

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

Aeterna Zentaris Inc.
Form 6-K
August 13, 2004

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 first and second quarters of 2004

AETERNA ZENTARIS INC.
(Formerly named AETerna Laboratories 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

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

1. Press Release of May 4, 2004 - AETerna Laboratories Reports First Quarter 2004 Financial and Operating Results
 2. Press Release of August 11, 2004 - AETerna Zentaris Reports Second Quarter 2004 Financial and Operating Results
-

PRESS RELEASE
FOR IMMEDIATE RELEASE

AETERNA LABORATORIES REPORTS FIRST QUARTER 2004 FINANCIAL AND OPERATING RESULTS

- O AETERNA CONSOLIDATED RESULTS
 - O REVENUES INCREASED 43% TO \$58.4 MILLION
 - O OPERATING INCOME OF \$1.6 MILLION
 - O NET LOSS PER SHARE REDUCED BY HALF TO \$0.06 PER SHARE
- O SUBSIDIARY ATRIUM SALES INCREASED 62% TO \$45.8 MILLION AND NET EARNINGS INCREASED 119% TO \$3.6 MILLION

ALL AMOUNTS ARE IN CANADIAN DOLLARS

QUEBEC CITY, CANADA, MAY 4, 2004 - AETerna Laboratories Inc. (TSX: AEL; Nasdaq: AELA) today reported financial results for the first quarter ended March 31, 2004. Revenues for the first quarter 2004 were \$58.4 million, an increase of 43% compared with \$40.8 million for the same period in 2003. R&D expenses net of tax credits and grants decreased from \$10.9 million in the first quarter of 2003 to \$8.0 million in the first quarter of 2004, reflecting the realignment of the clinical development program initiated in December 2003, including the refocusing of the pipeline on perifosine and cetorelix.

Operating income was \$1.6 million for the first quarter of 2004, compared with an operating loss of \$1.3 million for the same period in 2003, primarily reflecting strong revenue growth of 62% from the majority-owned subsidiary Atrium. The net loss for the first quarter 2004 was \$2.6 million, or \$0.06 per share, a decrease of nearly 50% compared with a net loss of \$4.9 million or \$0.12 a share for the same period in 2003.

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

Commenting on the Company's first quarter results, Gilles Gagnon, AETerna's President and Chief Executive Officer, said, "We are very pleased by the financial results and strategic achievements we've had in the first quarter of 2004. The significant increase in revenues was driven by strong performances from all our sectors of activity. On the strategic front, we continued to advance and expand our rich product portfolio. We entered into development and marketing alliances with Roche for Impavido(R) and with Solvay Pharmaceuticals for our orally-available LHRH antagonist peptidomimetic. We also had an exciting development last week, with the announcement of positive results from six Phase II trials on cetrorelix in three indications: uterus myoma, endometriosis and benign prostatic hyperplasia. Our partner Solvay Pharmaceuticals is already planning for initiation of registration studies on cetrorelix. We believe these accomplishments continue to reflect the breadth and depth of our pipeline as well as the value of our international network of current and potential partners, which are two key components of our long-term growth strategy."

Dennis Turpin, AETerna's Vice President and CFO, added, "The Company's financial position

remains solid, with over \$52 million in cash and short-term investments, combined with the continued strong financial performance of both Atrium and Zentaris."

ATRIUM CONSOLIDATED FIRST QUARTER RESULTS

First quarter 2004 revenues for Atrium, AETerna's majority-owned subsidiary, were \$45.8 million, an increase of 62% compared with \$28.3 million in revenues for the comparable period in 2003. Operating income was \$6.1 million during the quarter, compared with \$3.5 million for the same period in 2003, representing a 72% increase. Net earnings increased 119% to \$3.6 million, compared with \$1.6 million for the same period in 2003. The increase reflects the combination of internal growth as well as growth driven by acquisition of Chimiray/Interchemical and Pure Encapsulations Inc., completed in August 2003 and March 2004, respectively.

