

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

Aeterna Zentaris Inc.
Form 6-K
June 23, 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 June 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 Material Change Report

FORM 51-102F3

MATERIAL CHANGE REPORT

AETERNA ZENTARIS INC.

1. NAME AND ADDRESS OF COMPANY

AEterna Zentaris Inc. (the "CORPORATION")
1405 du Parc-Technologique Blvd.
Quebec City, Quebec G1P 4P5

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

2. DATE OF MATERIAL CHANGE

June 15, 2009

3. NEWS RELEASE

On June 15, 2009, the Corporation issued a news release indicating the material change, which was disseminated in Canada on the CanadaNewsWire service. A copy of such news release is attached hereto as SCHEDULE A.

4. SUMMARY OF MATERIAL CHANGE

On June 15, 2009, the Corporation announced that patient follow-up in the open-label safety study (study 041) of its Phase 3 program in benign prostatic hyperplasia (BPH) with its lead endocrinology compound, cetorelix pamoate, is scheduled to be completed at the end of this week. Therefore, data analysis and reporting will be brought forward from the scheduled fourth quarter into the third quarter of 2009, and will follow the disclosure of results from the first double-blind placebo controlled efficacy study (study 033).

5. FULL DESCRIPTION OF MATERIAL CHANGE

On June 15, 2009, the Corporation announced that patient follow-up in the open-label safety study (study 041) of its Phase 3 program in benign prostatic hyperplasia (BPH) with its lead endocrinology compound, cetorelix pamoate, is scheduled to be completed at the end of this week. Therefore, data analysis and reporting will be brought forward from the scheduled fourth quarter into the third quarter of 2009, and will follow the disclosure of results from the first double-blind placebo controlled efficacy study (study 033).

The safety study (041) titled, "Cetorelix pamoate in patients with symptomatic BPH: an open-labeled safety and efficacy assessment study", will assess an intermittent dosage regimen of cetorelix pamoate as a potential safe and tolerable treatment providing prolonged improvement in BPH-related signs and symptoms. Patients receive cetorelix 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.

- 2 -

6. RELIANCE ON SUBSECTION 7.1(2) OF NATIONAL INSTRUMENT 51-102

Not applicable.

7. OMITTED INFORMATION

Not applicable.

8. EXECUTIVE OFFICER

Further information regarding the matters described in this report may be obtained from Dennis Turpin, Senior Vice President and Chief Financial Officer. Mr. Turpin is knowledgeable about the details of the material change and may be contacted at (418) 652-8525.

9. DATE OF REPORT

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

June 23, 2009.

SCHEDULE A

NEWS RELEASE
(June 15, 2009)

AETERNA ZENTARIS TO REPORT DATA FROM SAFETY STUDY OF PHASE 3 PROGRAM IN BENIGN PROSTATIC HYPERPLASIA WITH CETRORELIX AHEAD OF SCHEDULE

QUEBEC CITY, CANADA, JUNE 15, 2009 - AETerna Zentaris Inc. (NASDAQ: AEZS; TSX: AEZ), a global biopharmaceutical company focused on endocrine therapy and oncology, today reported that patient follow-up in the open-label safety study (study 041) of its Phase 3 program in benign prostatic hyperplasia (BPH) with its lead endocrinology compound, cetrorelix pamoate, is scheduled to be completed at the end of this week. Therefore, data analysis and reporting will be brought forward from the scheduled fourth quarter into the third quarter of 2009, and will follow the disclosure of results from the first double-blind placebo controlled efficacy study (study 033). BPH is a benign enlargement of the prostate, affecting more than 20 million men in the U.S. alone.

"We are very pleased to have reached this stage of the Phase 3 development of cetrorelix in BPH and look forward to the data emerging in the next quarter. We are also pleased that the ongoing reviews of safety data from our Data and Safety Monitoring Committee have not shown any need for protocol or study procedure amendments to the studies," said Paul Blake M.D., Senior Vice President and Chief Medical Officer of AETerna Zentaris.

The safety study (041) titled, "CETRORELIX PAMOATE IN PATIENTS WITH SYMPTOMATIC BPH: AN OPEN-LABELED SAFETY AND EFFICACY ASSESSMENT STUDY", 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. More information on this trial may be obtained at www.clinicaltrials.gov under the reference number NCT00670306.

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.

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.

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

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 cetorelix 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 528 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.

Recently, Aeterna Zentaris also announced that patients completing two years of therapy with cetorelix in the first efficacy study (study 033), will be eligible to continue with the cetorelix treatment, according to treatment regimen of the ongoing Phase 3 study, until the end of 2011. Patients entering this extension study sponsored by the Company's partner sanofi-aventis, will be followed-up for safety, International Prostate Symptom Score (IPSS) and quality of life during the extended treatment, providing follow-up data on cetorelix for up to 5 years.

ABOUT CETRORELIX

Cetorelix 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. Cetorelix 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.

Cetorelix 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.

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.

- 3 -

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.

INVESTOR RELATIONS

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

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

AETERNA ZENTARIS INC.

Date: June 23, 2009

By: /s/Dennis Turpin

Dennis Turpin

Senior Vice President and Chief Financial Officer