

Aeterna Zentaris Inc.
Form 6-K
August 11, 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 August 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 ☒ Form 40-F ☐

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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 August 10, 2011: Aeterna Zentaris Reports Second Quarter 2011 Financial and Operating Results

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Press Release

For immediate release

Aeterna Zentaris Reports Second Quarter 2011 Financial and Operating Results

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

Quebec City, Canada, August 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 June 30, 2011.

Second Quarter 2011 Highlights

Perifosine

- April 4, 2011: The Company announced that two posters on perifosine were presented at the 102nd annual meeting of the American Association for Cancer Research (AACR) held in Orlando, Florida. The first poster illustrated perifosine's antitumor activity in a variety of gastric cell lines, and also enhanced the antitumor activity of 5-FU in parts of the cell lines - including 5-FU resistant cell lines. The second poster demonstrated that perifosine markedly enhanced the antitumor activity of the cellular TRAIL-based treatment and was able to overcome TRAIL resistance both *in vitro* and *in vivo*.

- Subsequent to quarter-end, on July 26, 2011, the Company announced the completion of patient recruitment for the ongoing Phase 3 trial with perifosine in refractory advanced colorectal cancer. The trial, involving over 430 patients, is being conducted pursuant to a Special Protocol Assessment (SPA) with the Food and Drug Administration (FDA) and with Fast Track designation.

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- Subsequent to quarter-end, on July 12, 2011, the European Patent Office granted a patent for the use of alkyl phosphocholines, and, more specifically for perifosine, in the preparation of a medicament for the treatment of benign and malignant tumors, prior to and/or during the treatment with approved antitumor antimetabolites including 5-FU (fluorouracil) and capecitabine. This patent will expire on July 28, 2023.

AEZS-108

- Parallel Scientific Advice process granted by and initiated with the FDA and EMA, with the aim to have the pivotal program in endometrial cancer defined by year-end.
 - Progression of ongoing Phase 1/2 studies in castration refractory prostate cancer and in refractory bladder cancer.
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AEZS-130

- Subsequent to quarter-end, on July 27, 2011, the Company announced the completion of the Phase 3 trial with AEZS-130 as an oral diagnostic test for Adult Growth Hormone Deficiency (AGHD). The preliminary Phase 3 results were encouraging and the Company expects to file a New Drug Application (NDA).

AEZS-120

- Subsequent to quarter-end, on July 20, 2011, the Company announced that it had reached a key milestone in the non-clinical development of its live recombinant prostate cancer vaccine candidate, AEZS-120, for oral administration. The program, partially funded through a grant from the German government, encompassed the full development of a GMP process, including GMP production and quality testing of a clinical batch, as well as a non-clinical safety and toxicology package, as previously agreed with regulatory authorities. Subject to a positive review by German regulatory authorities, the Company aims to start Phase 1 clinical development in 2012.

AEZS-131

- April 5, 2011: The Company announced that a poster on AEZS-131 was presented at the 102nd annual meeting of the AACR. The poster showed AEZS-131 to be a highly selective Erk 1/2 inhibitor oral anticancer compound with *in vivo* antitumor potency. In *in vivo* mouse xenograft experiments utilizing the HCT-116 colon cancer model, AEZS-131 significantly inhibited tumor growth and was well tolerated at daily doses up to 120 mg/kg.

Corporate Developments

- During the quarter, the Company completed the drawdowns remaining under the At-the-Market (ATM) Sales Agreement entered into in February 2011. During the quarter, the Company raised a total of \$14.7 million in gross proceeds, bringing the total aggregate gross proceeds raised under this ATM Sales Agreement, on a year-to-date basis, to \$19.7 million.
- June 29, 2011: The Company entered into an additional ATM Sales Agreement under which, during the 24-month term of the agreement, the Company could sell up to a maximum of 9.5 million of its common shares through ATM issuances on the NASDAQ Stock Market for aggregate gross proceeds not to exceed \$24.0 million. Subsequent to quarter-end and pursuant to this ATM agreement, the Company issued a total of approximately 1.9 million common shares for aggregate gross proceeds of \$4.3 million, less cash and non-cash transaction costs totalling \$0.3 million.

Cash, cash equivalents and short-term investment totalled \$49.6 million as at June 30, 2011. With the aforementioned ATM drawdowns that were completed subsequent to quarter-end, the Company's pro forma cash, cash equivalents and short-term investment at June 30, 2011 would

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total \$53.8 million.

Juergen Engel, Ph.D., Aeterna Zentaris President and Chief Executive Officer, commented, "This quarter was marked by key drug development milestones. The patient recruitment of over 430 patients was completed for the ongoing Phase 3 trial in advanced refractory colorectal cancer with perifosine. Furthermore, we were granted a European use patent for perifosine, which will expire in July 2023. We also successfully completed our Phase 3 trial with AEZS-130 as an oral diagnostic test for Adult Growth Hormone Deficiency, and we are undertaking the necessary steps leading to a New Drug Application filing in the United States. In addition, we reached a key non-clinical milestone in the

development of our live oral recombinant prostate cancer vaccine candidate, AEZS-120, and are now planning to start its clinical development.

