

Aeterna Zentaris Inc.
Form 6-K
March 25, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

**Pursuant to Rule 13a-16 or 15d-16 under
the Securities Exchange Act of 1934**

For the month of March 2010

Commission file number 0-30752

ÆTERNA ZENTARIS INC.

1405, boul. du Parc-Technologique

Québec, Québec

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.

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Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

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 ☒

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 2009 Financial and Operating Results

Aeterna Zentaris Inc. 1405 du Parc-Technologique Blvd.

Québec (Québec) 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 2009 Financial and Operating Results

All amounts are in U.S. dollars

Quebec City, Canada, March 24, 2010 - Aeterna Zentaris Inc. (NASDAQ: AEZS, TSX: AEZ) (the Company), a late-stage drug development company specialized in oncology and endocrine therapy, today reported financial and operating results as at and for the fourth quarter and the full year ended December 31, 2009.

2009 Highlights

Perifosine

- Updated positive Phase 2 efficacy and safety data as well as new survival data for perifosine in combination therapy for relapsed/refractory multiple myeloma, were presented at the American Society of Hematology's (ASH) annual meeting. Results showed that the overall response rate was 41% and median overall survival was reported at 25 months for all evaluable patients. The combination therapy maintained an acceptable safety profile and no unexpected adverse events were reported.
- Positive Phase 2 data on perifosine in advanced metastatic colon cancer and in advanced renal cell carcinoma were presented at the American Society of Clinical Oncology's (ASCO) annual meeting. The data demonstrated perifosine's anti-cancer activity and efficacy both as a single agent and in combination therapy. Data at ASCO and ASH meetings were generated by the Company's North American partner, Keryx Biopharmaceuticals (Keryx).

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- A Phase 3 registration trial with perifosine in relapsed/refractory multiple myeloma was initiated under a Special Protocol Assessment (SPA). Perifosine was also granted Orphan Drug and Fast Track designations by the Food and Drug Administration (FDA) in this same indication. The trial is being conducted by Keryx.

AEZS-108

- Positive Phase 2 preliminary results with AEZS-108 in platinum-resistant and taxane-pretreated ovarian cancer were disclosed, which showed that the study met its primary efficacy endpoint of 5 or more responders in 41 evaluable patients.
- Positive Phase 2 preliminary results with AEZS-108 in advanced or recurrent endometrial cancer were disclosed. The study met its pre-defined primary efficacy endpoint of 5 or more responder patients. The trial in endometrial and ovarian cancer was conducted in collaboration with the German oncology study cooperative group, *Arbeitsgemeinschaft Gynackologisehe Onkologie* (AGO). Data for both indications were presented at the American Association for Cancer Research s (AACR) annual meeting.

AEZS-112

- Phase 1 results with AEZS-112 in advanced solid tumors or lymphoma were disclosed, showing prolonged courses of stable disease, excellent tolerability and potential for long-term use as a combination treatment for cancer.

AEZS-130

- A Poster was presented at the Endocrine Society s (ENDO) annual meeting, on AEZS-130 (Solorel™), reporting the first clinical data relating to its use as a simple oral diagnostic test for adult Growth Hormone Deficiency (GHD).

Cetrorelix

- A licensing agreement with sanofi-aventis U.S. (sanofi-aventis) for the development, registration and marketing of cetrorelix in benign prostatic hyperplasia (BPH) for the U.S. market was signed. The agreement provided Aeterna Zentaris with a \$30 million gross upfront payment.
- Results of two Phase 3 efficacy studies with cetrorelix in BPH which did not achieve their primary endpoint were disclosed.
- The Company s licensing agreement with sanofi-aventis for cetrorelix in BPH, subsequent to the aforementioned Phase 3 results, was terminated.

Corporate Developments

- The Company completed two registered direct offerings of common shares and warrants to certain U.S. institutional investors, for combined gross proceeds of \$15.5 million.

Subsequent to Year-End

- A statistically significant benefit in survival from updated results of a Phase 2 study of perifosine in advanced metastatic colon cancer was reported by Keryx.
- A publication in the February 2010 issue of the *Journal of Clinical Cancer Research* reported positive Phase 2 results for perifosine as a single agent for the treatment of advanced Waldenstrom's macroglobulinemia.
- The FDA granted a SPA for the Phase 3 trial of perifosine in combination therapy for refractory metastatic colorectal cancer. The trial is to be conducted by Keryx.
- The Committee for Orphan Medicinal Products of the European Medicines Agency issued a positive opinion to Aeterna Zentaris for orphan medicinal product designation for perifosine in multiple myeloma.

