

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

Aeterna Zentaris Inc.
Form 6-K
July 20, 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 June 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 of June 3, 2004: AETERNA ZENTARIS TO PRESENT AT THREE

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

2. UPCOMING CONFERENCES: ASCO, BIO 2004 AND NEEDHAM BIOTECHNOLOGY CONFERENCE
Press release of June 7, 2004: AETERNA ZENTARIS REPORTS
ENCOURAGING RESULTS FROM PHASE I TRIAL OF PERIFOSINE IN
COMBINATION WITH RADIOTHERAPY AT THE 2004 AMERICAN SOCIETY OF
CLINICAL ONCOLOGY (ASCO) ANNUAL MEETING
-

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

AETERNA ZENTARIS

PRESS RELEASE
For immediate release

AETERNA ZENTARIS TO PRESENT AT THREE UPCOMING CONFERENCES:
ASCO, BIO 2004 AND NEEDHAM BIOTECHNOLOGY CONFERENCE

QUEBEC CITY, CANADA, JUNE 3, 2004 - Aeterna Zentaris Inc. (TSX: AEZ; Nasdaq: AEZS) announced today presentations at three upcoming conferences - ASCO, BIO 2004 and Needham Biotechnology Conference - in June 2004.

The first presentation will be at the American Society of Clinical Oncology Annual Meeting at the Ernest Memorial Convention Center in New Orleans, LA, on June 7, between 8:00 am and 12:00 noon CT. Marcel Verheij, M.D., of the Netherlands Cancer Institute, will present poster #N3-3064 "PHASE I STUDY OF COMBINED TREATMENT WITH THE ORAL ALKYL-LYSOPHOSPHOLIPID (ALP) PERIFOSINE AND RADIATION IN PATIENTS WITH ADVANCED SOLID TUMORS."

Also on June 7, Gilles Gagnon, President and Chief Executive Officer of Aeterna Zentaris, will provide a corporate update at BIO 2004 at 12:00 noon PT, at the Moscone Convention Center in San Francisco, CA.

Finally, on June 17, at 8:30 a.m. ET, Dr. Jurgen Engel, Executive Vice President, Global R&D and COO at Aeterna Zentaris, will provide a corporate update at the Third Annual Biotechnology Conference of Needham & Co., at the Palace Hotel in New York City, NY. A live webcast of the presentation will be available on the Company's website at WWW.AETERNAZENTARIS.COM in the Investors section. A replay of the webcast will be available for a period of 90 days at the same address.

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 owns 100% of Zentaris GmbH in Germany. It also owns 62% of Atrium Biotechnologies Inc., which develops, distributes and markets active

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

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 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

AETerna Zentaris Inc. 1405 du Parc-Technologique Blvd.
Quebec (Quebec) Canada G1P 4P5 T 418 652-8525 F 418 652-0881

AETerna Zentaris

PRESS RELEASE
For immediate release

AETERNA ZENTARIS REPORTS ENCOURAGING RESULTS FROM PHASE I TRIAL
OF PERIFOSINE IN COMBINATION WITH RADIOTHERAPY AT THE 2004
AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) ANNUAL MEETING

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

Data demonstrated acceptable safety/tolerability and preliminary evidence of antitumor activity, including multiple complete and partial responses, at all dosage levels.

NEW ORLEANS, JUNE 7, 2004 - AETerna Zentaris Inc. (TSX: AEZ; NASDAQ: AEZS) announced today encouraging final results from recently completed Phase I trial evaluating perifosine, the Company's novel, first-in-class, oral AKT inhibitor, in combination with radiotherapy in patients with unresectable locally advanced tumors, in a poster session at the 2004 ASCO Annual Meeting, which takes place in New Orleans, LA. Marcel Verheij, M.D., of the Netherlands Cancer Institute, presented poster #N3-3064 entitled "Phase I Study of Combined Treatment with the Oral Alkyl-Lysophospholipid (ALP) Perifosine and Radiation in Patients with Advanced Solid Tumors."

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 antitumor 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 (see Phase I trial data summary table at the end of the press release).

Importantly, in the cohort of 10 patients who were treated with 150 mg/day established as the dose recommended for use in subsequent clinical trials, there were 3 complete responses (2 non-small cell lung cancer (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.

These Phase I results support the ongoing clinical development of perifosine and will form the basis for subsequent placebo-controlled trials evaluating perifosine in combination with radiotherapy as a potential treatment for multiple types of cancer. Based on perifosine's pharmacokinetic profile (plasma concentration fluctuations), in future trials, perifosine will be administered 1 week prior to radiotherapy. AETerna Zentaris plans to initiate Phase II trials on perifosine in combination with radiotherapy through the ongoing collaboration with the Netherlands Cancer Institute of Amsterdam.

The ongoing clinical development of perifosine in North America includes nine open-label, single agent Phase II trials in six cancer types that are being conducted through collaboration with Keryx Biopharmaceuticals Inc. (NASDAQ: KERX) and the United States National Cancer Institute (NCI). AETerna Zentaris holds ex-North America rights to perifosine through Zentaris GmbH, which originally discovered and developed perifosine.

To date, five Phase I trials have been conducted on perifosine, including the trial highlighted at ASCO. In the four preceding trials, use of perifosine as a single agent in a total of 94 patients provided initial, encouraging evidence of antitumor activity. Namely, investigators observed two partial responses (>50% reduction) in patients with sarcoma and sixteen stable disease in patients with breast, prostate, pancreatic and other forms of cancer.

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

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 owns 100% of Zentaris GmbH in Germany. It 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 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

SEE ATTACHED DOCUMENT

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

AETERNA ZENTARIS INC.

PHASE I TRIAL DATA SUMMARY, POSTER #N3-3064

PERIFOSINE DOSE	NUMBER OF PATIENTS (N)	RESPONSE	TUMOR TYPE
50 mg/day	3	SD (N=2) CR (N=1)	Bladder
100 mg/day	3	SD (N=2) PR (N=1)	NSCLC
150 mg /day	10	SD (N=4) PR (N=3) CR (N=3)	1 Prostate; 2 NSCLC 2 NSCLC; 1 Esophageal
200 mg/day	5	SD (N=4) CR (N=1)	NSCLC

SD=stable disease; PR=partial response; CR=complete response

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: JULY 20, 2004

By: /S/MARIO PARADIS

Mario Paradis

Senior Director, Finance and Corporate Sec