

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

Aeterna Zentaris Inc.  
Form 6-K  
April 15, 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 April 2008

Commission File No. 000-30752

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. Press Release dated April 15, 2008: Aeterna Zentaris Completes Patient Recruitment for First Phase 3 Efficacy Trial with Cetrorelix in Benign Prostatic Hyperplasia

AETERNA ZENTARIS

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

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

PRESS RELEASE  
For immediate release

### AETERNA ZENTARIS COMPLETES PATIENT RECRUITMENT FOR FIRST PHASE 3 EFFICACY TRIAL WITH CETRORELIX IN BENIGN PROSTATIC HYPERPLASIA

QUEBEC CITY, CANADA, APRIL 15, 2008 - Aeterna Zentaris Inc. (NASDAQ: AEZS; TSX: AEZ), a global biopharmaceutical company focused on endocrine therapy and oncology, today reported the completion of patient recruitment for the Company's first efficacy trial of its Phase 3 program in benign prostatic hyperplasia (BPH), a non-cancerous enlargement of the prostate, with its flagship product candidate, cetorelix. The study involves approximately 600 patients primarily in the United States and Canada, with additional sites in Europe.

"We are very proud to have reached this important milestone. The Phase 3 program in BPH with cetorelix is on track and we expect to provide results in the third quarter of 2009 as stated previously," commented Paul Blake, M.D., Senior Vice President and Chief Medical Officer of Aeterna Zentaris.

This first efficacy study, titled "CETRORELIX PAMOATE INTERMITTENT IM DOSAGE REGIMENS IN PATIENTS WITH SYMPTOMATIC BPH: A 1-YEAR PLACEBO-CONTROLLED EFFICACY STUDY AND LONG-TERM SAFETY ASSESSMENT", will assess an intermittent dosage regimen of cetorelix as a safe and tolerable treatment providing prolonged improvement in BPH-related signs and symptoms.

#### ABOUT THE PHASE 3 PROGRAM WITH CETRORELIX IN BPH

The first multi-center efficacy study commenced first patient randomization in April 2007 and completion of patient recruitment was announced today. It 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 cetorelix or placebo in a double-blind fashion. Patients are administered cetorelix 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 cetorelix by IM injection at Week 52, 54, 78 and 80, and will be followed up to Week 90.

The second multi-center Phase 3 efficacy study for which first-patient dosing was announced March 26, 2008, will enroll approximately 400 patients in Europe. Patients in this randomized placebo-controlled study with open-label extension will receive cetorelix according to similar dosing regimens used in the first study.

The primary endpoint for both 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.

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

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

### 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.

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

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 U.S. 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.

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](http://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 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

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

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.

CONTACTS

Dennis Turpin, CA  
Senior Vice President and Chief Financial Officer  
(908) 626-5517  
dturpin@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: April 15, 2008  
-----

By: /s/Dennis Turpin  
-----

Dennis Turpin  
Senior Vice President, Chief Financial Officer