

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

Aeterna Zentaris Inc.
Form 6-K
August 05, 2005

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 August 2005

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 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 August 3, 2005 - AEterna Zentaris
 Reports 2005 Second Quarter Financial and Operating Results

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

AETERNA ZENTARIS

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 REPORTS 2005 SECOND QUARTER FINANCIAL AND OPERATING RESULTS

ALL AMOUNTS ARE IN CANADIAN DOLLARS

Second quarter 2005 highlights:

Financial

- >> Consolidated revenues of \$74.8 million, compared to \$65.8 million for Q2 2004;
- >> Consolidated R&D expenses of \$7.6 million, compared to \$8.7 million for Q2 2004;
- >> Consolidated earnings from operations of \$4.3 million, compared to \$9.2 million for Q2 2004;
- >> Consolidated net earnings of \$16.4 million, or \$0.36 per share, compared to \$1.3 million, or \$0.03 per share for Q2 2004;
- >> Consolidated cash and short-term position was \$64 million at the end of Q2 2005.

Product development

- >> Ozarelix (D-63153) - Initiation of Phase II trials in hormone-sensitive prostate cancer and benign prostate hyperplasia in Europe;
- >> Ozarelix (D-63153) - Initiation of a Phase I/II trial in hormone-sensitive prostate cancer in the United States;
- >> Perifosine - Disclosure of positive Phase II results in hormone-sensitive prostate cancer;
- >> EP-1572 - Disclosure of positive Phase I results confirming growth hormone secretagogue property.

QUEBEC CITY, CANADA, AUGUST 3, 2005 - AEterna Zentaris Inc. (TSX: AEZ; NASDAQ: AEZS) today reported financial and operating results for the second quarter ended June 30, 2005. Consolidated revenues for the second quarter 2005 were \$74.8 million compared to \$65.8 million for the same period in 2004, an increase of 13.7%. Consolidated R&D expenses net of tax credits amounted to \$7.6 million in the second quarter of 2005 compared to \$8.7

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

million in the second quarter of 2004, a decrease of 12.6%. Consolidated earnings from operations for the second quarter 2005 were \$4.3 million, compared to \$9.2 million for the second quarter 2004, a decrease of 53.2%. On the other hand, the Company's consolidated net earnings were \$16.4 million, or \$0.36 per basic share and \$0.35 per diluted share for the

AETERNA ZENTARIS

second quarter of 2005 compared to \$1.3 million, or \$0.03 per basic and diluted share for the comparable period in 2004.

The \$9 million increase in consolidated revenues during the second quarter 2005 is attributable to an increase of \$15.1 million revenues from our subsidiary Atrium combined with a decrease of \$6.1 million revenues from our biopharmaceutical segment. This decrease in the biopharmaceutical revenues is all attributable to a \$6.5 million non-recurring milestone payment gained from Solvay Pharmaceuticals in the 2004 second quarter. Net earnings for the second quarter of 2005 include a non-cash and non-recurring gain on dilution of \$20.3 million recorded following the decrease of Aeterna Zentaris' interest in its subsidiary Atrium from 61.1% to 50.1% mainly as a result of Atrium's April 6, 2005 IPO.

As of June 30, 2005, the Company had consolidated cash and short-term investments of \$64 million, including \$46.7 million dedicated to the biopharmaceutical segment. The Company generated consolidated positive cash flow from operating activities of \$4.3 million in the second quarter 2005. The burn rate for the biopharmaceutical segment in the second quarter 2005 was \$3 million as expected.

During the second quarter 2005, the Company continued to advance the product pipeline with the initiation of three new clinical trials in Europe and the United States with ozarelix, the new name for D-63153. Ozarelix is a fourth generation LHRH (Luteinizing Hormone Releasing Hormone) antagonist product administered as a depot formulation. These trials include one Phase II in Europe in hormone-sensitive prostate cancer and another Phase II in Europe in benign prostate hyperplasia, together with a Phase I/II in the United States in hormone-sensitive prostate cancer that was initiated in collaboration with our North American partner Spectrum Pharmaceuticals (NASDAQ: SPPI). Ozarelix (D-63153), which allows for chronic intermittent treatment, could improve clinical symptoms of these diseases while overcoming some of the limitations associated with currently marketed therapies.

Furthermore, our lead signal transduction inhibitor in cancer, perifosine, yielded positive Phase II results in 25 patients suffering from hormone-sensitive prostate cancer. Investigators concluded that perifosine is feasible, well-tolerated and can reduce PSA (Prostatic Specific Antigen) in some patients. Following those results, Phase II trials with perifosine in combination with androgen ablation and chemotherapy are expected to be initiated by our North American partner Keryx Biopharmaceuticals (NASDAQ:KERY) later this year.

In the field of growth hormone modulators, EP-1572 also yielded positive Phase I results. The study provided clear evidence that this compound is able to induce a significant rise in growth hormone levels after oral administration in healthy volunteers. Potential applications include treatment for growth retardation in children and cachexia associated with chronic disease such as AIDS and cancer. EP-1572, the orally-administered specific growth hormone secretagogue in development, presents a major competitive advantage in terms of ease and convenience of delivery over current treatments which are only

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

available through injections. Other Phase I clinical trials are currently ongoing to further assess the potential of EP-1572 in growth hormone related disorders.

