

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

Aeterna Zentaris Inc.
Form 6-K
March 12, 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 March 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. Aeterna Zentaris Reports Fourth Quarter and Full-Year 2008 Financial and
Operating Results

[AETERNA ZENTARIS LOGO]

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

PRESS RELEASE
For immediate release

AETERNA ZENTARIS REPORTS FOURTH QUARTER AND FULL-YEAR 2008 FINANCIAL AND
OPERATING RESULTS

ALL AMOUNTS ARE IN U.S. DOLLARS

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

QUEBEC CITY, CANADA, MARCH 11, 2009 - Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ) ("the Company"), a global biopharmaceutical company focused on endocrinology and oncology, today reported financial and operating results for the fourth quarter and the full year ended December 31, 2008.

2008 HIGHLIGHTS

- February
 - First patients treated with AEZS-108 for a Phase 2 trial in advanced ovarian and endometrial cancers.

 - March
 - Patient dosing commenced with cetrorelix in the second efficacy study of the Phase 3 program in benign prostatic hyperplasia ("BPH").
 - Completion of the sale to Paladin Labs of the marketed product, Impavido(R) (miltefosine), for approximately \$9.2 million.

 - April
 - Appointment of Juergen Ernst, as Interim President and CEO, the Company's Chairman of the Board at the time, following the departure of our former President and CEO;
 - Completion of patient recruitment for the first efficacy study of the Phase 3 program in BPH with cetrorelix.

 - May
 - First patients treated with cetrorelix for the safety trial of the Phase 3 program in BPH.

 - June
 - Completion of the sale of the Company's Quebec City property for a purchase price of \$7.1 million.
- [AETERNA ZENTARIS LOGO]
- September
 - Appointment of Juergen Engel, Ph.D., as Company President and CEO, succeeding Juergen Ernst who, at the same time, was appointed as Executive Chairman of the Company.

 - October and November
 - Completion of patient recruitment for the second efficacy trial of the Phase 3 program with cetrorelix in BPH.
 - Initiation of the second stage of patient recruitment for AEZS-108 Phase 2 trial in advanced ovarian and endometrial cancers.

 - December
 - Sale of Aeterna Zentaris rights to royalties on future sales of Cetrotide(R), covered by the Company's license agreement with Merck Serono, to Cowen Healthcare Royalty Partners L.P. ("Cowen") for gross consideration of \$52.5 million.
 - Completion of patient recruitment for the safety trial of the Phase 3 program in BPH with cetrorelix.
 - Appointment of Matthias Seeber, MBA, as Company Senior Vice President, Administration and Legal Affairs.

 - Subsequent to year end
 - The Company entered into a development, commercialization and

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

license agreement with sanofi-aventis for the development, registration and marketing of cetrorelix in BPH for the United States market. The agreement includes an initial upfront payment of \$30 million and up to \$135 million in additional payments upon achieving certain pre-established regulatory and commercial milestones, as well as escalating double-digit royalties on future net sales of cetrorelix for BPH in the United States.

Juergen Engel, Ph. D., Aeterna Zentaris' President and Chief Executive Officer commented, "I am proud of our achievements of the past 12 months. At the financial level, we generated nearly \$100 million in 2008 and in the first few months of 2009, through multiple non-dilutive transactions and a major pharmaceutical partnership with sanofi-aventis for our lead compound, cetrorelix. At the drug development level, we completed the recruitment of over 1,600 patients for our Phase 3 program in BPH with cetrorelix, according to schedule. We now look forward to disclosing results of this program throughout the second half of 2009. We also made significant progress with our lead oncology compound, AEZS-108, in endometrial and ovarian cancer with results expected by the end of this year.

Moving forward, we will continue to concentrate our efforts on bringing cetrorelix closer to market in collaboration with our partner, sanofi-aventis. We believe that this compound could prove to be a novel treatment for the benefit of millions of men with BPH and also build value for our shareholders."

Dennis Turpin, Senior Vice President and Chief Financial Officer of Aeterna Zentaris added, "The non-dilutive transactions and the recent partnership with sanofi-aventis have provided the Company with an overall stronger financial position and with the necessary funds to pursue our growth strategy."

