

Aeterna Zentaris Inc.
Form 6-K
November 10, 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 November 2011

Commission file number 0-30752

ÆTERNA ZENTARIS INC.

1405, boul. du Parc-Technologique

Québec, Québec

Canada, G1P 4P5

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(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 ☐

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	Press release dated November 10, 2011: Aeterna Zentaris Reports Third Quarter 2011 Financial and Operating Results

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Press Release

For immediate release

Aeterna Zentaris Reports Third Quarter 2011 Financial and Operating Results

All amounts are in U.S. dollars (except for share data).

Quebec City, Canada, November 10, 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 for the quarter ended September 30, 2011.

Third Quarter 2011 Highlights

Perifosine

July 12, 2011: the Company announced that the European Patent Office had granted a patent for the use of alkylphosphocolines, more specifically perifosine, in combination with anti-tumor anti-metabolites, which include among others 5FU (fluorouracil) and capecitabine in the preparation of a medicament for the treatment of benign and malignant tumors. This patent will expire on July 28, 2023.

July 27, 2011: the Company announced the completion of patient recruitment (over 465 patients) for the ongoing Phase 3 trial with perifosine in refractory advanced colorectal cancer.

August 31, 2011: the Company announced the completion of the pre-specified safety and futility interim analysis by the Data Safety Monitoring Board (DSMB) for the Phase 3 trial with perifosine in refractory advanced colorectal cancer. The DSMB recommended that the trial proceed as planned.

Subsequent to quarter-end, the Company announced that two articles on perifosine had been published in the October 2011 online issue of the *Journal of Clinical Oncology*, in which positive Phase 2 results in metastatic colorectal cancer and positive Phase 1/2 results in relapsed/refractory multiple myeloma were reported.

AEZS-108

September 14, 2011: the Company presented positive final Phase 2 efficacy and safety data for AEZS-108 in advanced endometrial cancer at the 17th International Meeting of the European Society of Gynecological Oncology in Milan, Italy.

September 26, 2011: the Company announced positive interim data for the Phase 1 portion of its Phase 1/2 trial with AEZS-108 in castration and taxane resistant prostate cancer at the European Society of Medical Oncology meeting in Stockholm, Sweden.

October 25, 2011: Subsequent to quarter-end, the Company announced that the United States Food and Drug Administration (FDA) had granted an Investigational New Drug approval to Alberto J. Montero, M.D., of the Sylvester Comprehensive Cancer Center, for a Phase 2 trial in triple-negative breast cancer with AEZS-108.

AEZS-130

July 26, 2011: the Company announced the completion of the Phase 3 study for AEZS-130 as a first oral diagnostic test for adult growth hormone deficiency (AGHD).

August 30, 2011: the Company announced favorable top-line results for the completed Phase 3 study for AEZS-130 as first oral diagnostic test for AGHD and its intent to meet with the FDA for the future filing of a New Drug Application.

AEZS-120

July 20, 2011: the Company announced that it had reached a key milestone in the non-clinical development of AEZS-120, its oral prostate cancer vaccine candidate. The program encompassed the full development of Good Manufacturing Practice process as well as a safety and toxicology package.

AEZS-131

August 30, 2011: the Company announced pre-clinical results demonstrating anti-tumor activity in different human tumor cell lines for AEZS-131, its novel, orally active anti-cancer Erk inhibitor, at the American Chemical Society National Meeting in Denver, Colorado.

Corporate Developments

During the three-month period ended September 30, 2011, the Company raised a total of approximately \$9.6 million in gross proceeds pursuant to the At-the-Market (ATM) sales agreement of June 2011 (the June ATM Sales Agreement).

Subsequent to quarter-end, from October 1, 2011 through November 9, 2011, the Company issued a total of approximately 3.8 million common shares under the June ATM Sales Agreement for aggregate gross proceeds of approximately \$6.2 million.

Cash and cash equivalents totalled \$48.1 million as at September 30, 2011. With the aforementioned ATM drawdowns that were completed subsequent to quarter-end, the Company's pro forma cash and cash equivalents as at September 30, 2011 would total \$54.3 million.

Juergen Engel, Ph.D., Aeterna Zentaris President and Chief Executive Officer, commented, "This quarter was marked by three key drug development milestones. First, patient recruitment was completed for the ongoing Phase 3 trial in advanced refractory colorectal cancer with perifosine. We were also granted a European use patent for perifosine that will expire in July 2023. Second, we reported positive Phase 3 results for AEZS-130 as an oral diagnostic test for Adult Growth Hormone Deficiency. Third, we presented final positive Phase 2 data in endometrial cancer and encouraging interim Phase 1/2 data in prostate cancer for our second lead anticancer compound, AEZS-108. We are proud of these accomplishments and look forward to 2012, as we continue to focus our efforts on the final stage of the development program with perifosine in colorectal cancer leading to the Phase 3 results, on the approval procedures for AEZS-130 in AGHD and on the initiation of a Phase 3 trial in endometrial cancer with AEZS-108."

Dennis Turpin, CA, Senior Vice President, Chief Financial Officer at Aeterna Zentaris, stated, "With our pro forma cash and cash equivalents standing at \$54.3 million, we believe we are in a solid financial position to pursue our focused strategy as planned."