FIRST QUARTER AND YEAR-TO-DATE 2004 HIGHLIGHTS

- o ATRIUM ACQUISITION OF PURE ENCAPSULATIONS INC. - Atrium acquired Pure Encapsulations Inc., a US-based company specializing in the development, manufacturing and marketing of nutritional supplements to a network of some 36,000 physicians and other healthcare professionals, for \$50 million. Pure Encapsulations Inc. had 2003 revenue of nearly \$25 million.
- o PARTNERSHIP WITH ROCHE FOR IMPAVIDO(R) - Agreement for the marketing, in Brazil, of Impavido(R) (miltefosine), the first oral treatment for leishmaniasis, a parasitic disease prevalent in tropical countries that affects over 12 million people worldwide.
- o PARTNERSHIP WITH SOLVAY FOR ORAL LHRH ANTAGONIST - Agreement for the development of a novel, orally-bioavailable luteinizing hormone-releasing hormone (LHRH) antagonist peptidomimetic for non-malignant indications, including endometriosis, uterine myoma and benign prostate hyperplasia (HPB), as well as breast and prostate cancer. Upon signing, AETerna received a \$5 million payment from Solvay.

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

- o POSITIVE RESULTS FOR ZEN-014 - Disclosure of positive preclinical results with ZEN-014, a novel tubulin inhibitor, at the annual American Association for Cancer Research (AACR). ZEN-014 represents a new class of antiangiogenic compounds that may have significant potential as potent anticancer agents.
- o INITIATION OF DOSE RANGING STUDY WITH ARDANA FOR EP-1572 - Initiation of a dose ranging study for this novel, orally-available peptidomimetic agent which could be used, among different indications, for the treatment of growth hormone deficiency disorders. Aeterna received an undisclosed milestone payment from its development partner, Ardana Bioscience.
- o EXPANDED PARTNERSHIP WITH ARDANA FOR TEVERELIX - Ardana acquired full global rights and was assigned the intellectual property relating to teverelix and the underlying microcrystalline suspension technology. In return, Zentaris received a substantial payment at signature, fixed annual guaranteed payments until 2006, as well as potential future income on sales of teverelix.
- o POSITIVE PHASE II RESULTS FOR CETRORELIX - Announcement of positive results with cetrorelix (LHRH antagonist) in six Phase II trials in endometriosis, pre-surgical

treatment of uterine myomas and benign prostatic hyperplasia (BPH). Solvay plans to initiate pivotal program with cetrorelix.

CONFERENCE CALL INFORMATION

Management will be hosting a conference call for the investment community at 10:00 a.m. Eastern Time today, Tuesday, May 4, to discuss first quarter financial and operating results.

To participate in the live conference call by telephone, please dial 514-807-8791, 416-640-4127 or 800-814-4890. Individuals interested in listening to the conference call via the Internet may do so by visiting www.aeterna.com. A replay will be available on the Company's Web site for 30 days.

ABOUT AETERNA LABORATORIES

Aeterna Laboratories Inc., along with its wholly-owned subsidiary Zentaris GmbH, is a biopharmaceutical company with an extensive product portfolio, including two marketed products and 14 other product candidates under development in oncology, endocrinology and infectious diseases. Cetrorelix (Cetrotide(R)) is sold in the U.S., Europe and several other countries to the IN VITRO fertilization market, and has positively completed six Phase II clinical trials for endometriosis, uterus myoma and enlarged prostate (BPH). Miltefosine (Impavido(R)) is sold for black fever and has successfully completed a Phase III trial in parasitic skin disease. Neovastat(R) is in a Phase III trial for non-small cell lung cancer. Perifosine, the first orally-active AKT inhibitor, is in Phase II trials for multiple cancers. Several other clinical programs are underway with various potential development candidates, supported by a worldwide network of scientific and marketing partnerships. Furthermore, Aeterna benefits from a discovery platform of 100,000 molecules, which is generating promising new compounds.