Juergen Engel, Ph.D., Aeterna Zentaris President and Chief Executive Officer, commented, "2009 was obviously a year of mixed results for us, starting off well with the licensing agreement with sanofi-aventis for cetrorelix in BPH, and ending with the disappointing results for our Phase 3 efficacy studies with this compound. Nevertheless, we achieved great successes with other innovative compounds from our pipeline, namely the initiation of the registration Phase 3 study with perifosine in multiple myeloma by our partner Keryx following encouraging Phase 2 results, and the positive preliminary Phase 2 results for AEZS-108 in ovarian and endometrial cancer. Additionally, we re-acquired all rights to AEZS-130, currently in Phase 3 as a promising oral diagnostic test for adult GHD. Over the course of this year, we look forward to further progress in North America with Keryx's Phase 3 trial with perifosine in multiple myeloma, as well as their initiation of a Phase 3 trial with this same compound in colon cancer. We hope to benefit from this development in order to ultimately achieve registration in other territories. As for AEZS-108, we anticipate reporting final results for our Phase 2 trial in endometrial and ovarian cancer. We also expect to perform additional studies with this compound in either one of these indications, as well as in prostate and bladder cancer, based on available financial resources and sponsorships. As for AEZS-130, we aim to successfully complete the Phase 3 trial as a diagnostic test for adult GHD and file a New Drug Application to the FDA. Overall in 2010, our focus will be on continuing the development of our innovative late-stage compounds and on garnering interest from potential partners for the benefit of both patients and shareholders."

Dennis Turpin, the Company's Senior Vice President and Chief Financial Officer, added, "As at December 31, 2009, we had a cash position of \$38.1 million with no debt. In 2010, with our partner Keryx assuming significant R&D costs related to the Phase 3 program with perifosine, and our earlier-stage projects associated with grants, R&D credits or collaboration agreements, we can expect a substantial reduction of our R&D expenses. With these measures, we feel we are in a relatively comfortable position to execute our business plan throughout the year."

CONSOLIDATED RESULTS AS AT AND FOR THE FOURTH QUARTER ENDED DECEMBER 31, 2009

Revenues were \$40.2 million for the quarter ended December 31, 2009, compared to \$7.2 million for the same quarter in 2008. The significant increase in revenues is due primarily to the Company's having recognized the remaining unamortized portion, or approximately \$30.4 million, of the upfront payment received from sanofi-aventis as part of its development and marketing agreement for cetrorelix in BPH.

Net research and development (R&D) expenses were \$10.6 million for the quarter ended December 31, 2009, compared to \$12.2 million for the same quarter in 2008. The decrease in R&D expenses primarily relates to lower costs having been incurred in connection with the Company's Phase 3 program for cetrorelix in BPH, given the progressive completion through the end of 2009 of efficacy and safety studies associated with that compound.

Selling, general and administrative (SG&A) expenses were \$6.2 million for the quarter ended December 31, 2009, compared to \$3.0 million for the same quarter in 2008. The increase in SG&A expenses is predominantly related to the expensing of the remaining unamortized portion, or approximately \$3.0 million, of the royalty paid to Tulane University in connection with the agreement entered into with, and subsequently terminated by, sanofi-aventis.

Net earnings were \$12.0 million, or \$0.19 per basic and diluted share, for the quarter ended December 31, 2009, compared to a net loss of \$14.5 million, or \$0.27 per basic and diluted share, for the same quarter in 2008. The significant increase in net earnings is largely attributable to the significant increase in license fee revenues, combined with lower comparative R&D expenses, as discussed above, partly offset by increased SG&A expenses and depreciation and amortization charges.

Cash and cash equivalents were \$38.1 million as at December 31, 2009.

CONSOLIDATED RESULTS AS AT AND FOR THE FULL YEAR ENDED DECEMBER 31, 2009

Revenues were \$63.2 million for the year ended December 31, 2009, compared to \$38.5 million for the year ended December 31, 2008. The increase in revenues in 2009 is almost exclusively attributable to license fee revenues related to the upfront payment received from sanofi-aventis, partly offset by lower royalty revenues having been recognized in 2009 in connection with our agreement with Merck Serono for Cetrotide®.

