

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

Aeterna Zentaris Inc.
Form 6-K
March 27, 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 March 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 March 26, 2008: AETerna Zentaris Begins Second Phase 3 Trial of Cetrorelix for Benign Prostatic Hyperplasia

[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.aeternazentaris.com

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

PRESS RELEASE
For immediate release

AETERNA ZENTARIS BEGINS SECOND PHASE 3 TRIAL OF CETRORELIX FOR BENIGN PROSTATIC HYPERPLASIA

QUEBEC CITY, CANADA, MARCH 26, 2008 - Aeterna Zentaris Inc. (NASDAQ: AEZS; TSX: AEZ), a global biopharmaceutical company focused on endocrine therapy and oncology, today reported dosing has commenced with its flagship product candidate, cetrorelix, the Company's lead luteinizing hormone-releasing hormone (LHRH) antagonist, in the second efficacy study of its Phase 3 program in benign prostatic hyperplasia (BPH), a non-cancerous enlargement of the prostate.

"We are very pleased to be on track with our Phase 3 clinical program for cetrorelix in BPH," said David J. Mazzo, Ph.D., President and CEO, Aeterna Zentaris. "Based on our new understanding of the multiple processes involved in the development of BPH and its symptoms, cetrorelix may offer a novel therapeutic approach to doctors and patients currently making trade-offs in care. We look forward to continuing our investigation of cetrorelix in this comprehensive clinical program."

The study, titled, "CETRORELIX PAMOATE IN PATIENTS WITH SYMPTOMATIC BPH: A DOUBLE-BLIND, PLACEBO-CONTROLLED EFFICACY STUDY", will involve approximately 400 patients, and will assess an intermittent dosage regimen of cetrorelix as a potential safe and tolerable treatment providing prolonged improvement in BPH-related signs and symptoms. This Phase 3 trial, conducted in Europe under the supervision of lead investigator, Prof. Dr. Frans M.J. Debruyne, MD, of the Andros Mannenkliniek, Arnhem, The Netherlands, is part of the Company's Phase 3 program with cetrorelix being studied in approximately 1,500 patients in North America and Europe in men with symptomatic BPH.

ABOUT THE PHASE 3 PROGRAM WITH CETRORELIX IN BPH

The first multi-center efficacy study for which first patient randomization commenced in April 2007, is currently being conducted primarily in the United States and Canada, with additional sites in Europe and involves approximately 600 patients under the supervision of lead investigator, Herbert Lepor, MD, Professor at NY University School of Medicine, New York. Patients enter a 4-week run-in no-treatment observation period to confirm severity and stability of voiding symptoms based on the International Prostate Symptom Score (IPSS). Patients are then randomly allocated to cetrorelix or placebo in a double-blind fashion. Patients are administered cetrorelix by intra-muscular (IM) injection at Week 0, 2, 26 and 28 and are followed up to Week 52. Then, in an open-label extension, patients will receive cetrorelix by IM injection at Week 52, 54, 78 and 80 will be followed up to Week 90.

The second multi-center Phase 3 efficacy study for which first patient dosing was announced today, will enroll approximately 400 patients in Europe. Patients in this randomized placebo-controlled study with open-label extension, will receive cetrorelix according to similar dosing regimens used in the first study.

The primary endpoint for both North American and European efficacy studies is absolute change in IPSS between baseline and Week 52. Other efficacy endpoints include additional measures of BPH symptom progression and the need for BPH-related surgery. Safety endpoints include changes in sexual function. Other important endpoints include plasma changes in levels of testosterone, and assessment of other adverse events.

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

The third study in the Phase 3 program, a multi-center safety study, expected to commence shortly, is an open-label, single-armed study involving approximately 500 patients in both North America and Europe.

ABOUT BENIGN PROSTATIC HYPERPLASIA

Benign prostatic hyperplasia (BPH) is one of the most common diseases of aging men - affecting more than 20 million men in the United States - but its etiology is far from being completely understood. Data from ongoing research suggest BPH and lower urinary tract symptoms (LUTS) are more complex conditions than once thought. While previous research on BPH etiology tended to focus on testosterone and other hormones, more recent research suggests other factors - including inflammation, various growth factors, and adrenoreceptors - actually may play a greater role in the development of BPH and LUTS.

BPH is associated with LUTS, including: frequent urination, a sudden, uncontrollable urge to urinate, waking at night to urinate (nocturia), difficulty starting a urine stream (hesitancy and straining), decreased strength of the urine stream (weak flow), feeling that the bladder is not completely empty, an urge to urinate again soon after urinating and pain during urination (dysuria). Currently available therapies may improve symptoms to some degree, but often come with sexual and other side effects.

ABOUT CETRORELIX

Cetrorelix pamoate is an investigational agent that has shown in Phase 2 studies to provide fast and long lasting relief of BPH symptoms and was well tolerated, with a low incidence of sexual side effects. Cetrorelix is part of AETerna Zentaris' LHRH antagonist therapeutic approach. This peptide-based active substance was developed by the Company in cooperation with Nobel Prize winner Prof. Andrew Schally, currently of the U.S. Veterans Administration in Miami.

Cetrorelix acetate is marketed under the brand name Cetrotide(R), the first LHRH antagonist approved for therapeutic use as part of IN VITRO fertilization programs (controlled ovulation stimulation/assisted reproductive technologies) in Europe, the USA and Japan. It was launched on the market through Serono (now Merck Serono) in the U.S., Europe and in several other countries, as well as in Japan through Shionogi.

In addition to the Phase 3 program in BPH, cetrorelix is also being studied in a Phase 2b program in this same indication in Japan, sponsored by the Company's partner, Shionogi.

2

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.

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

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

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. 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

3

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: March 27, 2008

By: /s/Mario Paradis

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