Aeterna Zentaris Inc.
Form 6-K
March 22, 2011

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 2011

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.

Form 20-F x Form 40-F o

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): o

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): o

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 o 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 2010 Financial and Operating Results

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Press Release
For immediate release

Aeterna Zentaris Reports Fourth Quarter and Full-Year 2010 Financial and Operating Results

All amounts are in U.S. dollars (unless otherwise noted)

Quebec City, Canada, March 22, 2011 - 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, 2010.

2010 Highlights

Perifosine (oral Akt inhibitor)

- February 3, 2010: Special Protocol Assessment (SPA) granted by the United States Food and Drug Administration (FDA) for Phase 3 registration trial with perifosine in refractory advanced colorectal cancer to be conducted and sponsored by partner, Keryx Biopharmaceuticals, Inc. (Keryx).

- March 1, 2010: European Medicines Agency (EMA) issued a positive opinion for orphan medicinal product designation for perifosine in multiple myeloma.

- April 5, 2010: Perifosine receives FDA Fast Track Designation for Phase 3 registration trial in refractory advanced colorectal cancer.

- April 8, 2010: Initiation of Phase 3 registration X-PECT trial in refractory advanced colorectal cancer.

- April 15, 2010: Positive Scientific Advice from EMA for Phase 3 registration trial in multiple myeloma, indicating that the data from the ongoing trial are expected to be sufficient for perifosine s registration in Europe.

- June 7, 2010: Phase 1 data on perifosine in monotherapy for recurrent pediatric solid tumors, including brain tumors and neuroblastoma, presented at the annual meeting of the American Society of Clinical Oncology (ASCO). No dose-limiting toxicity was observed at different dose levels of perifosine.

- June 8, 2010: Final Phase 2 results for perifosine in advanced metastatic colorectal cancer reported at ASCO, confirming a statistically significant improvement in both time to tumor progression and overall survival.

- June 29, 2010: EMA issues positive Scientific Advice for Phase 3 trial with perifosine in colorectal cancer, indicating that the data from the ongoing Phase 3 trial are expected to be sufficient for product registration in Europe.

- July 14, 2010: FDA granted orphan-drug designation to perifosine for neuroblastoma.

- December, 6, 2010: Positive Phase 2 safety and tolerability data of perifosine in advanced chronic lymphocytic leukemia and Hodgkin s lymphoma, as well as positive Phase 1 results of perifosine combined with lenalidomide (Revlimid®) + dexamethasone in multiple myeloma, presented at the American Society of Hematology s (ASH) meeting.

AEZS-108 (LHRH targeted cytotoxic conjugate)

- May 6, 2010: FDA granted orphan-drug designation to AEZS-108 for ovarian cancer.

- May 12, 2010: FDA granted approval for Investigational New Drug application for AEZS-108 in luteinizing hormone-releasing hormone (LHRH) receptor-positive urothelial (bladder) cancer.

- May 17, 2010: AEZS-108 received positive opinion from EMA for orphan medicinal product designation in ovarian cancer.

- June 7, 2010: Positive Phase 2 efficacy and safety data for AEZS-108 in ovarian cancer presented at the ASCO s annual meeting.

- June 28, 2010: Collaboration with Almac Group s Diagnostic division to develop a companion diagnostic for AEZS-108 in cancer.

- November, 18, 2010: Positive Phase 2 results for AEZS-108 in advanced endometrial cancer presented at EORTC-NCI-AACR symposium.

- December 14, 2010: Initiation of Phase 1/2 trials with AEZS-108 in castration refractory prostate cancer and refractory bladder cancer.

AEZS-130 / Solorel® (oral ghrelin agonist)

- October 5, 2010: Interim Phase 3 data on Solorel® presented at International Congress of Growth Hormone Research Society and the Insuline-like Growth Factors Society, demonstrated the potential to provide a simple, well tolerated and safe oral diagnostic test for Adult Growth Hormone Deficiency (AGHD).

- December 20, 2010: Agreement with the FDA on an SPA for Solorel® to complete Phase 3 study for the diagnosis of AGHD.

Corporate Developments

- April 20, 2010: Completion of a $15.0 million registered direct offering with institutional investors.

- June 21, 2010: Completion of a $12.1 million registered direct offering with institutional investors.

Subsequent to Year-End

- On February 22, 2011: At-the-Market sales agreement to sell up to 12.5 million of the Company s common shares through issuances on the NASDAQ not to exceed $19.8 million over a 24-month period. On March 10, 2011, the Company issued 1.7 million common shares in connection with the aforementioned ATM agreement, for gross proceeds of approximately $3.2 million.

- On February 28, 2011: The Company received $2.5 million milestone payment from Cowen Healthcare Royalty Partners, L.P. (Cowen) that had been contingent on 2010 net sales of Cetrotide® reaching a specified level.