-2-

[AETERNA ZENTARIS LOGO]

CONSOLIDATED RESULTS FOR THE FOURTH QUARTER ENDED DECEMBER 31, 2008

CONSOLIDATED REVENUES were \$7.2 million for the quarter ended December 31, 2008, compared to \$10.2 million for the same quarter in 2007. The decrease in revenues is primarily due to lower quarter-over-quarter royalties related to our license agreement with Merck Serono. Subsequent to the sale of the Company's rights to royalties on future sales of Cetrotide(R), covered by the Company's license agreement with Merck Serono, to Cowen, which was effective, for royalty determination purposes, on October 1, 2008, our periodic amortization of the gross proceeds received from Cowen, while still recognized as royalty revenues, has been lower than the royalty revenues recognized in the past, as receivable directly from Merck Serono. Additionally, quarter-over-quarter sales and royalties decreased due to the absence of sales of Impavido(R) in the fourth quarter of 2008, while license revenues witnessed a decrease due to the non-recurrence in 2008 of milestone payments received from one of our partners, related to the perifosine Phase 2 trials.

CONSOLIDATED SELLING, GENERAL AND ADMINISTRATIVE ("SG&A") EXPENSES were \$3.0 million for the quarter ended December 31, 2008, compared to \$5.1 million for the same quarter in 2007. The decrease in SG&A expenses is mainly related to the continued results of cost-saving measures that were implemented beginning in the second quarter of 2008.

CONSOLIDATED RESEARCH AND DEVELOPMENT ("R&D") EXPENSES were \$12.3 million for the quarter ended December 31, 2008, compared to \$13.6 million for the same quarter in 2007. The decrease in R&D expenses primarily relates to the

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

comparative reduction in expenses incurred in connection with our Phase 3 program with cetorelix in BPH, which by the fourth quarter of 2008 was fully enrolled and less subject to larger front-end expenditures that were necessary in the earlier, fourth quarter 2007 stage of the program.

CONSOLIDATED NET LOSS was \$14.5 million, or \$0.27 per basic and diluted share for the quarter ended December 31, 2008, compared to \$13.6 million, or \$0.26 per basic and diluted share, for the same quarter in 2007. The increase in consolidated net loss is largely attributable to a combination of lower sales and royalties, lower license fee revenues, lower manufacturing margins on Cetrotide(R) due in part to a \$0.7 million write-down to net realizable value of certain components of inventory, as well as to higher amortization expense, partly offset by lower quarter-over-quarter SG&A expenses, higher net foreign exchange gains and lower income tax expense.

CONSOLIDATED CASH, CASH EQUIVALENTS AND SHORT-TERM INVESTMENTS were \$49.7 million as at December 31, 2008.

CONSOLIDATED RESULTS FOR THE FULL YEAR ENDED DECEMBER 31, 2008

CONSOLIDATED REVENUES were \$38.5 million for the year ended December 31, 2008, compared to \$42.1 million for the year ended December 31, 2007. The decrease in consolidated revenues in 2008 compared to 2007 is primarily related to lower sales of Impavido(R), a decrease in consolidated license fee revenues mainly attributable to non-recurring milestone payments and the termination of a partner licensing agreement in 2007, partly offset by an increase in sales of Cetrotide(R).

CONSOLIDATED SG&A EXPENSES decreased to \$17.3 million for the year ended December 31, 2008, compared to \$20.4 million for the year ended December 31, 2007. The decrease in SG&A expenses is primarily related to the organizational changes and cost-saving measures that were implemented beginning in the second quarter of 2008.

-3-

[AETERNA ZENTARIS LOGO]

CONSOLIDATED R&D COSTS were \$57.4 million for the year ended December 31, 2008, compared to \$39.2 million for the year ended December 31, 2007. The increase in consolidated R&D costs for the year 2008 compared to 2007 is mainly attributable to the advancement of our Phase 3 program with our lead compound, cetorelix, in BPH.

CONSOLIDATED NET LOSS was \$59.8 million, or \$1.12 per basic and diluted share, for the year ended December 31, 2008, compared to \$32.3 million, or \$0.61 per basic and diluted share, for the year ended December 31, 2007. The increase in consolidated net loss is attributable to a combination of lower license fee revenues, lower manufacturing margins, higher R&D costs, higher depreciation and amortization and higher income tax expense, partly offset by lower SG&A expenses and higher net foreign exchange gains.

CONFERENCE CALL

Management will be hosting a conference call for the investment community beginning at 10:00 a.m. Eastern Time today, Wednesday, March 11, 2009, to discuss fourth quarter and full-year 2008 results. Individuals interested in participating in the live conference call by telephone may dial 416-646-3095, 514-807-8791 or 800-814-4859, or may listen through the Internet at www.aezsinc.com. A replay will be available on the Company's website for 30 days following the live event.

