Aeterna Zentaris Inc.
Form 6-K
December 08, 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 December 2009

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 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. Æterna Zentaris Partner, Keryx, Reports Updated Phase 1/2 Data, Including New Survival Data, on Perifosine (KRX-0401) in the Treatment of Advanced Multiple Myeloma at the 51st Annual Meeting of the American Society of Hematology

Æterna 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

Æterna Zentaris Partner, Keryx, Reports Updated Phase 1/2 Data, Including New Survival Data, on Perifosine (KRX-0401) in the Treatment of Advanced Multiple Myeloma at the 51st Annual Meeting of the American Society of Hematology

Response Rate Increases to 41% and Median Overall Survival Reported at 25 Months for All Evaluable Patients

Quebec City, Canada, December 7, 2009 Æterna Zentaris Inc. (NASDAQ: AEZS; TSX: AEZ) (the Company), a global biopharmaceutical company focused on endocrine therapy and oncology, today announced that its partner Keryx Biopharmaceuticals Inc. (Keryx) (Nasdaq: KERX) reported updated efficacy and safety data as well as new survival data on the clinical activity of perifosine (KRX-0401) in combination with bortezomib (Velcade®) (+/- dexamethasone) in patients with relapsed/refractory multiple myeloma. Data from the study entitled *A Multicenter Phase 1/2 Study Evaluating the Safety and Efficacy of Perifosine (KRX-0401) + Bortezomib (Velcade(R)) in Patients with Relapsed or Relapsed / Refractory Multiple Myeloma Who Were Previously Treated with Bortezomib*, was presented on Saturday, December 5th at the 51st annual meeting of the American Society of Hematology, in a poster presentation by Dr. Paul Richardson, Clinical Director of the Jerome Lipper Multiple Myeloma Center, Dana-Farber Cancer Institute. Keryx is Æterna Zentaris partner and licensee for perifosine in the United States, Canada and Mexico. Perifosine is also out-licensed to Handok in South Korea while Æterna Zentaris retains rights for the rest of the world.

Trial Results

Eighty-four patients with relapsed/refractory multiple myeloma were enrolled in a combined Phase 1/2 study (18 patients in the Phase 1 component and 66 patients in the Phase 2 component). The patients enrolled were heavily pre-treated with a median of 5 prior lines of therapy (range 1 - 13), including:

- 100% of patients had been treated with bortezomib (55% of the patients were previously treated with at least two bortezomib-based therapies (range 1 4) and 81% were previously treated with bortezomib plus dexamethasone);
- 98% of patients were previously treated with dexamethasone;
- 94% of patients were previously treated with lenalidomide (Revlimid®) and/or thalidomide (Thalomid®); and

- 58% of patients had prior stem cell transplant.

Overall Response Rate (ORR), defined as the percentage of patients achieving a complete, partial or minor response (CR, PR or MR), was the primary endpoint, with Time to Progression (TTP), Progression-Free Survival (PFS), Overall Survival (OS) and Safety as secondary endpoints.

Seventy-three patients were evaluable for efficacy. Evaluable patients are defined as those patients who had received at least two cycles of therapy on the combination of perifosine with bortezomib. Of the 73 evaluable patients, 53 patients (73%) were previously refractory to bortezomib (defined as progression on or within 60 days of treatment to a bortezomib-based regimen), including 44 patients who were refractory to the combination of bortezomib + dexamethasone. Twenty evaluable patients (27%) were relapsed to a prior bortezomib-based regimen. Best response for all 73 evaluable patients was as follows:

Evaluable Patients	**CR /nCR***		**PR**		**MR**		**ORR**		**SD****	
All Evaluable Patients (n=73)	3	4%	13	18%	14	19%	30	41%	30	41%
Bortezomib Relapsed (n=20)	2	10%	7	35%	4	20%	13	65%	7	35%
Bortezomib Refractory (n=53)	1	2%	6	11%	10	19%	17	32%	23	43%

* nCR = Near Complete Response is defined as meeting the criteria for CR (non-detectable monoclonal protein by serum and urine), except with detectable monoclonal protein by immunofixation.

