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Æterna Zentaris Inc. Is Well Positioned With Their Perifosine In Phase III Studies For Multiple Myeloma And Metastatic Colorectal Cancer And Their AEZS-130 In Phase III Studies For Diagnosing Growth Hormone Deficiency As Well As Partners In Place To Support Development And Commercialization

**Healthcare
Biotechnology
(AEZS-NASDAQ, AEZ-TSX)**

Æterna Zentaris Inc.

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**Prof. Jüergen Engel, Ph.D.
President and CEO**

BIO:

Dr. Engel has been with Æterna Zentaris since the acquisition of Zentaris in December 2002 and was appointed President and CEO of our Company in September 2008. Before joining our Company, he was CEO of Zentaris (a spin-off of ASTA Medica, AG) based in Frankfurt, Germany, where he was actively involved in strategic partnerships and acquisitions. At ASTA Medica, AG, Dr. Engel was in charge of all R&D activities where he supervised more than 700 scientists and clinical professionals. He successfully headed projects from drug discovery right

through to New Drug Application (NDA).

Dr.Engel holds a doctorate degree in organic chemistry from the Technical University of Braunschweig and an academic degree in pharmaceutical science from the University of Regensburg where he is an adjunct full professor at its School of Pharmacy. He is also Honorary Professor at the Dresden Technical University. In 1995, he received the Galenus-von-Pergamon prize for having developed alkylphospholipids as a new class of anti-tumor agents. Dr. Engel is the author of more than 250 scientific articles, several books and he applied for more than 100 patent applications.

Company Profile:

Æterna Zentaris Inc. operates as a late-stage drug development company specialized in oncology and endocrinology. Its lead oncology compounds include perifosine, an orally active PI3K/Akt pathway inhibitor that is in Phase III registration trial for multiple myeloma and colorectal cancer; and AEZS-108, a doxorubicin-targeted conjugate in Phase II for the treatment of advanced ovarian and endometrial cancer. The company's lead endocrinology compound, AEZS-130, is an oral ghrelin antagonist in Phase III trial as a diagnostic test for Adult Growth Hormone Deficiency. Its pipeline also includes earlier-stage compounds, such as AEZS-112 that is in a Phase I trial in advanced solid tumors and lymphoma, as well as AEZS-120, an anti-cancer vaccine in pre-clinical development. The company was founded in 1991 and is headquartered in Quebec City, Canada.



Media Æterna Building

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com**

CEOCFO: Dr. Engel, what is the main focus and strategy of Æterna Zentaris?

Dr. Engel: The focus of our company is oncology and endocrinology and we have promising products in our pipeline in the final stage of development just before the commercialization. These new treatments, especially in oncology, could prove to be novel treatments with less side-effects and better efficacy for different types of cancer. The company has a very solid financial position, no debt, and enough cash available to pursue our business plan into 2012. Our long-term goal is to become a fully integrated pharmaceutical company; we already have one product on the market, Cetrotide®, for *in vitro* fertilization marketed and sold by our partners Merck Serono and Shionogi in more than ninety countries in the world. We provide them with the finished product.

CEOCFO: What is the science behind your products, and what is it that you are doing overall that is different?

Dr. Engel: The principle strategy behind this is to get selective treatments leading most probably to the personalized medicinal approach. In oncology, our main program is a Phase III trial in multiple myeloma (a form of bone marrow cancer) and colorectal cancer with perifosine. This program is conducted and sponsored by our North American partner, Keryx Biopharmaceuticals, under an SPA (Special Protocol Assessment) and a Fast-Track designation granted by the FDA, and also under a positive advice from the European Medicinal Agency. This means that these studies will benefit from an accelerated review process and that the data from these studies, if conclusive, will be sufficient to get an approval in Europe, without having to conduct additional clinical trials.

The second lead project in oncology is a Phase II program in endometrial and ovarian cancer with AEZS-108. This compound is part of what is called "targeted therapies" which aim at delivering the drug to specific cancerous cells. In this case, we are selecting receptors which are expressed and over-expressed on the cell surface of tumors, and then attack these receptors in order to deliver the anti-cancer agent directly to the core of these specific cancerous cells. This is what targeted therapy is about; trying to adapt the treatment according to specific characteristics of the cancer.