Aeterna also owns 62% of its subsidiary Atrium Biotechnologies Inc. which develops and markets active ingredients and speciality fine chemicals in the

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

health and personal care industry for the cosmetics, chemical, pharmaceutical and nutritional industries.

AEterna shares are listed on the Toronto Stock Exchange (AEL) and the NASDAQ National Market (AELA). News releases and additional information about AEterna are available on its Web site at www.aeterna.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:

AETERNA LABORATORIES

MEDIA RELATIONS

Paul Burroughs
(418) 652-8525 ext. 406
(418) 573-8982 cell.
paul.burroughs@aeterna.com

INVESTOR RELATIONS

Jacques Raymond
(418) 652-8525 ext. 360
(514) 703-5654 cell.
jacques.raymond@aeterna.com

U.S. INVESTOR RELATIONS

Lippert/Heilshorn & Associates
Kim Golodetz
(212) 838-3777
kgolodetz@lhai.com

EUROPE

Zentaris GmbH
Mathias Pietras
phone: + 49 69 42 602 3423
mathias.pietras@zentaris.de

Attachement: Financial summary

AETERNA LABORATORIES INC. (TSX: AEL; NASDAQ: AELA)

FINANCIAL SUMMARY

(in thousands of Canadian dollars, except share

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

and per share data)

	THRE
CONSOLIDATED RESULTS	2
Unaudited	

REVENUES	
OPERATING EXPENSES	
Cost of sales	
Selling, general and administrative	
R&D costs, net of tax credits and grants	
Depreciation and amortization	

Operating income (loss)	
Interest income	
Interest and financial expenses	
Foreign exchange gain (loss)	

INCOME (LOSS) BEFORE THE FOLLOWING ITEMS	
Current income taxes	
Future income taxes	
Non-controlling interest	

NET LOSS FOR THE PERIOD	

Basic and diluted net loss per share	
Weighted average number of shares	45,4
Issued and outstanding shares	45,4

	MA

CONSOLIDATED BALANCE SHEETS	

Cash and short-term investments	
Other current assets	

Long-term assets	1 2

Total assets	3

Current liabilities	
Deferred revenues	

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

Convertible term loans and long-term debt
Other long-term liabilities
Non-controlling interest

Shareholders' equity

Total liabilities and shareholders' equity

2

1

3

AEterna Zentaris Inc. 1405 du Parc-Technologique Blvd.
Quebec (Quebec) Canada G1P 4P5 T 418 652-8525 F 418 652-0881

AETERNA ZENTARIS

Quebec
Frankfurt

PRESS RELEASE
For immediate release

AETERNA ZENTARIS REPORTS SECOND QUARTER 2004 FINANCIAL AND OPERATING RESULTS

ALL AMOUNTS ARE IN CANADIAN DOLLARS

- o Consolidated revenues increased 69% to \$65.8 million
- o Consolidated operating income of \$9.2 million and net earnings of \$1.3 million
- o Reported positive Phase II data for cetrotorelix and Phase I data for perifosine
- o 62% subsidiary Atrium generated \$47 million in sales, an increase of 90%, \$7.4 million in operating income, an increase of 131% and \$4.1 million in net earnings, an increase of 154%

QUEBEC CITY, CANADA, AUGUST 11, 2004 - AEterna Zentaris Inc. (TSX: AEZ; Nasdaq: AEZS) today reported financial and operating results for the second quarter ended June 30, 2004. Total revenue for the second quarter 2004 was \$65.8 million, an increase of 69% compared with total revenue of \$38.9 million for the same period in 2003. R&D expenses net of tax credits and grants decreased from \$10.6 million in the second quarter of 2003 to \$8.7 million in the second quarter of 2004, reflecting the streamlining of the clinical development program.

