 nausea or vomiting seen in this trial.

The authors concluded in summary that the regimen was tolerable and that the preliminary observation of another responder in soft tissue sarcoma, such as was seen in the Phase I program, raises the question of whether specific histologies or tumor characteristics might predict a more sensitive subpopulation of soft tissue sarcoma patients.

I. Craig Henderson, M.D., President of Keryx Biopharmaceuticals, commented, "The level of activity seen in this study, combined with the previous Phase I single-agent experience where two partial responses were reported out of ten sarcoma patients enrolled, provides us with very strong evidence for the potential single-agent activity of this drug in soft tissue sarcoma,

Aeterna Zentaris

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

particularly in one or more subtypes." Dr. Henderson added, "Soft tissue sarcoma is a very aggressive disease characterized by many heterogeneous subtypes or histologies, for which few, if any, drugs work across multiple subtypes. The overall response rate of sarcomas to the most effective front-line chemotherapy treatments is about 10-20%, and some subtypes are totally unresponsive to any form of chemotherapy."

Dr. Henderson also stated, "We believe that our correlative science program will help us to potentially identify at least one subtype of soft tissue sarcoma for which we may be able to conduct a single-agent registration trial with perifosine in the near future."

Gilles Gagnon, Chief Executive Officer and President of AEterna Zentaris, concluded, "We are pleased with the continued advancement of clinical development of perifosine by our partner Keryx and their ongoing commitment to aggressively develop perifosine as a single agent or in combination with other cancer treatments."

To access the abstract, entitled "Tolerability and limited activity of perifosine in patients with advanced soft tissue sarcoma (STS): a multi-center phase 2 consortium (P2C) study," please click [here](#).

Perifosine is in-licensed by Keryx from AEterna Zentaris Inc. (TSX: AEZ, Nasdaq: AEZS), which holds ex-North American rights to the drug.

ABOUT AETERNA ZENTARIS INC.

AEterna Zentaris Inc. is a biopharmaceutical company focused in oncology and endocrine therapy. Its extensive portfolio, from drug discovery to marketed products, includes perifosine, an orally-active AKT inhibitor in several Phase II trials for multiple cancers, and cetrorelix, an LHRH antagonist already marketed for IN VITRO fertilization under the brand name Cetrotide(R), and also in advanced clinical development for the treatment of uterine myoma, endometriosis and benign prostatic hyperplasia (BPH).

AEterna Zentaris also owns 62% of Atrium Biotechnologies Inc., which develops, distributes and markets active ingredients, specialty fine chemicals, cosmetic and nutritional products for the cosmetics, chemical, pharmaceutical and nutritional industries.

News releases and additional information about AEterna Zentaris are available on its new Web site 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

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

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

INVESTOR RELATIONS

Jacques Raymond
(418) 652-8525 ext. 360
jacques.raymond@aeternazentaris.com

U.S. INVESTOR RELATIONS

Lippert/Heilshorn & Associates
Kim Golodetz
(212) 838-3777
kgolodetz@lhai.com

EUROPE

Matthias Seeber
+49 69 42602 3425
matthias.seeber@zentaris.de

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 30, 2004

By: /s/ MARIO PARADIS

Mario Paradis
Senior Finance Director and
Corporate Secretary