

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

Aeterna Zentaris Inc.  
Form 6-K  
May 14, 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 May 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  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

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 May 13, 2008: Aeterna Zentaris: Article on Phase 2  
Trial with Cetrorelix in BPH to be Published in European Urology Journal

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

[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: ARTICLE ON PHASE 2 TRIAL WITH CETRORELIX IN BPH TO BE  
PUBLISHED IN EUROPEAN UROLOGY JOURNAL

QUEBEC CITY, CANADA, MAY 13, 2008 - Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ), a global biopharmaceutical company focused on endocrine therapy and oncology, today announced that the article titled "PLACEBO-CONTROLLED DOSE-RANGING PHASE 2 STUDY OF SUBCUTANEOUSLY ADMINISTERED LHRH ANTAGONIST CETRORELIX IN PATIENTS WITH SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA (BPH)", has been accepted for publication in an upcoming issue of the European Urology Journal. Written by F.M.J. Debruyne, Department of Urology, Academic Hospital Nijmegen, The Netherlands, A.A. Gres, Clinical Urology MOKB, Minsk, Belarus, and D.L. Arustamov, Center of Urology, Ministry of Health of Republic of Uzbekistan, the article refers to results of a Phase 2 trial with cetorelix in BPH, which showed a prolonged improvement in BPH symptoms and uroflow, persisting up to the end of the 20-week observation period.

These results are part of previously disclosed Phase 2 data on cetorelix in BPH through prior abstracts and poster presentations. The article is available online at [WWW.EUROPEANUROLOGY.COM](http://WWW.EUROPEANUROLOGY.COM)

Prof. Jurgen Engel, Ph.D., Executive Vice President, Scientific Affairs at Aeterna Zentaris commented, "We are very proud to have the work of Prof. Debruyne and his colleagues on cetorelix published in this prestigious peer reviewed European journal. The article, along with the recent Best Poster Presentation Award that Prof. Debruyne received last March at the 23rd Annual European Association of Urology Meeting, is another acknowledgement of the quality of our development program with cetorelix in BPH."

## THE ABSTRACT

### BACKGROUND AND OBJECTIVES

Pilot studies with daily dosing suggested the use of the luteinizing hormone-releasing hormone antagonist cetorelix for the treatment of symptoms from BPH. The objective was to assess efficacy and safety of three dosing schemes of cetorelix in patients with symptomatic BPH.

### TRIAL DESIGN

After a run-in period with four weekly injections of placebo, 140 patients with an international prostate symptoms score (I-PSS) =13 and a peak urinary flow rate (PFR) 5-13 ml/s were randomly allocated to four treatment groups. Patients received either cetorelix at dosages of 5 mg/wk x 4, 10 mg/wk x 2 or 10 mg/wk x 4 or placebo.

Main and secondary endpoints included I-PSS, PFR and mean uroflow, residual

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

urinary volume, prostate volume, plasma testosterone, quality of life, and sexual function which were evaluated over a total of 20 weeks after randomization.

### RESULTS

In all cetrorelix groups, a rapid improvement in mean I-PSS was obtained, with a peak effect of -5.4 to -5.9 (placebo: -2.8). After all dosages of cetrorelix given, changes from baseline and differences to placebo were statistically significant up to week 20. Similarly, secondary parameters showed a significant, rapid, and persistent improvement for all cetrorelix dosages. All dosage regimens were well tolerated. The study evaluated a single treatment course only; further studies with repeated treatment courses will be required to establish a dose regimen for long-term disease management.

### CONCLUSIONS

In summary, the trial showed a rapid onset in improvement of I-PSS, urinary symptoms and quality of life, accompanied by a slight reduction in prostate size with a short course therapy with cetrorelix. The improvement lasted well beyond the dosing period. This should, therefore, allow for the development of intermittent dosage regimens of cetrorelix with two or three treatment courses per year, thus relieving concerns about treatment compliance with drugs requiring daily dosing.

### ABOUT CETRORELIX

Cetrorelix is part of Aeterna Zentaris' LHRH antagonist therapeutic approach that has demonstrated in Phase 2 studies to provide fast and long-lasting relief of BPH symptoms while being well tolerated, with a low incidence of sexual side effects. Cetrorelix peptide-based drugs were 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 ovarian stimulation/assisted reproductive technologies) in Europe, the U.S. and Japan. It was launched on the market through Serono (now Merck Serono) in the United States, Europe and in several other countries, as well as in Japan through Shionogi.

### ABOUT THE CETRORELIX PHASE 3 PROGRAM IN BPH

Cetrorelix pamoate is being studied in three Phase 3 trials which will include approximately 1,500 men with symptomatic BPH in the United States, Canada and Europe. One Phase 3 efficacy trial, primarily in the United States and Canada and with additional sites in Europe, involves approximately 600 patients (which are fully enrolled) and is being led by Herbert Lepor, M.D., Professor and Martin Spatz Chairman of Urology, New York University School of Medicine, New York. In the trial, patients enter a no-treatment run-in observation period to confirm severity and stability of voiding symptoms based on the International Prostate Symptom Score (I-PSS). 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.

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

A second, similarly designed ongoing multi-center Phase 3 efficacy study, being led by Prof. Frans M.J. Debruyne, M.D., Ph.D., from The Netherlands, will enroll approximately 400 patients in Europe. The third Phase 3 trial currently screening patients, is an open-label, single-armed multi-center safety study involving approximately 500 patients in both North America and Europe, and is being led by Joel Kaufman, M.D., Associate Clinical Professor of Urology, University of Colorado School of Medicine, Denver, Colorado, and Urology Research Options, Aurora, Colorado.

The primary endpoint for both North American and European efficacy studies is the change in I-PSS 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 cetrorelix Phase 3 program is based on comprehensive clinical practice guidelines to ensure quality control, including input from expert advisors on study design, publishing results in peer-reviewed journals and discussion of the studies with regulatory agencies.

### 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 its associated 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 may play a greater role in the development of BPH and LUTS - including inflammation, various growth factors, and adrenoreceptors.

BPH-associated LUTS include frequent urination and/or urgent need to urinate, waking at night to urinate (nocturia), difficulty starting urination and/or weak urinary stream, and feeling that the bladder is not completely empty after urination. While current therapies provide some efficacy in BPH they are often associated with troublesome sexual side effects.

### 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.AEVSINC.COM](http://WWW.AEVSINC.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,

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

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.

### CONTACTS

Dennis Turpin, CA  
Senior Vice President and Chief Financial Officer  
(908) 626-5503  
DTURPIN@AEZSINC.COM

### MEDIA RELATIONS

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: MAY 14, 2008  
-----

By: /S/DENNIS TURPIN  
-----

Dennis Turpin  
Senior Vice President, Chief Financial Officer