R&D costs were \$44.2 million for the year ended December 31, 2009, compared to \$57.4 million for the year ended December 31, 2008. The decrease in R&D costs is largely attributable to a lower volume of expenses having been incurred in 2009 related to the continued advancement during the first nine months of 2009, followed by the winding down of the Company's development activities linked to cetrorelix in BPH subsequent to its announcements that its related Phase 3 studies did not reach their primary endpoints.

SG&A expenses decreased to \$16.0 million for the year ended December 31, 2009, compared to \$17.3 million for the year ended December 31, 2008. The decrease is related to comparative euro-to-US dollar exchange rate fluctuations and to the absence in 2009 of certain non-recurring corporate expenses due to cost-saving measures that were implemented beginning in the second quarter of 2008, despite the additional selling expenses charged during 2009 as pertaining to the royalty paid to Tulane University.

Net loss was \$24.7 million, or \$0.43 per share for the year ended December 31, 2009, compared to \$59.8 million, or \$1.12 per basic and diluted share, for the year ended December 31, 2008. The significant decrease in net loss is due to the significant year-over-year increase in license fee revenues, associated mainly with agreements for cetrorelix and ozarelix, combined with lower comparative R&D, SG&A and income tax expenses, partly offset by lower comparative sales and royalties and increased depreciation and amortization expenses and foreign exchange losses.

Adoption of New Shareholder Rights Plan

The Company's Board of Directors (the "Board") adopted a new shareholder rights plan to be dated March 29, 2010 (the "Rights Plan"). The Rights Plan will ensure that the Company and its shareholders continue to receive the benefits associated with the Company's current shareholder rights plan, which expires on March 29, 2010. The Rights Plan has been adopted at this time to prevent any gap in shareholder protection and will be effective at the close of business on March 29, 2010.

The Rights Plan is designed to encourage the fair treatment of the Company's shareholders, should an unsolicited take-over bid be made for the Company, by providing the Board and shareholders sufficient time to explore and, if appropriate, develop alternatives for maximizing shareholder value, providing adequate time for competing bids to emerge, by ensuring that shareholders have an equal opportunity to participate in such a bid and receive full and fair value for their shares and by giving the Board and shareholders adequate time to properly assess the bid and to lessen the pressure to tender that is typically encountered by a shareholder of a corporation that is subject to a bid.

The Rights Plan was not adopted by the Board in response to any offer or specific takeover bid for the Company, and the Company is not aware of any such offer or takeover bid that has been made or is contemplated. The Rights Plan has received conditional acceptance from the Toronto Stock Exchange. The Rights Plan must be ratified by shareholders of the Company within six months of the Rights Plan adoption, and shareholders will be asked to ratify and approve the Rights Plan at the annual and special meeting of shareholders of the Company to be held on May 13, 2010 (the "Meeting"). If ratified by the shareholders, the Rights Plan will remain in effect until the close of business on the date of termination of the Company's annual meeting of shareholders in 2016, subject to reconfirmation by the shareholders at the Company's 2013 annual meeting and subject to earlier termination or expiration of the Rights Plan in accordance with its terms. The Rights Plan must be ratified by a majority of the votes cast at the Meeting by independent shareholders. If the Rights Plan is not ratified at the Meeting, all rights issued pursuant to the Rights Plan and the Rights Plan itself will terminate and be null and void and of no further force and effect.

Upon the occurrence of certain triggering events, including the acquisition by a person or group of persons of 20% or more of the Company's outstanding voting shares in a transaction that does not meet the "Permitted Bid" requirements of the Rights Plan (or other than pursuant to an exemption available under the Rights Plan), the rights issued under the Rights Plan will, upon exercise, entitle holders (other than the acquiring person or group of persons) to acquire additional common shares of the Company at a significant discount to the prevailing market price at that time.

The Rights Plan is not intended to prevent take-over bids. A Permitted Bid must be made to all holders of the Company's voting shares on identical terms and conditions by way of a take-over bid circular prepared in compliance with applicable securities laws and, in addition to certain other conditions, must remain open for not less than 60 days. Certain holdings of shares, such as positions held by investment managers, trust companies for managed accounts and pension plans, will not trigger the Rights Plan unless the holders are participating in making a take-over bid for the Company.

The issuance of the rights is not dilutive until the rights separate from the underlying common shares, and become exercisable, or until the exercise of the rights. The issuance of the rights will not change the manner in which shareholders currently trade their shares of the Company.