"At the clinical level, the last quarter was marked by the progress of ozarelix, the new name for D-63153, in prostate cancer and in benign prostate hyperplasia," said Gilles Gagnon, Aeterna Zentaris' President and Chief Executive Officer. "Ozarelix, which we intend to aggressively

AETERNA ZENTARIS

pursue the development over the next year, is now considered as another lead product in our promising LHRH antagonist therapeutic approach, along with cetrorelix which is currently in late-stage clinical trials in benign prostate hyperplasia and in endometriosis. As for perifosine, our lead product in the signal transduction inhibitor therapeutic approach, it pursued its progress into further Phase II trials. In addition, we continued to advance other clinical and preclinical products through our pipeline according to our strategic drug development program focused on oncology and endocrinology. In doing so, we feel confident that we are well on our way of developing a deep pipeline of innovative products for the benefit of patients coping with serious diseases while building value for our shareholders," concluded Mr. Gagnon.

Dennis Turpin, Vice President and Chief Financial Officer of Aeterna Zentaris, added, "Our financial position continues to be strong. On a consolidated basis, we remained cash flow positive and our cash and short-term position reached \$64 million as of June 30, 2005. Considering our strong financial position, we will continue to make high-level R&D investments to maintain and grow a broad pipeline of drug development programs with both near-term and long-term potential.

AETERNA ZENTARIS SIX-MONTH CONSOLIDATED FINANCIAL RESULTS

Consolidated revenues for the first half of 2005 increased 21.2% to \$150.7 million, compared to \$124.3 million for the first half of 2004. The Company reported year-to-date 2005 consolidated earnings from operations of \$12.3 million, compared to \$10.8 million for the same period a year earlier. Consolidated net earnings for the first six months of 2005 were \$16.5 million, or \$0.36 per basic and diluted share, compared to a consolidated net loss of \$1.2 million, or \$0.03 per basic and diluted share, for the first six months of 2004.

CONFERENCE CALL INFORMATION

Management will be hosting a conference call for the investment community beginning at 10:00 a.m. Eastern Time today, Wednesday, August 3, to discuss 2005 second quarter financial and operating results and answer questions.

To participate in the live conference call by telephone, please dial 514-807-8791, 416-640-4127 from Canada or 800-814-4941 from outside Canada. Individuals interested in listening to the conference call on the Internet may do so by visiting WWW.AETERNAZENTARIS.COM. A replay will be available on the Company's Web site for 30 days.

ABOUT AETERNA ZENTARIS INC.

Aeterna Zentaris Inc. is an oncology and endocrine therapy focused

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

biopharmaceutical company with proven expertise in drug discovery, development and marketing. The Company's broad 20 product pipeline leverages six different therapeutic approaches, including LHRH antagonists and signal transduction inhibitors. The lead LHRH antagonist compound, cetrorelix, is currently marketed for IN VITRO fertilization under the brand name Cetrotide(R). Cetrorelix is also in late-stage clinical development for endometriosis and benign prostatic hyperplasia (BPH). The lead signal transduction inhibitor compound, perifosine, is a novel, first-in-class, oral anticancer agent that modulates several key signal transduction pathways, including AKT, MAPK, and JNK that have been shown to be critical for the survival of cancer cells. Perifosine has demonstrated single agent anti-tumor activity in Phase I and Phase II studies and is currently being studied as a

AETERNA ZENTARIS

single agent and in combination with several forms of anti-cancer treatments for various forms of cancer, including non-small cell lung cancer and breast cancer.

Aeterna Zentaris also owns 50.1% of Atrium Biotechnologies Inc. (TSX: ATB.sv), a leading developer, manufacturer and marketer of value-added products for the cosmetics, pharmaceutical, chemical and nutritional industries.

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. 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.

-30-

CONTACTS

MEDIA RELATIONS

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

INVESTOR RELATIONS

Ginette Vallieres
(418) 652-8525 ext. 265
ginette.vallieres@aeternazentaris.com

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

EUROPE

Matthias Seeber

+49 69 42602 3425

matthias.seeber@aeternazentaris.com

ATTACHMENT: Financial summary

AETERNA ZENTARIS

(in thousands of Canadian dollars, except share
and per share data)

QUARTERS ENDED
JUNE 30,

CONSOLIDATED RESULTS

Unaudited

REVENUES

74,828

65,840

15

OPERATING EXPENSES

Cost of sales

47,958

34,922

9

Selling, general and administrative

12,456

10,712

2

R&D costs, net of tax credits and grants

7,589

8,731

1

Depreciation and amortization

2,500

2,298

1

70,503

56,663

13

Earnings from operations

4,325

9,177

1

Interest income

529

288

(

Interest expenses

(3,315)

(2,095)

(

Foreign exchange gain (loss)

(189)

227

(

EARNINGS BEFORE THE FOLLOWING ITEMS

1,350

7,597

(

Current income taxes

(2,650)

(8,484)

(

Future income taxes

(90)

4,160

(

Gain on dilution

20,253

-

2

Non-controlling interest

(2,459)

(1,943)

(

NET EARNINGS (LOSS) FOR THE PERIOD

16,404

1,330

1

Net earnings (loss) per share

Basic

0.36

0.03

Diluted

0.35

0.03

Weighted average number of shares

Basic

46,139,814

45,594,326

46,13

Diluted

46,448,125

46,457,409

46,50

Issued and outstanding shares

46,13

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

CONSOLIDATED BALANCE SHEETS

JUNE 30,
2005

Cash and short-term investments	6
Other current assets	9

	16
Long-term assets	21

Total assets	37

Current liabilities	9
Deferred revenues	2
Long-term debt	2
Other long-term liabilities	2
Non-controlling interest	6

	23
Shareholders' equity	13

Total liabilities and shareholders' equity	37

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: AUGUST 3, 2005

By: /s/ Mario Paradis

Mario Paradis
Senior Finance Director and
Corporate Secretary