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

Operating income for the second quarter 2004 was \$9.2 million, compared to an operating loss of \$1.1 million for the second quarter 2003, primarily reflecting the strong revenue growth of 90% from the majority-owned subsidiary Atrium, and a non-recurrent \$6.5 million milestone gained from Solvay Pharmaceuticals, the Company's worldwide (ex-Japan) exclusive development and marketing partner for cetorelix. This milestone was triggered by Solvay's decision to proceed with further clinical development of cetorelix. The Company's net earnings were \$1.3 million for the second quarter of 2004, or \$0.03 per share, compared with a net loss of \$4.7 million, or \$0.11 per share, for the comparable period in 2003. The profitability for this quarter is primarily a result of the non-recurrent milestone gained from Solvay.

"During the second quarter of 2004, we delivered a solid financial performance while also achieving our strategic objectives," said Gilles Gagnon, Aeterna Zentaris President and Chief Executive Officer. "In addition to across-the-board strong financial performance from all our sectors of activity, we continued to advance our product pipeline and reported positive results on perifosine and cetorelix, which support the ongoing and planned clinical development of these drug candidates in their respective indications. To that end, we are planning the initiation

of Phase II trials on perifosine in combination with radiotherapy, while further clinical development of cetorelix in endocrine therapy is being planned with our partner Solvay Pharmaceuticals. We believe that our accomplishments in the recent months have established a sound foundation for us to continue to grow our business and to achieve our objectives for the remainder of 2004."

Dennis Turpin, Aeterna Zentaris' Vice President and CFO, added, "With over \$64 million in cash and short-term investments, as well as our continued strong financial performance, we are in an excellent financial position to continue to carry out our business plan."

ATRIUM BIOTECHNOLOGIES' SECOND QUARTER RESULTS

Second quarter 2004 operating results for Atrium, Aeterna Zentaris' 62% owned subsidiary, included, for the first time, full three months of operations from US-based Pure Encapsulations which was acquired in March 2004. During the second quarter of 2004, sales for Atrium were \$47 million, an increase of 90% compared with \$24.7 million in sales for the comparable period in 2003. Operating income was \$7.4 million during the quarter, compared with \$3.2 million for the same period in 2003, representing a 131.8% increase. Net earnings increased 154.3% to \$4.1 million, compared with \$1.6 million for the same period in 2003. The increase reflects the combination of internal growth, as well as growth driven by the acquisition in March 2004 of Pure Encapsulations Inc., as well as of Chimiray/ Interchemical and Siricie in the second half of 2003. "The recent acquisition of Pure Encapsulations Inc. and its successful integration brought us an important strategic presence in USA in the field of nutritional supplements dedicated to healthcare professionals and largely contributed to deliver this growth," said Luc Dupont, President of the Executive Committee and CEO of Atrium Biotechnologies Inc. "We intend to continue to aggressively pursue our acquisition strategy."

SECOND QUARTER 2004 HIGHLIGHTS

- > POSITIVE PHASE II RESULTS FOR CETRORELIX IN ENDOMETRIOSIS, UTERINE MYOMA AND BENIGN PROSTATE HYPERPLASIA - Favorable data continues to

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

support the ongoing and planned clinical development of cetrorelix

- > POSITIVE PHASE I RESULTS FOR PERIFOSINE IN COMBINATION WITH RADIOTHERAPY IN CANCER - Results support the planned initiation of Phase II trials on perifosine in combination with radiotherapy
- > NEW AGREEMENT WITH ARDANA BIOSCIENCE FOR LHRH ANTAGONIST TEVERELIX IN PROSTATE CANCER
- > NAME CHANGE TOAETERNA ZENTARIS AND ADDITION TO THE NASDAQ BIOTECH INDEX
- > ATRIUM REVENUES OF \$47 MILLION, AN INCREASE OF 90% AND NET EARNINGS OF \$4.1 MILLION, AN INCREASE OF 154.3%

AETERNA ZENTARIS SIX-MONTH CONSOLIDATED FINANCIAL RESULTS

Total revenue for the first half of 2004 increased 56% to \$124.3 million, compared with \$79.7 million for the first half of 2003. The Company reported a year-to-date 2004 operating income of \$10.8 million, compared with an operating loss of \$2.4 million for the comparable prior-year period. The operating income in 2004 increased 100.5% to \$13.5 million compared with \$6.7 million for the same period in 2003. Net loss for the first six months of 2004 was \$1.2 million, or \$0.03 per share, compared with a net loss of \$9.6 million, or \$0.23 per share, for the first six months of 2003.