The Rights Plan is similar to other shareholder rights plans recently adopted by other Canadian companies. The foregoing description of the Rights Plan is qualified in its entirety by the full text of such plan, which will be filed on SEDAR at www.sedar.com and on EDGAR at www.sec.gov.

CONFERENCE CALL

Management will be hosting a conference call for the investment community beginning at 10:00 a.m. Eastern Time today, Wednesday, March 24, 2010, to discuss the 2009 fourth quarter and full-year results. Individuals interested in participating in the live conference call by telephone may dial 888-231-8191 (North America), or 647-427-7450 or 514-807-9895 (Canada). They may also 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.

About Aeterna Zentaris Inc.

Aeterna Zentaris Inc. is a late-stage drug development company specialized in oncology and endocrine therapy. 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. 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 required by a governmental authority or applicable law.

Investor Relations

Ginette Vallières

Investor Relations Coordinator

(418) 652-8525 ext. 265

gvallieres@aezsinc.com

Media Relations

Paul Burroughs

Director of Communications

(418) 652-8525 ext. 406

pburroughs@aezsinc.com

Attachment: Financial summary

Interim Unaudited and Annual Audited Consolidated Statements of Operations

(in thousands, except share and per share data)

	Three months ended December 31,		Year ended December 31,		
	2009	2008	2009	2008	2007
	(unaudited)			(audited)	
	\$	\$	\$	\$	\$
Revenues					
License fees	35,162	2,092	42,221	8,504	12,843
Sales and royalties	5,020	4,640	20,957	29,462	28,825
Other		512	59	512	400
	40,182	7,244	63,237	38,478	42,068
Operating expenses					
Cost of sales, excluding depreciation and amortization	3,774	4,930	16,501	19,278	12,930
Research and development costs	10,744	12,328	44,217	57,448	39,248
Research and development tax credits and grants	(181)	(137)	(403)	(343)	(2,060)
Selling, general and administrative expenses	6,191	3,038	16,040	17,325	20,403
Depreciation and amortization					
Property, plant and equipment	2,302	316	3,285	1,515	1,562
Intangible assets	5,841	3,084	7,555	5,639	4,004
Impairment of long-lived asset held for sale					735
	28,671	23,559	87,195	100,862	76,822
Earnings (loss) from operations	11,511	(16,315)	(23,958)	(62,384)	(34,754)
Other income (expenses)					
Interest income	34	131	349	868	1,904
Interest expense	(1)	(50)	(5)	(118)	(85)
Foreign exchange gain (loss)	488	2,642	(1,110)	3,071	(1,035)
Other		46		(79)	(28)
	521	2,769	(766)	3,742	756
Income (loss) before income taxes	12,032	(13,546)	(24,724)	(58,642)	(33,998)
Income tax (expense) recovery		(947)		(1,175)	1,961
Net earnings (loss) from continuing operations	12,032	(14,493)	(24,724)	(59,817)	(32,037)
Net loss from discontinued operations					(259)
Net earnings (loss)	12,032	(14,493)	(24,724)	(59,817)	(32,296)
Net earnings (loss) per share					
Basic and diluted	0.19	(0.27)	(0.43)	(1.12)	(0.61)
Weighted average number of shares					
Basic and diluted	61,993,939	53,187,470	56,864,484	53,187,470	53,182,803

Consolidated Balance Sheet Information (Unaudited)

(in thousands)	As at December 31, 2009 \$	As at December 31, 2008 \$
Cash and cash equivalents	38,100	49,226
Short-term investments		493
Accounts receivable and other current assets	10,913	12,005
Restricted cash	878	
Property, plant and equipment, net	4,358	6,682
Other long-term assets	32,013	39,936
Total assets	86,262	108,342
Accounts payable and other current liabilities	19,211	22,121
Current portion of long-term payable	57	49
Long-term payable	143	172
Non-financial long-term liabilities*	57,625	64,525
Total liabilities	77,036	86,867
Shareholders' equity	9,226	21,475
Total liabilities and shareholders' equity	86,262	108,342

* Comprised mainly of deferred revenues and employee future benefits.

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.

ÆTERNA ZENTARIS INC.

Date: March 25, 2010

By: /s/Dennis Turpin
Dennis Turpin
Senior Vice President and Chief Financial
Officer