

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

Aeterna Zentaris Inc.
Form 6-K
May 24, 2007

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 May 2007

AETERNA ZENTARIS INC.

1405, Parc-Technologique Boulevard
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 Form 40-F X
----- -----

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 May 23, 2007: AEterna Zentaris' Partner, Spectrum,
 Discloses Detailed Phase 2 Data for Ozarelix in BPH at Annual AUA Meeting

AETERNA ZENTARIS

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

AETERNA ZENTARIS INC.
1405 du Parc-Technologique Blvd.
Quebec (Quebec) Canada G1P 4P5
T 418 652-8525 F 418 652-0881
www.aeternazentaris.com

PRESS RELEASE
For immediate release

AETERNA ZENTARIS' PARTNER, SPECTRUM, DISCLOSES DETAILED PHASE 2 DATA FOR
OZARELIX, IN BPH AT ANNUAL AUA MEETING

OZARELIX IMPROVED LUTS SYMPTOMS AND URINE FLOW OVER 28-WEEK PERIOD

ALL AMOUNTS ARE IN U.S. DOLLARS

QUEBEC CITY, CANADA, MAY 23, 2007 - AEterna Zentaris Inc. (TSX: AEZ; NASDAQ: AEZS), a global biopharmaceutical company focused on endocrine therapy and oncology, today announced that its partner Spectrum Pharmaceuticals (NASDAQ: SPPI) presented an abstract outlining detailed Phase 2 results for AEterna Zentaris' fourth-generation luteinizing hormone-releasing hormone (LHRH/GnRH) antagonist, ozarelix, in benign prostatic hyperplasia (BPH). Results indicate that ozarelix was well tolerated and demonstrated statistically significant as well as clinically meaningful efficacy in the treatment of lower urinary tract symptoms (LUTS) secondary to BPH. Results also showed no statistically significant impact on quality of life or erectile function. The abstract was presented yesterday afternoon at the American Urological Association (AUA) Annual Meeting being held this week at the Anaheim Convention Center in Anaheim, California.

"We are encouraged by these data with ozarelix and look forward to seeing further results from the fully-enrolled Phase 2b trial," said David J. Mazzo, Ph.D., President and CEO of AEterna Zentaris. "With cetrorelix in an ongoing Phase 3 program and ozarelix completing a Phase 2b trial this year, we are fortunate to be leading the LHRH antagonist class with two very promising compounds for the treatment of BPH."

DETAILS

The abstract #93629 (Poster #1552) titled, "THE EFFICACY AND SAFETY OF OZARELIX, A NOVEL GnRH ANTAGONIST IN MEN WITH LOWER URINARY TRACT SYMPTOMS (LUTS) DUE TO BENIGN PROSTATIC HYPERPLASIA (BPH)" reviewed results of a randomized, double-blind, placebo-controlled, multi-center, dose-ranging Phase 2 trial in BPH.

Ozarelix was given intramuscularly (IM) to men with moderate to severe LUTS due to BPH, to assess the compound's efficacy and safety. Eligible patients were treated with placebo for

AETERNA ZENTARIS

4 weeks to establish baseline International Prostate Symptom Score (IPSS) and uroflow values. Afterwards, 144 patients meeting the inclusion criteria were randomly allocated to one of five treatment groups with the following dosage regimens:

- Placebo;
- Ozarelix 5 mg on Day 1 + 5 mg on Day 15;
- Ozarelix 10 mg on Day 1 +10 mg on Day 15;
- Ozarelix 15 mg on Day 1 + 15 mg on Day 15; or

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

- Ozarelix 20 mg on Day 1 only.

Patients were followed for 28 weeks. The primary efficacy endpoint was change in IPSS at week 12 compared to baseline. Secondary efficacy endpoints included changes in IPSS, Quality of Life (QoL), patients with GREATER THAN OR EQUAL TO 30% and GREATER THAN OR EQUAL TO 40% improvement in IPSS, uroflow values (Q SUB(max)), postvoid residual (PVR) urine volume and prostate volume. Safety analysis included changes in sexual function (IIEF-5), treatment of emergent adverse events (AEs), lab values (including testosterone (T), PSA) and vital signs. Mean age was 69.1 (range 52 - 85), IPSS 19.8, (Q SUB(max)) 9.7 mL/sec. and prostate size (cm (TO THE POWER OF 3)) 41.6 at baseline.

RESULTS

The effects developed rapidly, with noticeable activity at four weeks from starting treatment, were maximal at 12-16 weeks, and persisted for the 6 month observation period. At week 12, all ozarelix-treated groups showed improvement with the greatest improvement in the 15 mg + 15 mg group. Change from baseline in IPSS was 8.6 (p LESS THAN 0.001); change from baseline in urine flow was 4.7 (p=0.002); T levels declined transiently and returned to baseline in most patients by 4 weeks and all patients by 6 weeks following dosing. Based on IIEF, there was no effect seen on erectile function.

