

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 second quarter of 2003

AETERNA ZENTARIS INC.

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(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  
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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  
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If "Yes" is marked, indicate below the file number assigned to the registrant in  
connection with Rule 12g3-2(b): 82-

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DOCUMENTS INDEX

DOCUMENTS DESCRIPTION

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1.                      AEterna's Interim Report 2003 - Second Quarter (Q2)  
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## Edgar Filing: Aeterna Zentaris Inc. - Form 6-K

August 6, 2003

To Our Stockholders:

I am pleased to report to you that AEterna Laboratories is realizing substantial financial benefit from our late 2002 acquisition of Zentaris, as Cetrotide(R) and Impavido(R) helped drive an 18% gain in product sales during the second quarter of 2003, compared with the second quarter of 2002. Including license income and research contract fees related to marketed products and products in development, total revenues increased by 66% during the quarter.

In addition, we were delighted with the recently announced positive Phase III results for Impavido(R) to treat cutaneous leishmaniasis, a severe skin disease prevalent in South America. Impavido(R) is currently sold in India to treat the visceral form of leishmaniasis. As a result of our successful Phase III results, we are preparing to file for regulatory approval in South America.

In addition to progress with our marketed products, the extension of our license agreement to 2010 with Serono for Cetrotide(R) illustrates our ability to add value from strategic alliances with world-class partners. As we move ahead to the balance of 2003, we look forward to reporting results from our Phase III clinical trial with Neovastat(R) for the treatment of renal cell carcinoma. Neovastat(R) holds potential to be the first anti-angiogenic drug on the market for the treatment of kidney cancer.

AEterna's cash and short-term investments of \$49.2 million as of June 30, 2003 were further supplemented by net proceeds of \$33.8 million from a bought deal financing that closed in late July. Reflecting this financing, today our cash position stands at approximately \$83 million. We are comfortable that we have the necessary capital to pursue our strategic objectives.

During the second quarter of 2003 and subsequent weeks, the Company's accomplishments included the following:

- o ATRIUM ACQUISITION - Atrium acquired 100% of all issued and outstanding shares of the privately-owned French company Chimiray/Interchemical for approximately E11.5 million (\$18.4 million), payable by the issuance of a long-term debt of E5 million (\$8 million) and the residual of E6.5 million (\$10.4 million) in cash. Based in Paris, Chimiray/Interchemical is focused mainly in the distribution of fine chemicals and active ingredients. Net sales for the last twelve-month period were approximately E35 million (\$52 million), and the company generated net earnings.
- o POSITIVE PHASE III RESULTS FOR IMPAVIDO(R) IN CUTANEOUS LEISHMANIASIS - Subsequent to the close of the quarter, we reported results of a Phase III trial evaluating Impavido(R) for the treatment of cutaneous leishmaniasis, a severe skin disease. The data showed that patients taking Impavido(R) had a cure rate of 70%, which is 220% better than for those in the placebo group. This favorable data enables Zentaris, which develops the drug, to apply for marketing authorization in South American countries where the cutaneous form of the disease is predominant.
- o NEW NEOVASTAT(R) DATA - In April, we disclosed new scientific data on our lead antiangiogenic compound Neovastat(R), which reinforce the drug's antiangiogenic properties. The data was obtained from two

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studies conducted by Dr. Francois Berger, Coordinator of the Neuroscience molecular team of the INSERM 318 unit in Grenoble, France. Abstracts reflecting the results of these studies were to be presented at the American Association for Cancer Research (AACR) meeting in Toronto, which was cancelled due to Severe Acute Respiratory Syndrome (SARS).

- o NEOVASTAT(R) UPDATE AT ASCO - In June, Dr. Bernard Escudier, Head of the Immunotherapy Unit at Institut Gustave-Roussy in Paris and lead investigator in Europe for our Neovastat(R) Phase III trial in renal cell carcinoma, gave a status report on the trial at the American Society of Clinical Oncology (ASCO) Meeting in Chicago. Dr. Charles Lu of the M.D. Anderson Cancer Center in Houston and lead investigator for our Phase III trial in non-small cell lung cancer also gave a status report on this trial. In his presentation, Dr. Escudier stated that data from the kidney cancer study would be analyzed upon the death of 230 patients, or September 30, 2003, whichever was sooner. At the time of his presentation, 218 patients had died.
- o EXTENDED AGREEMENT WITH SERONO UNTIL 2010 FOR CETROTIDE(R) - In June, we announced an extension of the existing license agreement between our subsidiary Zentaris and Serono for worldwide marketing rights, excluding Japan, for Cetrotide(R), a novel compound used for IN VITRO fertilization. The amended agreement provides for Zentaris to receive a signature fee, as well as fixed annual payments until 2010.
- o AETERNA ANNUAL MEETING - In May, we held our annual meeting of stockholders, where I presented the Company's strategy for growth and our value creation objectives. At the meeting, Dr. Harmut Michel, Director of the prestigious Max-Planck Institute for Biophysics in Frankfurt, Germany and 1988 Nobel Prize laureate in chemistry, was appointed to the Company's Scientific Advisory Board, and Dr. Eric Dupont, AETerna's Chairman, announced the conversion of all of his 4,725,000 multiple voting shares into the same number of subordinate voting shares. This conversion left the Company with a single class of voting shares.