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

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, and 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 to do so by a governmental authority or applicable law.

INVESTOR RELATIONS

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

-4-

[AETERNA ZENTARIS LOGO]

MEDIA RELATIONS

Paul Burroughs
Director of Communications
(418) 652-8525 ext. 406
pburroughs@aezsinc.com

ATTACHMENT: Financial summary

-5-

[AETERNA ZENTARIS LOGO]

CONSOLIDATED RESULTS OF OPERATIONS (UNAUDITED)

	QUARTERS ENDED DECEMBER 31,		YEARS ENDED DECEMBER 31,	

(in thousands, except per share data)	2008	2007	2008	2007

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

	\$	\$	\$	\$
REVENUES				
Sales and royalties	4,640	6,435	29,462	28,825
License fees	2,092	3,705	8,504	12,843
Other	512	100	512	400
	7,244	10,240	38,478	42,068
OPERATING EXPENSES				
Cost of sales	4,930	3,255	19,278	12,930
Selling, general and administrative expenses	3,038	5,146	17,325	20,403
Research and development costs	12,328	13,574	57,448	39,248
R&D tax credits and grants	(137)	(1,941)	(343)	(2,060)
Depreciation and amortization				
Property, plant and equipment	316	378	1,515	1,562
Intangible assets	3,084	757	5,639	4,004
Impairment of long-lived asset held for sale	-	735	-	735
	23,559	21,904	100,862	76,822
LOSS FROM OPERATIONS	(16,315)	(11,664)	(62,384)	(34,754)
OTHER INCOME (EXPENSES)				
Interest income	131	535	868	1,904
Interest expense	(50)	(23)	(118)	(85)
Foreign exchange gain (loss)	2,642	(269)	3,071	(1,035)
Other	46	(27)	(79)	(28)
	2,769	216	3,742	756
SHARE IN THE RESULTS OF AN AFFILIATED COMPANY	-	-	-	-
LOSS BEFORE INCOME TAXES FROM CONTINUING OPERATIONS	(13,546)	(11,448)	(58,642)	(33,998)
INCOME TAX (EXPENSE) RECOVERY	(947)	(2,406)	(1,175)	1,961
NET (LOSS) EARNINGS FROM CONTINUING OPERATIONS	(14,493)	(13,854)	(59,817)	(32,037)
NET (LOSS) EARNINGS FROM DISCONTINUED OPERATIONS	-	218	-	(259)
NET (LOSS) EARNINGS FOR THE PERIOD	(14,493)	(13,636)	(59,817)	(32,296)
NET (LOSS) EARNINGS PER SHARE FROM CONTINUING OPERATIONS				
BASIC	(0.27)	(0.26)	(1.12)	(0.61)
DILUTED	(0.27)	(0.26)	(1.12)	(0.61)
NET (LOSS) EARNINGS PER SHARE FROM DISCONTINUED OPERATIONS				
BASIC	-	-	-	-
DILUTED	-	-	-	-
NET (LOSS) EARNINGS PER SHARE				

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

BASIC	(0.27)	(0.26)	(1.12)	(0.61)
DILUTED	(0.27)	(0.26)	(1.12)	(0.61)

-6-

[AETERNA ZENTARIS LOGO]

CONSOLIDATED BALANCE SHEET INFORMATION
(UNAUDITED)

	AS AT DECEMBER 31,		
(in thousands)	2008	2007	2006
	\$	\$	\$
Cash and cash equivalents	49,226	10,272	8,939
Short-term investments	493	31,115	51,550
Accounts receivable and other current assets	12,005	18,193	41,234
Property, plant and equipment, net	6,682	7,460	13,001
Other long-term assets	39,936	56,323	108,767
TOTAL ASSETS	108,342	123,363	223,491
Accounts payable and other current liabilities	22,121	21,480	15,624
Current portion of long-term debt and payable	49	775	686
Long-term debt and payable	172	-	687
Non-financial long-term liabilities	64,525	12,517	27,615
TOTAL LIABILITIES	86,867	34,772	44,612
SHAREHOLDERS' EQUITY	21,475	88,591	178,879
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	108,342	123,363	223,491

-7-

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: March 11, 2009

By: /s/Dennis Turpin

Dennis Turpin
Senior Vice President and Chief Financial Officer