Aeterna Zentaris Inc.
Form 6-K
March 29, 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. Message to Shareholders

MESSAGE TO SHAREHOLDERS

Dear Shareholders,

2010 was an exciting and successful year for the Company as we delivered on our drug development and business goals. Our registration Phase 3 programs in colorectal cancer and multiple myeloma with our lead anticancer compound, perifosine, continued their progress, while a new strategic partnership was recently established for Japan to maximize the worldwide potential of this future commercial opportunity. We also reported very encouraging Phase 2 results for AEZS-108 as well as for earlier-stage compounds, further demonstrating the breadth of our innovative product pipeline.

DRUG DEVELOPMENT

Perifosine

Perifosine, the most advanced oral Akt/PI3K inhibitor in clinical development, could become a novel oral combination treatment of great benefit to patients suffering from colorectal cancer and multiple myeloma, a form of bone marrow cancer. These indications also represent large market opportunities. Colorectal cancer is the fourth most common cancer in men and the third most common in women. Multiple myeloma is the second most prevalent blood cancer. Global markets for colorectal cancer and multiple myeloma are expected to be $6.7 billion and $5.8 billion in 2019, respectively.

In April 2010, a registration Phase 3 X-PECT trial in refractory advanced colorectal cancer comparing the efficacy and safety of perifosine + Xeloda® vs placebo + Xeloda® was initiated. It will involve 430 patients in 60 sites with the primary endpoint being overall survival. A few months earlier, a registration Phase 3 trial had been initiated, comparing the efficacy and safety of perifosine vs placebo when combined with Velcade® and dexamethasone for relapsed/refractory multiple myeloma. The trial will involve some 400 patients in over 100 sites with progression-free survival as the main endpoint. Both trials are being conducted under a Special protocol Assessment (SPA) and Fast Track designation from the FDA, which should accelerate the review process. Furthermore, perifosine has been granted orphan-drug designation by the FDA and orphan medicinal product designation by the European Medicines Agency (EMA) for multiple myeloma, therefore also providing it with extra market exclusivity protection. Both trials are being conducted and sponsored by our North American partner and licensee, Keryx Biopharmaceuticals Inc., (Keryx) who expect to complete the colorectal cancer trial by the end of this year, and the multiple myeloma trial in the second half of 2012.

During the course of the year, we received a positive Scientific Advice from the EMA indicating that the data from both of these trials are expected to be sufficient for product registration in Europe, without conducting additional trials. As a result of the EMA s advice, the Asian market became the priority in our worldwide partnering strategy for perifosine, since additional clinical trials will be required in Asia. This led to the signing, a few weeks ago, of a partnership agreement for the Japanese market with Yakult Honsha Co. Ltd. (Yakult) who have a proven track record in oncology, as shown in particular by the sales for their two marketed products in colon cancer, irinotecan and oxaliplatin, which reached

$420 million in 2010. The agreement provided us with an initial $8.3 million upfront payment and up to $60.9 million in additional payments upon achieving certain pre-established milestones, including clinical and regulatory events, as well as double-digit royalties on future net sales of perifosine in Japan. We also agreed to supply perifosine on a cost-plus-basis to Yakult. In 2019, the colorectal market in Japan is expected to be $1.3 billion and the multiple myeloma market is expected to be about $540 million.

As for our strategy in Europe, we are currently examining different options, including the possibility of marketing perifosine ourselves through wholesale distributors or a traditional out-licensing, retaining certain co-promotion/co-marketing rights for selected countries.

AEZS-108

AEZS-108, our second lead anticancer compound, represents a new targeting concept in oncology providing a personalized medicine approach, using a targeted cytotoxic peptide conjugate. AEZS-108 is a hybrid molecule composed of a synthetic peptide carrier, which is a LHRH agonist linked to the widely used and well known cytotoxic agent, doxorubicin. LHRH receptors are present in many cancers affecting organs such as the ovaries, endometrium, bladder and prostate, indications that we are currently exploring with AEZS-108.

During the year, we successfully completed our Phase 2 program in advanced ovarian and endometrial cancer with AEZS-108. Very encouraging final data from both of these trials presented at two major oncology conferences, prompted us to initiate a first pivotal trial in endometrial cancer by the end of this year. Furthermore, the FDA granted orphan-drug designation, and the EMA, orphan medicinal product designation to AEZS-108 for ovarian cancer, providing our compound with extra market exclusivity protection in the U.S. and Europe. These two indications represent good market opportunities; for example, in 2019, the seven major markets for ovarian cancer are expected to be around $1.5 billion.

Finally, in the fourth quarter of 2010, we initiated Phase 1/2 trials in castration refractory prostate cancer and refractory bladder cancer, further proof that, as stated earlier, we believe this compound has potential for the treatment of different types of cancer.

AEZS-130 / SOLOREL®

In December 2010, we reached an agreement on a SPA with the FDA enabling us to complete the ongoing Phase 3 trial with Solorel® required to gain approval as the first available oral diagnostic test for Adult Growth Hormone Deficiency (AGHD). Earlier in 2010, preliminary interim Phase 3 results showed that Solorel®, our oral ghrelin agonist for which we hold worldwide rights, demonstrated better sensitivity and specificity in identifying patients who should receive therapy for AGHD, as compared to the then available standard intravenous test of GHRH followed by arginine. We expect to complete this Phase 3 trial and file a New Drug Application over the course of the year. The FDA has also granted orphan-drug designation to Solorel® for AGHD, providing it with extra market exclusivity protection in the U.S.

FINANCE

Our cash, cash equivalents and short-term investment as of December 31, 2010, stand at $33.9 million. Adding the recent $8.3 million up-front payment from Yakult for perifosine in Japan and with the continuous sponsorship of the ongoing Phase 3 trials in colorectal and multiple myeloma by Keryx, we are in a solid financial position from which we can continue to execute our business plan.

MOVING FORWARD

We look forward with great anticipation to the next 12 to 18 months which could prove to be an exciting turning point for our Company. Overall, our focus will be on completing the development of our late-stage compounds in collaboration with our different partners, in order to bring them closer to market in a timely matter, for the benefit of patients and shareholders. We believe that state-of-the-art, novel anticancer compounds such as perifosine, as well as innovative targeted therapies such as AEZS-108 and other earlier-stage compounds, could allow us to become a key player in oncology for years to come.

In closing, we would like to thank all our employees and collaborators for their hard work and valuable contribution, as well as you, our shareholders, for your continued support.

Sincerely,

Juergen Ernst, Chairman of the Board

Juergen Engel, Ph.D., President and CEO

March 22, 2011

*All amounts are in U.S. dollars

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 29, 2011

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