On behalf of my colleagues and our Board of Directors, I thank you for your continued interest and support.

Sincerely,

/s/ GILLES GAGNON

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Gilles Gagnon, MSc, MBA  
President and Chief Executive Officer

### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION

The following analysis explains the variations in the Company's results of operations, financial condition and cash flow. It provides an update to the discussion and analysis contained in our Annual Report of 2002. This discussion and analysis should be read in conjunction with the information contained in AETerna Laboratories Inc.'s interim consolidated financial statements and related notes for the six-month periods ended June 30, 2003 and 2002. All figures are in Canadian dollars.

### CRITICAL ACCOUNTING POLICIES

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Our critical accounting policies are disclosed in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section and the annual consolidated financial statements contained in our 2002 Annual Report. Our financial statements are prepared in accordance with the Canadian Generally Accepted Accounting Principles (GAAP) and access to a summary of differences between Canadian and US GAAP is possible by consulting note 20 of our annual 2002 financial statements.

### RESULTS OF OPERATIONS

#### REVENUES

Revenues for the second quarter ended June 30, 2003 were \$38.9 million compared to \$23.4 million for the same period last year. For the six-month period ended June 30, 2003, the consolidated revenues were \$79.7 million compared to \$48.8 million in 2002. This increase for the quarter as well as for the first half of the year comes mainly from the Biopharmaceutical segment with revenues totalling \$26.7 million, as of June 30, 2003. The balance of \$4.2 million comes from the Cosmetics & Nutrition (C&N) and the Distribution segments, representing an increase of 8.6% compared to the first half of 2002 for these segments.

The acquisition of Frankfurt-based Zentaris, in December 2002, provided most of the revenues in the Biopharmaceutical segment for this quarter as well as for the six-month period. Revenues in this segment were generated by marketing of Cetrotide(R) and Impavido(R), milestone payments, research and development contract fees and the amortization of up-front payments.

#### OPERATING EXPENSES

The cost of sales during this quarter amounted to \$20.4 million compared to \$17.8 million for the same quarter in 2002. For the six-month period ended June 30, 2003, the cost of sales has gone up from \$37.5 million to \$43.6 million. These costs are in direct proportion to corresponding revenues and their percentage does not vary significantly from last year's same quarter even if we take into account sales generated by Cetrotide(R) and Impavido(R).

General, selling and administrative expenses amounted to \$6.5 million during this quarter compared to \$4.3 million in 2002. Regarding the six-month period, general, selling and

administrative expenses were \$12 million compared to \$8.2 million in 2002. This increase is attributed to the Biopharmaceutical segment, for an amount of \$2.7 million, as a result of the acquisition of Zentaris made last December. In addition, the C&N and Distribution segments increased their selling expenses by \$1.0 million as a result of the increase in their sales force.

Research and Development (R&D) investments, net of R&D tax credits and grants, amounted to \$11 million during this quarter in comparison with \$5.3 million last year. As of June 30, 2003, R&D investments reached \$21.9 million in comparison to \$10.5 million in 2002. This increase is attributed to the acquisition of Zentaris, whereby the investment in R&D amounted to \$5.7 million for this quarter and \$11.3 million for the six-month period. Therefore, the level of the investment for Neovastat, our lead antiangiogenic compound in oncology, was approximately the same as last year since the Phase III program is actively ongoing for renal cell carcinoma and non-small cell lung cancer. The residual amount of investment in R&D mainly relates to Cetrorelix, our lead compound in endocrinology, and to our recently acquired Zentaris drug discovery unit, including a 100,000 proprietary compound library.