Serious adverse events were reported in 4 patients on ozarelix (myocardial infarction, pneumonitis, hypotension, renal colic), but were not considered treatment related. No systemic allergic reactions were seen and the injections were well tolerated.

CONCLUSIONS

- Ozarelix was well tolerated;
- Statistically significant and clinically meaningful efficacy in the treatment of LUTS secondary to BPH;
- No statistically significant impact on quality of life or erectile function; and
- Intramuscular 15 mg + 15 mg was the most effective regimen in this study.

ABOUT OZARELIX AND PARTNERSHIPS

Ozarelix is a fourth generation luteinizing hormone-releasing hormone (LHRH) antagonist administered as a depot formulation for the treatment of benign and malign hormone-dependent diseases. It is currently in Phase 2b clinical trials for both BPH and prostate cancer.

In August 2004, Aeterna Zentaris granted Spectrum Pharmaceuticals an exclusive license to develop and market ozarelix for all potential indications in North America and India, while

AETERNA ZENTARIS

Aeterna Zentaris retains exclusive rights to the rest of the world. Spectrum will also receive 50% of any upfront and milestone payments, royalties and/or profits from sales of the product in Japan.

Furthermore, Aeterna Zentaris recently granted Japanese rights for all potential oncology indications to Nippon Kayaku, a key player in the Japanese oncology market.

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

ABOUT BENIGN PROSTATIC HYPERPLASIA

Benign prostatic hyperplasia (BPH) is a non-cancerous enlargement of the prostate frequently occurring in men over the age of 50. The enlargement can result in the gradual squeezing of the urethra, resulting in increased frequency or difficulty in urinating. Enlargement of the prostate is controlled by testosterone. According to the National Institutes of Health, BPH affects more than 50% of men over the age of 60 and as many as 90% of men over the age of 70. Treatment options for BPH include surgery and medications to reduce the amount of tissue and increase the flow of urine. Current treatment options are inconvenient, leading to ineffective compliance and are only effective in roughly half of the patients treated. According to Decision Resource, in 2004, the total prevalence cases of BPH in the major pharmaceutical markets was estimated at 56 million men and is expected to increase to 65 million cases by 2014. The BPH market is a significant market, with current annual sales of more than \$2.6 billion.

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.aeternazentaris.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. Statements that are not historical facts, including statements preceded by, followed by, or that include the words "believes", "anticipates", "intends", "plans", "expects", "estimates", "will," "may", "should", "approximately", and the negative or other variations of those terms or comparable terminology, are forward-looking statements. Such statements reflect management's current views, intentions, strategies and plans and are based on certain assumptions.

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 ability of AEterna Zentaris to implement its business strategies, the availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, the ability of AEterna Zentaris 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.

CONTACTS:

Jenene Thomas
Senior Director, Investor Relations & Corporate Communications
(418) 655-6420

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

jenene.thomas@aeternazentaris.com

Paul Burroughs
Media Relations
(418) 652-8525 ext. 406
paul.burroughs@aeternazentaris.com

4

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 24, 2007

By: /s/Mario Paradis

Mario Paradis
Vice President, Finance & Administration and
Corporate Secretary

Amount of Underlying Securities

(Instr. 3 and 4)8. Price of Derivative Security

(Instr. 5)9. Number of Derivative Securities Beneficially Owned Following Reported Transaction(s)

(Instr. 4)10. Ownership Form of Derivative Security: Direct (D) or Indirect (I)

(Instr. 4)11. Nature of Indirect Beneficial Ownership

(Instr. 4)CodeV(A)(D)Date ExercisableExpiration DateTitleAmount or Number of Shares Phantom Stock Units (1)04/01/2019 A
405.0432 (2) (2) Common Stock, \$1 2/3 Par Value 405.0432 \$ 48.81 1,651.1515 D

Reporting Owners

Table with columns: Reporting Owner Name / Address, Director, 10% Owner, Officer, Other. Row 1: Hewett Wayne M., 420 MONTGOMERY STREET, SAN FRANCISCO, CA 94104, X

Signatures

Wayne M. Hewett, by Anthony R. Augliera, as Attorney-in-Fact

04/03/2019

**Signature of Reporting Person

Date

Explanation of Responses:

- * If the form is filed by more than one reporting person, see Instruction 4(b)(v).
** Intentional misstatements or omissions of facts constitute Federal Criminal Violations. See 18 U.S.C. 1001 and 15 U.S.C. 78ff(a).
(1) Each phantom stock unit represents the right to receive one share of Wells Fargo & Company common stock.

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

(2) Deferred compensation shares payable in installments based upon director's election.

Note: File three copies of this Form, one of which must be manually signed. If space is insufficient, *see* Instruction 6 for procedure.

Potential persons who are to respond to the collection of information contained in this form are not required to respond unless the form displays a currently valid OMB number.