

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

Aeterna Zentaris Inc.
Form 6-K
May 01, 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 30, 2008: Aeterna Zentaris: Lead Investigator for Cetrorelis Trials in BPH Wins Best Poster Presentation Award at European Association of Urology Meeting in Milan

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

PRESS RELEASE
For immediate release

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

AETERNA ZENTARIS: LEAD INVESTIGATOR FOR CETRORELIX TRIALS IN BPH WINS BEST POSTER PRESENTATION AWARD AT EUROPEAN ASSOCIATION OF UROLOGY MEETING IN MILAN

QUEBEC CITY, CANADA, APRIL 30, 2008 - Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ), a global biopharmaceutical company focused on endocrine therapy and oncology, today announced that Prof. Frans M.J. Debruyne, M.D., Ph.D., Chairman and CEO of Andros Men's Health Institutes in The Netherlands, won the award for Best Poster Presentation in a Poster Session at the 23rd Annual European Association of Urology Meeting, which was held March 26-28, 2008 in Milan, Italy. Titled "LHRH ANTAGONIST CETRORELIX FOR SYMPTOMATIC BPH: PROLONGED IMPROVEMENT BEYOND END OF TREATMENT IN PLACEBO-CONTROLLED TRIALS." FMJ DEBRUYNE, A.A. GRES, A. BANTSCHIEV, M. TZVETKOV, K. GRDOVIC, the poster referred to previously disclosed results from two Phase 2 trials with cetrorelix in benign prostatic hyperplasia (BPH), which showed a prolonged duration of effect extending far beyond the end of the short-term treatment course.

Prof. Jurgen Engel, Ph. D., Executive Vice President, Scientific Affairs at Aeterna Zentaris commented, "We would like to congratulate Professor Debruyne for this prestigious award which acknowledges his significant contribution to the quality and achievements of our drug development program with cetrorelix in BPH. The data observed in these Phase 2 trials warranted our current extensive Phase 3 program with cetrorelix in this same indication and we look forward to presenting the results in Q3 2009, as stated previously. We believe cetrorelix could provide a novel, efficient, convenient and safe treatment for the millions of men with BPH."

THE POSTER

INTRODUCTION AND OBJECTIVES

Preliminary studies indicated prolonged, unmaintained improvement in signs and symptoms of BPH after short courses of cetrorelix. Two placebo-controlled trials investigated two formulations of cetrorelix to determine the extent and duration of symptomatic improvement and to select the interval between courses for an intermittent treatment scheme.

AETERNA ZENTARIS

TRIAL DESIGN

Trial-A compared 3 regimens of subcutaneous cetrorelix acetate with placebo (35 patients/group): 5mg x 4, 7 days apart; 10mg x 4, 7 days apart; and 10mg x 2, 14 days apart.

Trial-B compared 4 regimens of intramuscular cetrorelix pamoate with placebo (30 patients/group, 14 days between doses): 30mg x 2; 30mg x 3; 60mg and 30mg; 60mg x 2. Patients were followed up for 20 and 28 weeks after the first dose in Trial-A and B, respectively. International Prostate Symptom Score (I-PSS) primary endpoint was assessed in 4-weekly intervals; other endpoints included uroflow, prostate size, and testosterone levels.

RESULTS

In both trials, 4 weeks after first dose, all regimens showed a statistically significant reduction in I-PSS from baseline; at week 12, the difference from placebo was statistically significant for all dosage regimens except the 30mg x 2 in Trial-B (Trial-A: $p < 0.05$; Trial-B: $p < 0.001$). Generally, the improvement in I-PSS, which tended to be better in the higher dosage groups of Trial-B (reduction of 5-7 points, i.e. 30%-40%), was maintained throughout the follow-up

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

period and was paralleled by an improvement in uroflow. A slight, dose-dependent reduction in prostate size was noticed in both trials. All dosage regimens tested were well tolerated, and none were associated with sexual side effects.

CONCLUSIONS

In both studies, a prolonged duration of effect extending far beyond the end of the short-term treatment course was observed. For the long-term management of BPH patients, the results from both studies support a 6-month interval between subsequent treatment courses.

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. Both BPH studies of cetrorelix presented in Milan were chaired by Prof. Frans M.J. Debruyne, M.D., Ph.D., former President of EAU, now Chairman and CEO of Andros Men's Health Institutes in The Netherlands.

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.

AETERNA ZENTARIS

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.

A second, similarly designed 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 scheduled to start shortly, 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

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

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 cetorelix 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.

AETERNA ZENTARIS

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 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.

CONTACTS

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

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 1, 2008

By: /s/Dennis Turpin

Dennis Turpin
Senior Vice President, Chief Financial Officer