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Depreciation and amortization (D&A) for the last quarter amounted to \$2 million compared to \$0.6 million in 2002. For the six-month period ended June 30, 2003, D&A amounted to \$4.5 million compared to \$1 million for the same period last year. This significant increase is mainly related to the additional amortization on Zentaris technologies acquired in December 2002. The purchase price allocation has been completed during the last quarter and an amount of \$13.5 million was allocated to goodwill from identified intangible assets. We expect that the amortization expense for 2003 will increase significantly over that of the 2002 fiscal year due to the intangible additions incurred at the end of 2002.

Interest income has decreased from \$0.8 million to \$0.2 million for this quarter compared to 2002. This decrease is primarily due to the cash used for the Zentaris transaction as well as to the reduction in market yield available on short-term investments. The interest and financial expenses mainly include the financing cost on the convertible term loans, the balance of purchase price settled in March 2003 and the promissory note of \$43 million reimbursed last January as interim financing related to Zentaris' acquisition.

A net foreign exchange loss of \$1 million was recorded during the quarter ended June 30, 2003 in comparison with a net loss of \$0.3 million last year. This loss is attributable to the effect of the strengthening Canadian dollar on our US investment portfolio and working capital denominated in US dollar. We maintain US dollar cash and cash equivalent and short-term investments to meet our futures expenditures in US dollar.

The net loss for this quarter amounted to \$4.6 million or \$0.11 per share in 2003 compared to a net loss of \$5.9 million or \$0.15 per share for the same quarter in 2002. For the six-month period ended June 30, 2003, the net loss was \$9.4 million or \$0.23 per share compared to \$11.6 million or \$0.30 per share. This reduction is the result of new income from Zentaris within our biopharmaceutical segment.

### LIQUIDITY AND CAPITAL RESOURCES

The financial position of the Company remains strong with \$49.2 million in cash and short-term investments as at June 30, 2003. On a pro-forma basis, taking into account the issuance of 4.5 million subordinate voting shares at \$7.90 per share and a 5% underwriting fees from the bought deal closed on July 24, 2003, we would have \$83 million in cash and short-term investment. This financing will be used to further develop our product pipeline, to pursue our growth strategy based on strategic alliances and acquisition of new technologies and for general corporate purposes.

During this quarter, an amount of \$1.5 million was used for operating activities. The cash flow used in investing activities amounted to \$1 million for the acquisition of an additional portion of Unipex Finance S.A. as well as of long-lived assets. For the six-month period ended June 30, 2003, an amount of \$7.5 million was used in operational activities and \$3.6 million was used for the acquisition of a portion of Unipex Finance S.A. and long-lived assets.

### RISK FACTORS

Economic and sector related risks are the same as those identified in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in the Company's 2002 Annual Report.

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/s/ DENNIS TURPIN

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 Dennis Turpin, CA  
 Vice President and Chief Financial Officer

This report contains forward-looking statements, which are 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 the business opportunities in the pharmaceutical industry, uncertainties related to the regulatory process and general changes in economic conditions. Investors should consult the Company's ongoing 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.

AETERNA LABORATORIES INC.

INTERIM CONSOLIDATED BALANCE SHEETS  
 (expressed in thousands of Canadian dollars)

		AS JUNE 20
		-----
		(UNAUD
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$	30,5
Short-term investments		18,6
Accounts receivable		38,9
Inventory		15,2
Prepaid expenses and deferred charges		2,7
Future income tax assets		3
		-----
		106,4
PROPERTY, PLANT AND EQUIPMENT		
		20,6
DEFERRED CHARGES		
		1,2
INTANGIBLE ASSETS		
		65,6
GOODWILL		
		38,8
FUTURE INCOME TAX ASSETS		
		16,4
		-----
	\$	249,2
		-----
LIABILITIES		
CURRENT LIABILITIES		

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Promissory note	\$	
Accounts payable and accrued liabilities		37,8
Income taxes		3,6
Balance of purchase price		
Current portion of long-term debt		3,0
-----		
		44,5
DEFERRED REVENUES		13,0
CONVERTIBLE TERM LOANS		19,0
LONG-TERM DEBT		9,5
EMPLOYEE FUTURE BENEFITS		6,2
FUTURE INCOME TAX LIABILITIES		25,5
NON-CONTROLLING INTEREST		24,5
-----		
		142,5
-----		
SHAREHOLDERS' EQUITY		
SHARE CAPITAL		153,5
CONTRIBUTED SURPLUS		7,0
DEFICIT		(54,26
CUMULATIVE TRANSLATION ADJUSTMENT		4
-----		
		106,7
-----		
	\$	249,2
-----		

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE INTERIM CONSOLIDATED FINANCIAL STATEMENTS

AETERNA LABORATORIES INC.

