Aeterna Zentaris Inc.
Form 6-K
March 09, 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 March 2009

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. AEterna Zentaris and Sanofi-Aventis Sign a Development, Commercialization and Licensing Agreement for Cetrorelix in Benign Prostatic Hyperplasia

[AETERNA ZENTARIS LOGO]

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PRESS RELEASE
For immediate release

AETERNA ZENTARIS AND SANOFI-AVENTIS SIGN A DEVELOPMENT, COMMERCIALIZATION AND LICENSING AGREEMENT FOR CETRORELIX IN BENIGN PROSTATIC HYPERPLASIA

ALL AMOUNTS ARE IN US DOLLARS

QUEBEC CITY, CANADA, MARCH 6, 2009 - AEterna Zentaris Inc. (NASDAQ: AEZS; TSX: AEZ), a global biopharmaceutical company focused on endocrine therapy and oncology, today announced the signing of a development, commercialization and licensing agreement with sanofi-aventis (EURONEXT: SAN; NYSE: SNY) for the development, registration and marketing of cetrorelix in benign prostatic hyperplasia (BPH) for the U.S. market. Cetrorelix, a luteinizing hormone-releasing hormone (LHRH) antagonist, is currently in a Phase 3 program in BPH, a non-cancerous enlargement of the prostate, affecting more than 20 million men in the U.S. alone.

Under the terms of the agreement, sanofi-aventis will make an initial $30 million upfront payment to AEterna Zentaris which will also be entitled to receive up to $135 million in additional payments upon achieving certain pre-established regulatory and commercial milestones. Furthermore, AEterna Zentaris will be entitled to receive escalating double-digit royalties on future net sales of cetrorelix for BPH in the United States. Sanofi-aventis will be responsible for the commercialization and booking of sales in the U.S.; however, AEterna Zentaris has retained certain rights to co-promote cetrorelix for BPH in the U.S. market. Finally, sanofi-aventis may perform future Phase 3b and Phase 4 clinical trials, while AEterna Zentaris will have free access to all data for other territories.

"We are delighted to have a partner such as sanofi-aventis who has a proven track record in urology. This partnership marks an important milestone in our quest to bring cetrorelix to market which could provide millions of men with a novel treatment for BPH. Furthermore, this compound could generate significant long-term revenue for the Company while building value for our shareholders," said Juergen Engel, Ph.D., President and CEO of AEterna Zentaris.

ABOUT THE PHASE 3 PROGRAM WITH CETRORELIX IN BPH

Cetrorelix pamoate is currently in three Phase 3 trials involving more than 1,600 patients with symptomatic BPH in Canada, the United States and Europe.

[AETERNA ZENTARIS LOGO]

The first multi-center efficacy study for which patient recruitment was completed in April 2008, is currently being conducted primarily in the United States and Canada, with additional sites in Europe and involves 667 patients under the supervision of lead investigator, Herbert Lepor, MD, Professor at NYU 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 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 receive cetrorelix by IM injection at Week 52, 54, 78 and 80 and are followed up to Week 90.

The second multi-center Phase 3 efficacy study for which patient recruitment was completed in October 2008, involves 420 patients, mainly in Europe. Patients in this randomized placebo-controlled study with open-label extension conducted under the supervision of lead investigator, Prof. Frans M.J. Debruyne, MD, of the Andros Mannenkliniek, Arnhem, The Netherlands, receive cetrorelix according to similar dosing regimens used in the first study.

The primary endpoint for both North American and European 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, a multi-center safety study, for which patient recruitment was completed in December 2008, is an ongoing open-label, single-armed study involving 529 patients in North America. The lead investigator is Joel Kaufman, M.D., Associate Clinical Professor in Urology at University of Colorado School of Medicine in Denver, Colorado and at Urology Research Options in Aurora, Colorado.

First efficacy results are expected during the third quarter of 2009 with an NDA filing targeted in 2010.

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' luteinizing hormone-releasing hormone (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.

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 USA 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.

[AETERNA ZENTARIS LOGO]

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 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.

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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.

AETERNA ZENTARIS INC.

Date: March 6, 2009

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