** SD = Stable Disease for a minimum of 3 months.

Approximately 60% (45 / 73) of patients demonstrated progression (or SD for 4 cycles) at some point in their treatment and received 20 mg dexamethasone, four times per week, in addition to perifosine plus bortezomib. Responses occurred both with patients taking perifosine in combination with bortezomib and with patients receiving the combination plus dexamethasone. Best response for each group was as follows:

Best Response	**CR /nCR**		**PR**		**MR**		**ORR**		**SD**	
Perifosine + Bortezomib (n=73)	2	3%	10	14%	6	8%	18	25%	19	26%
Dexamethasone added (n=45)	1	2%	6	13%	10	23%	17	38%	14	31%

Five patients achieved an initial response on perifosine + bortezomib alone, and subsequently responded again with the addition of dexamethasone. Three additional patients achieved stable disease on perifosine + bortezomib alone, and subsequently achieved stable disease again with the addition of dexamethasone.

Reported for the first time was median Progression-Free Survival (PFS) and Overall Survival (OS) data for all evaluable patients, as follows:

Evaluable Patients	**Median PFS***	**Median OS****

All Evaluable Patients (n=73)	6.4 months 95% CI (5.3, 7.1)	25 months 95% CI (15.5, NR)

NR = Not Reached

* Median PFS and median TTP were identical, as no patient deaths occurred prior to progression.

** Kaplan Meier methodology was used to determine overall survival figures.

Of particular interest was the comparison of evaluable patients who were previously refractory and the patients who were relapsed to a bortezomib-based regimen.

Median PFS and OS for bortezomib relapsed vs. refractory were as follows:

Bortezomib Relapsed vs. Refractory	**Median PFS***	**Median OS****
Bortezomib Relapsed (n=20)	8.8 months 95% CI (6.3, 11.2)	Not Reached at 38+ months 95% CI (25, NR)
Bortezomib Refractory (n=53)	5.7 months 95% CI (4.3, 6.4)	22.5 months 95% CI (12.3, NR)

* Median PFS and median TTP were identical, as no patient deaths occurred prior to progression.

** Kaplan Meier methodology was used to determine overall survival figures.

No unexpected adverse events have been observed. Toxicities were manageable with supportive care.

We congratulate our partner Keryx and their principle investigators Dr. Richardson and Dr. Anderson for the encouraging results for perifosine in multiple myeloma which further demonstrate perifosine s potential as a novel treatment for this indication. We now look forward to the initiation of the Phase 3 study in this same indication, this month , stated Juergen Engel, Ph.D., President and CEO at Æterna Zentaris.

Keryx has been granted a Special Protocol Assessment (SPA) from the FDA for the upcoming Phase 3 study of perifosine in multiple myeloma. Additionally, the FDA has granted perifosine Orphan Drug and Fast Track designations in this indication.

About Perifosine (KRX-0401)

Perifosine is a novel oral anticancer agent that modulates several key signal transduction pathways, including Akt, MAPK, and JNK that have been shown to be critical for the survival of cancer cells. Perifosine has demonstrated both safety and clinical efficacy in several tumor types, both as a single agent and in combination with novel therapies. Perifosine is currently in Phase 2 clinical development for multiple tumor types, with a Phase 3 in multiple myeloma, under Special Protocol Assessment (SPA), pending commencement by year-end. Perifosine has also received Orphan Drug designation from the U.S. Food and Drug Administration (FDA) for the treatment of multiple myeloma.

About Multiple Myeloma

Multiple myeloma, a cancer of the plasma cell, is an incurable but treatable disease. Multiple myeloma is the second most-common hematologic cancer, representing 1% of all cancer diagnoses and 2% of all cancer deaths. According to the American Cancer Society, in 2009 there will be an estimated 20,580 new cases of multiple myeloma and an estimated 10,500 deaths from multiple myeloma in the United States. To date, several FDA approved therapies exist for the treatment of multiple myeloma. Despite this progress, patients continue to relapse, become refractory to prior treatments and eventually die from their disease. Thus, new therapies are needed to treat these patients and extend their survival.

About Æterna Zentaris Inc.

Æterna 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. 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

Dennis Turpin, SVP and CFO

(418) 652-8525 ext. 242

dturpin@aezsinc.com

Media Relations

Paul Burroughs

Director of Communications

(418) 652-8525 ext. 406

pburroughs@aezsinc.com

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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: December 8, 2009

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