INTERIM CONSOLIDATED STATEMENTS OF OPERATIONS  
FOR THE PERIODS ENDED JUNE 30, 2003 AND 2002  
(expressed in thousands of Canadian dollars, except share and per share data)

UNAUDITED	QUARTERS ENDED JUNE 30,	
	2003	2002
-----		
REVENUES		
Sales	\$ 27,632	\$ 23,440
License income and research contract fees	11,243	-
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	38,875	23,440
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OPERATING EXPENSES

Cost of sales	20,393	17,803
General, selling and administrative	6,505	4,258
R&D costs, net of tax credits and grants	10,994	5,253
Depreciation and amortization		
Property, plant and equipment	862	497
Intangible assets	1,152	102
	39,906	27,913
OPERATING LOSS	(1,031)	(4,473)
Interest income	226	813
Interest and financial expenses	(1,295)	(74)
Foreign exchange loss	(971)	(282)
LOSS BEFORE THE FOLLOWING	(3,071)	(4,016)
INCOME TAX EXPENSE	(658)	(973)
NON-CONTROLLING INTEREST	(842)	(910)
NET LOSS FOR THE PERIOD	\$ (4,571)	\$ (5,899)
BASIC AND DILUTED NET LOSS PER SHARE	\$ (0.11)	\$ (0.15)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING	40,695,527	40,452,019

INTERIM CONSOLIDATED STATEMENTS OF DEFICIT  
FOR THE PERIODS ENDED JUNE 30, 2003 AND 2002  
(expressed in thousands of Canadian dollars, except share and per share data)

UNAUDITED

	2003
BALANCE - BEGINNING OF PERIOD	44,864
Net loss for the period	9,405
BALANCE - END OF PERIOD	54,269

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THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE INTERIM CONSOLIDATED  
FINANCIAL STATEMENTS

AETERNA LABORATORIES INC.

INTERIM CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE PERIODS ENDED JUNE 30, 2003 AND 2002

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

UNAUDITED	QUARTERS ENDED JUNE 30,	
	2003	2002
<hr/>		
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss for the period	\$ (4,571)	\$ (5,899)
Items not affecting cash and cash equivalents		
Depreciation and amortization	2,014	599
Future income taxes	(816)	470
Deferred charges	131	-
Deferred revenues	1,736	-
Accretion on convertible loans	415	-
Employee future benefits	88	-
Non-controlling interest	842	910
Stock-based compensation	-	54
Change in non-cash operating working capital items		
Accounts receivable	975	2,878
Inventory	206	(655)
Prepaid expenses	653	(86)
Accounts payable and accrued liabilities	(3,410)	(2,983)
Income taxes	223	(72)
	<hr/>	<hr/>
	(1,514)	(4,784)
<hr/>		
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of promissory note	-	-
Convertible term loans	(585)	-
Payment of balance of purchase price	-	-
Repayment of long-term debt	(29)	-
Issuance of warrants	-	747
Issuance of share capital, net of related expenses	(15)	54,804
	<hr/>	<hr/>
	(629)	55,551
<hr/>		
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of short-term investments	(11,531)	(51,563)
Proceeds from short-term investments	6,527	31,041
Business acquisition (note 2)	(250)	(1,316)
Purchase of a product line	-	(186)
Purchase of property, plant and equipment	(500)	(1,500)
Additions to intangible assets	(213)	(42)
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	(5,967)	(23,566)
NET CHANGE IN CASH AND CASH EQUIVALENTS	(8,110)	27,201
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(118)	423
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	38,757	9,971
CASH AND CASH EQUIVALENTS - END OF PERIOD	\$ 30,529	\$ 37,595
ADDITIONAL INFORMATION		
Interest paid	\$ 33	\$ 50
Income taxes paid	\$ 783	\$ 47

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE INTERIM CONSOLIDATED  
FINANCIAL STATEMENTS

AETERNA LABORATORIES INC.

NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

FOR THE PERIODS ENDED JUNE 30, 2003 AND 2002

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

UNAUDITED

1 BASIS OF PRESENTATION

These unaudited interim financial statements as at June 30, 2003 and for the periods ended June 30, 2003 and 2002, are unaudited. They have been prepared by the Company in accordance with Canadian generally accepted accounting principles (GAAP) for interim financial information. In the opinion of management, all adjustments necessary to present fairly the financial position, results of operations and cash flows for these periods have been included.

