Aeterna Zentaris Inc.
Form 6-K
December 08, 2009

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 2009

ÆTERNA ZENTARIS INC.

1405, boul. du Parc-Technologique

Québec, Québec

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 o

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 o 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

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www.aezsinc.com

Press Release
For immediate release

Æterna Zentaris Announces Results from its European Phase 3 Study with Cetrorelix in Benign Prostatic Hyperplasia

Quebec City, Canada, December 7, 2009 Æterna Zentaris Inc. (NASDAQ: AEZS; TSX: AEZ) (the Company), a global biopharmaceutical company focused on endocrine therapy and oncology, today reported Phase 3 results for its European efficacy trial Z-036 in benign prostatic hyperplasia (BPH), with cetrorelix pamoate.

Study Z-036 did not reach its primary endpoint. There were no clear differences in overall efficacy, with all 3 groups (including placebo) showing an improvement in International Prostate Symptom Score (IPSS) of approximately 6 points that was maintained throughout the 52 weeks. There was observation of an improvement in uroflow, both maximum and mean, and in residual volume in all treatment groups. These favorable changes are reflected in an overall improvement in Quality of Life measures. Cetrorelix was well tolerated, there were no relevant differences to placebo with regard to both clinical adverse events or changes in laboratory parameters with the exception of the anticipated hormonal changes.

Juergen Engel, Ph.D., Æterna Zentaris President and CEO stated, We are obviously disappointed by the failure of study Z-036 to reach its efficacy endpoint. Despite the disappointment, we would like to thank the investigators and all those involved in this project for their dedicated work. We will now focus our development efforts on our late-stage oncology compounds perifosine, our oral PI3K/AKT inhibitor and AEZS-108, our targeted doxorubicin conjugate, as well as our oral ghrelin agonist AEZS-130 in endocrinology.

About study Z-036

The multi-center efficacy trial Z-036 was conducted in 39 sites in 10 European countries, under the supervision of lead investigator, Prof. Frans MJ Debruyne, M.D., Director of the Andros Mannenkliniek in Arnhem, The Netherlands. Patients entered a 1- to 4-week screening period to confirm severity and stability of voiding symptoms based on the IPSS. Patients were then randomly allocated in a double-blind fashion to one of two cetrorelix dose groups or placebo, in a 2:1:1 ratio. Patients were administered cetrorelix by intra-muscular (IM) injection at Week 0, 2, 26 and 28 (for treatment Arm A, those in Arm B received IM injection at week 0, 2 and placebo injections both at Week 26 and 28). Patients in treatment Arm C received placebo injections at

Week 0, 2, 26 and 28. All patients were followed up to Week 52. The study included 420 patients overall, 212, 106, and 102 patients allocated to Arm A, B, and C, respectively.

Conference Call

The Company will host a conference call and webcast to discuss these results later today, Monday, December 7, 2009 at 4:30 p.m., Eastern Time.

Participants may access the live webcast via the Company s website at www.aezsinc.comin the Investors section, or by telephone using the following numbers: (outside Canada): 888-231-8191, (Canada): 514-807-9895 or 647-427-7450. A replay of the webcast will also be available on the Company s website for a period of 30 days.

About the Phase 3 Program with Cetrorelix in BPH

The Phase 3 trial program involving more than 1,600 patients with symptomatic BPH in Canada, the United States and Europe has been completed. In addition to the efficacy trial Z-036, the program included a placebo-controlled safety and efficacy trial Z-033, the single-armed safety study Z-041, and the Thorough QT study Z-043. Results for all of these trials were disclosed recently.

About Cetrorelix

Cetrorelix pamoate is a compound that was being investigated for the treatment of BPH. Cetrorelix is part of Æterna Zentaris luteinizing hormone-releasing hormone (LHRH) antagonist therapeutic approach.

About Æterna Zentaris Inc.

Æterna 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 required by a governmental authority or applicable law.

Investor Relations

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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.

ÆTERNA ZENTARIS INC.

Date: December 8, 2009

By: /s/Dennis Turpin
Dennis Turpin
Senior Vice President and Chief Financial Officer