- On March 9, 2011: The Company announced it had entered into an agreement with Yakult Honsha Co. Ltd. (Yakult) for the development, manufacture and commercialization of perifosine in Japan. Under the terms of this agreement, the Company received an initial non-refundable upfront payment of approximately 6 million Euro ($8.3 million) and will also be entitled to receive up to a total of approximately 44 million Euro ($60.9 million) upon achieving certain pre-established milestones including clinical and regulatory events in Japan, as well as double-digit royalties on future net sales of perifosine in the Japanese market. Furthermore, the Company agreed to supply perifosine to Yakult on a cost-plus-basis.

Juergen Engel, Ph.D., Aeterna Zentaris President and Chief Executive Officer, commented, 2010 has been a very exciting and successful year for the Company, as we reached our drug development and business goals. For our lead oncology compound, perifosine, we announced positive final Phase 2 results in colorectal cancer, initiated a registration Phase 3 trial in this same indication, while the registration Phase 3 trial in multiple myeloma is ongoing. More recently, we delivered on our commitment of partnering perifosine on the Asian market, with the signing of an agreement with Yakult for Japan.

As for our 2nd lead oncology compound, AEZS-108, we reported positive Phase 2 results in ovarian and endometrial cancer and also initiated Phase 1/2 trials in castration refractory prostate cancer and refractory bladder cancer.

Over the next twelve to eighteen months our main focus will be on completing the ongoing registration Phase 3 program with perifosine in colorectal cancer and multiple myeloma as it moves closer to commercialization, initiating a registration trial with AEZS-108 in endometrial cancer, as well as completing the Phase 3 trial and filing the NDA for the use of Solorel® as a diagnostic test for AGHD.

Dennis Turpin, CA, SVP, Chief Financial Officer at Aeterna Zentaris stated, We are very pleased with the completion of our recently announced transaction with Yakult, which generated nearly $8.3 million as an up-front payment. With this transaction, our cash, cash equivalents and short-term investments as at December 31, 2010, on a pro-forma basis, would be $42.2 million, a solid financial position from which we can continue to execute our business plan.

CONSOLIDATED RESULTS AS AT AND FOR THE FOURTH QUARTER ENDED DECEMBER 31, 2010

Revenues were $10.0 million for the quarter ended December 31, 2010, compared to $40.2 million for the same quarter in 2009. The significant decrease in revenues is due primarily to the Company s having recognized, in December 2009, the remaining unamortized portion, or approximately $30.4 million, of the upfront payment received from sanofi-aventis U.S L.L.C. (sanofi) in connection with a former collaboration agreement for the development of cetrorelix in benign prostatic hyperplasia (BPH), partly offset by the increase in 2010 royalties attributable to the contingent payment of $2.5 million due from Cowen.

Net research and development (R&D) costs were $5.1 million for the quarter ended December 31, 2010, compared to $10.6 million for the same quarter in 2009. The comparative decrease in R&D expenses primarily results from the progressive completion through the end of 2009 of efficacy and safety studies associated with the Phase 3 program for cetrorelix in BPH. The decrease is also explained by a comparatively lower overall volume of R&D expenses, most notably given the fact that most costs related to the ongoing Phase 3 program with perifosine are borne by the Company s North American partner, Keryx.

Selling, general and administrative (SG&A) expenses were $3.1 million for the quarter ended December 31, 2010, compared to $6.2 million for the same quarter in 2009. The decrease in SG&A expenses is predominantly related to the expensing, in December 2009, of the remaining unamortized portion, or approximately $3.0 million, of a royalty paid to the Tulane Educational Fund (Tulane) in connection with the agreement entered into with, and subsequently terminated by, sanofi, regarding the Phase 3 program with cetrorelix in BPH.

Net (loss) earnings amounted to ($2.7 million), or ($0.03) per basic and diluted share, for the quarter ended December 31, 2010, compared to $12.0 million, or $0.19 per basic and diluted share, for the same quarter in 2009. The significant quarter-over-quarter decrease in net earnings is largely attributable to the significant decrease in license fee revenues, partly offset by lower comparative R&D expenses and by decreased SG&A expenses and depreciation and amortization charges.

Cash, cash equivalents and short-term investment totalled $33.9 million as at December 31, 2010.

CONSOLIDATED RESULTS FOR THE FULL YEAR ENDED DECEMBER 31, 2010

Revenues were $27.7 million for the year ended December 31, 2010, compared to $63.2 million for the year ended December 31, 2009. The significant decrease in revenues is due primarily to the Company s having recognized, in December 2009, the remaining unamortized portion, or approximately $30.4 million, of the upfront payment received from sanofi for cetrorelix in BPH, partly offset by the increase in 2010 royalties attributable to the contingent payment of $2.5 million due from Cowen.

Net R&D costs were $19.9 million for the year ended December 31, 2010, compared to $43.8 million for the year ended December 31, 2009. The decrease is primarily attributable to the winding down and termination of development activities related to cetrorelix in BPH subsequent to our announcements that our related Phase 3 studies had not reached their primary endpoints in 2009. The decrease is also explained by a comparatively lower overall volume of R&D expenses, most

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notably given the fact that most costs related to our ongoing Phase 3 program with perifosine are borne by our North American partner, Keryx.