ATRIUM SIX-MONTH FINANCIAL RESULTS

For the six-month period ended June 30, 2004, Atrium sales were \$92.8 million compared to \$53 million in 2003, representing a 75.3% increase. The operating income increased 100.5% to \$13.5 million, compared to \$6.7 million for the same period in 2003. Net income increased 136.8% to \$7.7 million, compared to \$3.2 million for the same period in 2003.

OUTLOOK 2004

The Company's specific goals for the remainder of 2004 include:

- Initiate Phase II trials on perifosine in combination with radiotherapy
- Report preliminary monotherapy Phase II data on perifosine from multiple North American trials
- Develop new perifosine analogs
- Advance one or more preclinical compounds into Phase I clinical trials
- Report Phase II data on cetrorelix in BPH
- Advance clinical development of cetrorelix with Solvay
- Pending marketing approval for Cetrotide(R) in Japan for IN VITRO fertilization

CONFERENCE CALL INFORMATION

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

Management will be hosting a conference call for the investment community beginning at 10:00 a.m. Eastern Time today, Wednesday, August 11, to discuss second quarter financial and operating results and to 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 via 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 a biopharmaceutical company focused in oncology and endocrine therapy. Its extensive portfolio, from drug discovery to marketed products, includes perifosine, an orally-active AKT inhibitor in several Phase II trials for multiple cancers, and cetorelix, an LHRH antagonist already marketed for in vitro fertilization under the brand name Cetrotide(R), and also in advanced clinical development for the treatment of uterine myoma, endometriosis and benign prostatic hyperplasia (BPH).

AEterna Zentaris also owns 62% of Atrium Biotechnologies Inc., which develops, distributes and markets active ingredients, specialty fine chemicals, cosmetic and nutritional products for the cosmetics, chemical, pharmaceutical and nutritional industries.

News releases and additional information about AEterna Zentaris are available on its new Web site 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

Jacques Raymond
(418) 652-8525 ext. 360
jacques.raymond@aeternazentaris.com

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

U.S. INVESTOR RELATIONS
Lippert/Heilshorn & Associates
Kim Golodetz
(212) 838-3777
kgolodetz@lhai.com

EUROPE
Matthias Seeber
+49 69 42602 3425
matthias.seeber@zentaris.de

AETERNA ZENTARIS INC. (TSX: AEZ; NASDAQ: AEZS)
FINANCIAL SUMMARY
(in thousands of Canadian dollars, except share
and per share data)

	QUARTERS ENDED JUNE 30,		
CONSOLIDATED RESULTS	2004	2003	
Unaudited	\$	\$	
REVENUES	65,840	38,875	1
OPERATING EXPENSES			
Cost of sales	34,922	20,393	
Selling, general and administrative	10,712	7,030	
R&D costs, net of tax credits and grants	8,731	10,566	
Depreciation and amortization	2,298	2,014	
	56,663	40,003	1
Operating income (loss)	9,177	(1,128)	
Interest income	288	226	
Interest and financial expenses	(2,095)	(1,295)	
Foreign exchange gain (loss)	227	(971)	
INCOME (LOSS) BEFORE THE FOLLOWING ITEMS	7,597	(3,168)	
Current income taxes	(8,484)	(1,474)	(
Future income taxes	4,160	816	
Non-controlling interest	(1,943)	(842)	
NET EARNINGS (LOSS) FOR THE PERIOD	1,330	(4,668)	
Basic and diluted net earnings (loss) per share	0.03	(0.11)	
Weighted average number of shares			
Basic	45,594,326	40,695,527	45,5
Diluted	46,457,409	40,955,007	46,1
Issued and outstanding shares			45,6