The accounting policies and methods of computation adopted in these financial statements are the same as those used in the preparation of the Company's most recent annual consolidated financial statements. All disclosures required for annual financial statements have not been included in these financial statements. These consolidated financial statements should be read in conjunction with the Company's most recent annual consolidated financial statements. These interim results of operations are not necessarily indicative of the results for the full year.

2 BUSINESS ACQUISITION

Unipex Finance S.A.

On January 13, and May 27, 2003, the subsidiary Atrium Biotechnologies Inc. acquired 21,800 common shares of the outstanding capital stock of Unipex Finance S.A., increasing its interest in the latter to 76.6% (70.28% in 2002) for a cash

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consideration of \$2,588,412. The excess of the purchase price over the net identifiable assets on the date of acquisition is \$2,007,009 and is recorded as goodwill not deductible for income tax purposes.

### Zentaris AG

The allocation of the purchase price, following the acquisition of Zentaris' shares in December 2002 has been completed during this quarter. At the acquisition date, Zentaris AG had two products developed that provided benefits from the sale of these products. The developed technology and the in-process research and development (R&D) were valued using a discounted cash flow approach resulting in an allocated fair value of \$64.8 M. The in-process R&D would require further development. The goodwill related to this transaction was valued at \$13.5 M and, according to GAAP, it will be not amortized but tested annually for impairment in relation to the fair value this reporting unit to which goodwill applies.

### 3 COMPANY'S STOCK OPTION PLAN

The company has chosen not to use the fair value method to account for stock-based compensation costs arising from awards to employees but discloses the pro-forma information relating to net loss and loss per share as if the fair value method of accounting had been used.

	Three months ended June 30, 2003
Net loss for the period	\$ (4,571)
Pro-forma adjustment for stock-based compensation costs	(503)
Pro-forma net loss for the period	
	\$ (5,074)
Basic and diluted net loss per share	\$ (0.11)
Pro-forma basic and diluted net loss per share	\$ (0.12)

AETERNA LABORATORIES INC.

### NOTES TO INTERIM CONSOLIDATED FINANCIAL STATEMENTS

FOR THE PERIODS ENDED JUNE 30, 2003 AND 2002

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

### UNAUDITED

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The pro-forma amounts may not be representation of future disclosure as the estimated fair value of stock options is amortized to expense over the vesting period and additional options may be granted in future periods. Furthermore, these pro-forma amounts include a compensation cost based on a weighted-average grant date fair value of \$2.28 and \$2.13 per stock option options granted in the three and six months ended June 30, 2003 respectively as calculated using the

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Black-Scholes option pricing model with the following assumptions:

	Three months ended June 30, 2003
Annualized volatility	55%
Risk-free interest rate	3.59%
Expected life (years)	2.8
Dividend	Nil

#### 4 CONVERTIBLE TERM LOANS

The company issued convertible term loans in the aggregate principal amount of \$25 million, bearing interest at an annual rate of 12%, payable annually or at maturity at the option of the company. These term loans are secured by all assets of the company with the exception of equipments and the shares of Atrium Biotechnologie Inc. The term loans mature on March 31, 2006 and are convertible at all time at the option of the holders in subordinate voting shares of the company at a price of \$ 5.05 per share. The equity component, which corresponds to the option of the holders to convert term loans into shares of the company, was valued at the date of the loans and is classified as contributed surplus.

#### 5 SEGMENT INFORMATION

The company manages its business and evaluates performance based on three operating segments, which are the biopharmaceutical segment, the cosmetics and nutrition segment and the distribution segment. The accounting principles used for these three segments are consistent with those used in the preparation of these consolidated financial statements.

	QUARTERS ENDED JUNE 30,		
	2003	2002	
<b>REVENUES</b>			
Biopharmaceutical	\$ 14,185	\$ -	\$
Cosmetics and nutrition	3,654	2,972	
Distribution	21,063	20,540	
Consolidated adjustments	(27)	(72)	
	\$ 38,875	\$ 23,440	\$
<b>NET EARNINGS (LOSS) FOR THE PERIOD</b>			
Biopharmaceutical	\$ (5,570)	\$ (6,956)	\$
Cosmetics and nutrition	507	589	
Distribution	446	460	
Consolidated adjustments	46	8	
	\$ (4,571)	\$ (5,899)	\$

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6. SUBSEQUENT EVENT

On July 24, 2003, pursuant to a bought deal, the company issued 4,500,000 common shares at a price of \$7.90 per share for gross proceed of \$35,550,000.

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 13, 2004  
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By: /s/ MARIO PARADIS  
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Mario Paradis  
Senior Director, Finance and  
Corporate Secretary