SG&A expenses decreased to $11.9 million for the year ended December 31, 2010, compared to $16.0 million for the year ended December 31, 2009. The decrease is related primarily to the absence, in 2010, of the royalty paid to Tulane, amounting to approximately $3.0 million, as noted above, to euro-to-US dollar exchange rate fluctuations, largely due to the comparative weakening in 2010 of the euro against the US dollar and to the continued implementation of general and administrative cost-saving measures.

Net loss was $23.2 million, or $0.31 per basic and diluted share, for the year ended December 31, 2010, compared to $24.7 million, or $0.43 per basic and diluted share for the year ended December 31, 2009. The decrease in the Company s 2010 net loss, as compared to 2009, is attributable to a reduction in net R&D costs, lower SG&A expenses and lower depreciation and amortization charges, as well as to higher net foreign exchange gains, as discussed above, offset by the significant reduction of licence fee revenues and a lower margin on sales of Cetrotide®.

CONFERENCE CALL

Management will be hosting a conference call for the investment community beginning at 2 p.m. (Eastern Time) today, Tuesday, March 22, 2011, to discuss the 2010 fourth quarter and full-year results. Individuals interested in participating in the live conference call by telephone may dial, in Canada 514-807-8791 or 416-644-3426, outside Canada, 800-731-5319. They may also listen through the Internet at www.aezsinc.com in the newsroom section. A replay will be available on the Company s website for 30 days following the live event.

About Aeterna Zentaris Inc.

Aeterna Zentaris is a late-stage oncology drug development company currently investigating potential treatments for various cancers including colorectal, ovarian, endometrial cancer and multiple myeloma. The Company s innovative approach of personalized medicine means tailoring treatments to a patient s specific condition and to unmet medical needs. Aeterna Zentaris deep pipeline is drawn from its proprietary discovery unit providing the Company with constant and long-term access to state-of-the-art therapeutic options. For more information please visit www.aezsinc.com.

Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbour provisions of the U.S. Securities Litigation Reform Act of 1995. Forward-looking statements involve known and unknown risks and uncertainties that 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 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

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to any of the forward-looking statements contained herein to reflect future results, events or developments, unless required to do so by a governmental authority or by applicable law.

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Attachment: Financial summary

Consolidated Statements of Operations Information

(in thousands, except for share and per share data)

	Years ended December 31,		
	2010	**2009**	**2008**
	$	**$**	**$**
Revenues			
Sales and royalties	**24,857**	20,957	29,462
License fees and other	**2,846**	42,280	9,016
	27,703	63,237	38,478
Operating expenses			
Cost of sales, excluding depreciation and amortization	**18,700**	16,501	19,278
Research and development costs, net	**19,859**	43,814	57,105
Selling, general and administrative expenses	**11,875**	16,040	17,325
Depreciation and amortization			
Property, plant and equipment	**1,005**	3,285	1,515
Intangible assets	**1,492**	7,555	5,639
	52,931	87,195	100,862
Loss from operations	**(25,228)**	(23,958)	(62,384)
Other income (expenses)			
Unrealized gain on held-for-trading financial instrument	**687**		
Interest income	**207**	349	868
Interest expense	**(26)**	(5)	(118)
Foreign exchange gain (loss)	**1,170**	(1,110)	3,071
Other	**(28)**		(79)
	2,010	(766)	3,742
Loss before income taxes	**(23,218)**	(24,724)	(58,642)
Income tax expense			(1,175)
Net loss	**(23,218)**	(24,724)	(59,817)
Net loss per share			
Basic and diluted	**(0.31)**	(0.43)	(1.12)
Weighted average number of shares			
Basic and diluted	**75,659,410**	56,864,484	53,187,470

Consolidated Balance Sheet Information

(in thousands)

	As at December 31,		
	2010	**2009**	**2008**
	$	**$**	**$**
Cash and cash equivalents	**31,998**	38,100	49,226
Short-term investments	**1,934**		493
Accounts receivable and other current assets	**10,243**	10,913	12,005
Restricted cash	**827**	878	
Property, plant and equipment, net	**3,096**	4,358	6,682
Other long-term assets	**28,476**	32,013	39,936
Total assets	**76,574**	86,262	108,342
Accounts payable and other current liabilities	**13,427**	19,211	22,121
Current portion of long-term payable	**60**	57	49
Long-term payable	**90**	143	172
Non-financial long-term liabilities*	**50,558**	57,625	64,525
Total liabilities	**64,135**	77,036	86,867
Shareholders equity	**12,439**	9,226	21,475
Total liabilities and shareholders equity	**76,574**	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 22, 2011	By:	/s/ Dennis Turpin Dennis Turpin Senior Vice President and Chief Financial Officer