CONSOLIDATED RESULTS AS AT AND FOR THE THIRD QUARTER ENDED SEPTEMBER 30, 2011

Revenues were \$9.5 million for the three-month period ended September 30, 2011, as compared to \$5.7 million for the same period in 2010. This increase is largely related to comparative higher-than-normal deliveries of Cetrotide® to Merck Serono and to the comparative strengthening of the euro against the US dollar.

Research and development costs, net of tax credits and grants were \$5.7 million for the three-month period ended September 30, 2011, as compared to \$4.3 million for the same period in 2010. The comparative increase is attributable to a substantial comparative increase in third-party costs incurred in connection with the advancement of perifosine, AEZS-130 and Erk/PI3K compounds (AEZS-129, AEZS-131, AEZS-132)-related activities, as well as to the comparative strengthening of the euro against the US dollar.

Selling, general and administrative (SG&A) expenses were \$4.2 million for the three-month period ended September 30, 2011 as compared to \$2.6 million for the same period in 2010. The increase is most notably due to the recognition of an impairment loss, totalling \$1.1 million (non-cash), following impairment of the Company's Cetrotide® asset, as well as to the comparative strengthening of the euro against the US dollar.

Net finance income (costs) are comprised predominantly of net foreign exchange gains and losses, the change in fair value of the Company's warrant liability and the gain on the Company's short-term investment. For the three-month period ended September 30, 2011, net finance income totalled \$9.3 million, as compared to net finance costs of \$4.5 million for the same period in 2010. The significant increase in net finance income is due to the change in fair value of the Company's warrant liability. That change results from the periodic mark-to-market revaluation. Additionally, the Company's net finance income increased during that same period due to higher foreign exchange gains.

It can be noted that the gains resulting from the periodic mark-to-market valuation of the Company's share purchase warrants did not result in any cash receipt during the three-month period ended September 30, 2011.

Net income for the three-month period ended September 30, 2011 was \$1.1 million, or \$0.01 per basic and diluted share, as compared to net loss of \$9.9 million, or \$0.12 per basic and diluted share, for the same period in 2010. This significant increase in net income is due largely to higher net finance income, as mentioned above, partly offset by higher net R&D costs and higher selling expenses following the impairment loss related to Cetrotide®, as discussed above.

CONFERENCE CALL

Management will be hosting a conference call for the investment community beginning at 10:00 a.m. (Eastern Time) today, Thursday, November 10, 2011, to discuss the 2011 third quarter results. Individuals interested in participating in the live conference call by telephone may dial, in Canada, 514-807-8791 or 416-644-3424, outside Canada, 800-594-3790. 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, multiple myeloma, endometrial, ovarian, prostate and bladder cancer. 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 risk that safety and efficacy data from any of our Phase 3 trials may not coincide with the data analyses from previously reported Phase 1 and/or Phase 2 clinical trials, 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 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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Interim Consolidated Statements of Comprehensive Loss Information

(in thousands, except share and per share data)	Three months ended September 30,		Nine months ended September 30,	
	2011 \$	2010 \$	2011 \$	2010 \$
Revenues				
Sales and royalties	8,783	5,463	21,989	16,344
License fees and other	731	263	1,437	1,388
	9,514	5,726	23,426	17,732
Operating expenses				
Cost of sales	7,926	4,292	19,446	13,324
Research and development costs, net of tax credits and grants	5,663	4,340	16,724	15,859
Selling, general and administrative expenses	4,169	2,550	10,762	9,352
	17,758	11,182	46,932	38,535
Loss from operations	(8,244)	(5,456)	(23,506)	(20,803)
Finance income	9,324	22	4,805	767
Finance costs	(2)	(4,486)	(6)	(1,805)
Net finance income (costs)	9,322	(4,464)	4,799	(1,038)
Income (loss) before income taxes	1,078	(9,920)	(18,707)	(21,841)
Income tax expense			(841)	
Net income (loss)	1,078	(9,920)	(19,548)	(21,841)
Other comprehensive income (loss):				
Foreign currency translation adjustments	907	(648)	(958)	667
Comprehensive income (loss)	1,985	(10,568)	(20,506)	(21,174)
Net income (loss) per share				
Basic and diluted	0.01	(0.12)	(0.21)	(0.30)
Weighted average number of shares outstanding				
Basic	97,288,674	83,139,620	91,608,826	73,122,927
Diluted	100,863,997	83,139,620	91,608,826	73,122,927

Interim Consolidated Statement of Financial Position Information

<i>(in thousands)</i>	As at September 30, 2011 \$	As at December 31, 2010 \$
Cash and cash equivalents	48,114	31,998
Short-term investment		1,934
Trade and other receivables and other current assets	10,434	9,877
Restricted cash	828	827
Property, plant and equipment, net	3,084	3,096
Other non-current assets	12,304	13,716
Total assets	74,764	61,448
Payables and other current liabilities	15,416	13,350
Long-term payable (current and non-current portions)	86	150
Warrant liability (current and non-current portions)	9,474	14,367
Non-financial non-current liabilities*	53,855	51,156
Total liabilities	78,831	79,023
Shareholders' deficiency	(4,067)	(17,575)
Total liabilities and shareholders' deficiency	74,764	61,448

* Comprised mainly of deferred revenues, employee future benefits and provision.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has dully caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AETERNA ZENTARIS INC.

Date: November 10, 2011

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