

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

Aeterna Zentaris Inc.
Form 6-K
December 11, 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 December 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 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

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

1. Press Release dated December 11, 2008: AETerna Zentaris Completes Patient Recruitment for Safety Trial of Phase 3 Program with Cetrorelix in 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.aezsinc.com

PRESS RELEASE
For immediate release

AETERNA ZENTARIS COMPLETES PATIENT RECRUITMENT FOR SAFETY TRIAL OF PHASE 3 PROGRAM WITH CETRORELIX IN BENIGN PROSTATIC HYPERPLASIA

QUEBEC CITY, CANADA, DECEMBER 11, 2008 - AETerna Zentaris Inc. (NASDAQ: AEZS; TSX: AEZ), a global biopharmaceutical company focused on endocrine therapy and oncology, today reported it has reached its goal of recruiting 500 patients for the safety study of the Phase 3 program in benign prostatic hyperplasia (BPH) with its flagship product candidate, cetrorelix, a novel investigational luteinizing hormone-releasing hormone (LHRH) antagonist. This safety trial, the third of three Phase 3 studies - involving a total of over 1,500 patients will define the role of cetrorelix in the treatment of BPH, a non-cancerous enlargement of the prostate affecting millions of men.

"With today's announcement, all three trials of our Phase 3 program in BPH with cetrorelix are now fully recruited according to our scheduled timelines. We now look forward to the disclosure of the first efficacy results in the third quarter of 2009 which could be followed by an NDA in 2010," said Paul Blake, M.D., Senior Vice President and Chief Medical Officer at AETerna Zentaris. "Furthermore, this milestone brings us one step closer to our goal of providing a novel, safe and efficient therapeutic approach to the millions of men suffering from BPH."

The safety study titled, "CETRORELIX PAMOATE IN PATIENTS WITH SYMPTOMATIC BPH: AN OPEN-LABELED SAFETY AND EFFICACY ASSESSMENT STUDY", being conducted in North America, will assess an intermittent dosage regimen of cetrorelix pamoate as a potential safe and tolerable treatment providing prolonged improvement in BPH-related signs and symptoms. Patients receive cetrorelix pamoate by intra-muscular (IM) injection at Weeks 0 and 2, and are followed up to Week 26. The main endpoint is the incidence of possibly drug-related adverse events.

ABOUT CETRORELIX

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

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 CityplaceMiami.

[AETERNA ZENTARIS LOGO]

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 include over 1,500 men with symptomatic BPH in the United States, Canada and Europe. The first Phase 3 efficacy trial conducted primarily in the United States and Canada and with additional sites in Europe, involves approximately 600 patients (completion of patient recruitment announced on April 15, 2008) 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 and will be followed up to Week 90.

A second, similarly designed ongoing multi-center Phase 3 efficacy study (completion of patient recruitment announced on October 1, 2008), led by Prof. Frans M.J. Debruyne, M.D., Ph.D., from The Netherlands, involves approximately 400 patients, mainly in Europe.

The third Phase 3 trial (completion of patient recruitment was announced today) is an open-label, single-armed multi-center safety study involving approximately 500 patients in North America, 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.

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

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.

2

[AETERNA ZENTARIS LOGO]

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.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.

INVESTOR RELATIONS

Ginette Vallieres
Investor Relations Coordinator
(418) 652-8525 ext. 265

MEDIA RELATIONS

Paul Burroughs
Director of Communications
(418) 652-8525 ext. 406

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

gvallieres@aezsinc.com

pburroughs@aezsinc.com

-30-

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: DEC. 10, 2008

By: /S/ DENNIS TURPIN

Dennis Turpin
Senior Vice President and Chief
Financial Officer