Dennis Turpin, CA, Senior Vice President, Chief Financial Officer of Aeterna Zentaris stated, "We now benefit from over \$49.6 million in cash, cash equivalents and short-term investment and have gained additional flexibility to advance our key projects through our most recent At-the-Market Sales agreement."

CONSOLIDATED RESULTS AS AT AND FOR THE SECOND QUARTER ENDED JUNE 30, 2011

Revenues were \$6.5 million for the three-month period ended June 30, 2011, as compared to \$5.6 million for the same period in 2010. This increase is largely related to comparative higher-than-normal deliveries of Cetrotide® to certain customers, as well as to the comparative strengthening of the euro against the US dollar.

Research and development costs, net of tax credits and grants were \$5.6 million for the three-month period ended June 30, 2011, as compared to \$5.4 million for the same period in 2010.

Selling, general and administrative expenses were \$3.4 million for the three-month period ended June 30, 2011 as compared to \$3.7 million for the same period in 2010.

Net finance (costs) income are comprised predominantly of net foreign exchange gains and losses, the change in fair value of the Company's warrant liability and the unrealized gain on the Company's short-term investment (2011 only). For the three-month period ended June 30, 2011, net finance costs totalled \$2.6 million, as compared to a net finance income of \$1.8 million for the same period in 2010. This significant increase in net finance costs is due to the change in fair value of the Company's warrant liability. That change results from the periodic mark-to-market revaluation of currently outstanding share purchase warrants. Additionally, the increase is due to higher foreign exchange losses, which in turn resulted primarily from the comparative weakening of the US dollar against the euro during the second quarter of 2011, partially offset by the unrealized gains on the Company's short-term investment, which is carried at fair value. Neither the loss resulting from the periodic mark-to-market valuation of the warrants nor the gain resulting from the fair value adjustments to the short-term investment has resulted in any cash disbursement or cash receipt during the three-month period ended June 30, 2011.

Net loss for the three-month period ended June 30, 2011 was \$10.6 million, or \$0.12 per basic and diluted share, as compared to \$6.2 million, or \$0.08 per basic and diluted share, for the same period in 2010. This increase is mainly related to higher net finance costs related to the periodic mark-to-market valuation of the warrants (non-cash) and higher foreign exchange losses, partly compensated by the unrealized gains on the Company's short-term investment (non-cash).

CONFERENCE CALL

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Management will be hosting a conference call for the investment community beginning at 3:30 p.m. (Eastern Time) today, Wednesday, August 10, 2011, to discuss the 2011 second quarter results. Individuals interested in participating in the live conference call by telephone may dial, in Canada, 514-807-8791 or 416-644-3425, 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 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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Attachment: Financial summary

Interim Consolidated Statements of Comprehensive Loss Information

(In thousands, except for share and per share data)	Three months ended		Six months ended	
	June 30,		June 30,	
	2011	2010	2011	2010
	\$	\$	\$	\$
Revenues				
Sales and royalties	6,114	5,165	13,206	10,881
License fees and other	409	419	706	1,125
	6,523	5,584	13,912	12,006
Operating expenses				
Cost of sales	5,497	4,415	11,520	9,032
Research and development costs, net of tax credits and grants	5,563	5,374	11,061	11,519
Selling, general and administrative expenses	3,434	3,745	6,593	6,802
	14,494	13,534	29,174	27,353
Loss from operations	(7,971)	(7,950)	(15,262)	(15,347)
Finance income	265	2,332	1,089	3,874
Finance costs	(2,863)	(558)	(5,612)	(448)
Net finance (costs) income	(2,598)	1,774	(4,523)	3,426
Loss before income taxes	(10,569)	(6,176)	(19,785)	(11,921)
Income tax expense			(841)	
Net loss	(10,569)	(6,176)	(20,626)	(11,921)
Other comprehensive (loss) income:				
Foreign currency translation adjustments	(526)	573	(1,865)	1,315
Comprehensive loss	(11,095)	(5,603)	(22,491)	(10,606)
Net loss per share				
Basic and diluted	(0.12)	(0.08)	(0.23)	(0.17)
Weighted average number of shares outstanding				
Basic and diluted	90,690,019	72,918,880	88,721,832	68,031,569

Interim Consolidated Statements of Financial Position Information

(in thousands)	As at June 30, 2011 \$	As at December 31, 2010 \$
Cash and cash equivalents	46,612	31,998
Short-term investment	3,029	1,934
Trade and other receivables and other current assets	10,398	9,877
Restricted cash	900	827
Property, plant and equipment, net	3,558	3,096
Other non-current assets	14,731	13,716
Total assets	79,228	61,448
Payables and other current liabilities	18,233	13,350
Long-term payable (current and non-current portions)	124	150
Warrant liability (current and non-current portions)	15,652	14,367
Non-financial non-current liabilities*	60,511	51,156
Total liabilities	94,520	79,023
Shareholders' deficiency	(15,292)	(17,575)
Total liabilities and shareholders' deficiency	79,228	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 duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ÆTERNA ZENTARIS INC.

Date: August 11, 2011

By:

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