Our lead project in endocrinology is a Phase 3 trial with AEZS-130 as a diagnostic test for growth hormone deficiency in adults. We expect to complete the trial by the end of this year and if results are conclusive, we would file for a commercial license in the first half of 2011. AEZS 130 is the only oral test available and has the potential to become the only approved test.

AEZS-130 could also have applications as a therapeutic agent. This compound is a mimetic of ghrelin, a hormone which stimulates appetite. Therefore, this unique compound could be used to stimulate appetite in people suffering from cachexia, a disease frequently induced by

cancer, which produces loss of body mass. By stimulating their appetite, these patients could regain weight and muscle mass.

CEO CFO: What is the competitive landscape to treat the areas you are looking to treat, and what is different about your approach?

Dr. Engel: Perifosine is a first-in-class compound in late-stage clinical development. Its specific mechanism of action could provide a novel treatment with reduced side-effects. Phase 2 study results in multiple myeloma and colorectal cancer with perifosine have already demonstrated that there is a benefit for refractory patients who have already received a variety of prior treatments. Perifosine has also shown impressive data related to prolonging overall survival and progression-free survival. As for AEZS-108, there is no competitor at present in the diagnostic use.

We have promising products in our pipeline in the final stage of development just before the commercialization. These new treatments, especially in oncology, could prove to be novel treatments with less side-effects and better efficacy for different types of cancer.

- Prof. Jürgen Engel, Ph.D.

Current diagnostic products in development require an intravenous injection, short-term hospitalization and cause certain side-effects. On the other hand, AEZS-108 is administered orally, requires no hospitalization and has few side-effects.

CEO CFO: What is the timetable in the next year or two for your products?

Dr. Engel: Our partner, Keryx, who are conducting the Phase 3 trials with perifosine in multiple myeloma and colorectal cancer, have stated that they expect to complete the program in the second half of 2011. With the Fast-Track designation granted by the FDA for this program, there is the possibility of getting a priority review, meaning that we may end up, if results are conclusive, with a launch in the second half of 2012.

As for AEZS-130 as diagnostic test we expect to submit an approval in 2011 with the aim to get to market in 2012.

Finally, for AEZS-108, we expect to disclose Phase 2 results in endometrial cancer by year-end.

CEO CFO: Would you tell us about other projects in the pipeline?

Dr. Engel: In oncology, we have a small molecule called AEZS-112, which is interesting because it is targeting three different mechanisms of action in oncology. This is in Phase I trial and so far, it has shown to be very well tolerated. We are aiming to continue its clinical development in the next year.

We also have two interesting projects at the preclinical stage that I would like to point out. One is a tumor vaccine administered orally, which is a new technology platform with specific activity on PSA; therefore it could be used in refractory prostate cancer. We are aiming to initiate a Phase I study next year.

The second is with compounds which target two important signaling pathways involved in cancer: Erk and PI3K. These compounds are aimed at selectively inhibiting Erk and PI3K

and could have applications in different types of cancer. We are currently doing in vitro pharmacology research on these compounds with the aim to move one or two of these projects at the clinical stage (studies on humans) in the future.

CEO CFO: How are you going to move forward with commercialization?

Dr. Engel: At present, the main priority is to complete the Phase III program with perifosine and do all the necessary work to establish the production process. We have one partner already for North America, Keryx, which are doing a lot of work in this area and assuming the related costs. We are interested in finding marketing partners for this project in Europe and other markets, while retaining certain copromotion rights. With AEZS-108, we have already been approached by companies interested in licensing, but this is not our first priority. For AEZS-

130 as a diagnostic test for growth hormone deficiency, we want to complete its development and possibly market it ourselves in the U.S. It could be commercially interesting because it would be the first oral diagnostic test approved which would be a tremendous advantage.

CEO CFO: Would you tell us about the expertise of your management team?

Dr. Engel: We have people with a lot of experience at all levels of the pharmaceutical industry, from drug development up to marketed products. The Zentaris entity of Aeterna Zentaris was formerly a spin-off of Asta Medica, which developed the first anti-cancer drugs ever marketed successfully. Our chairman is the former CEO of Solvay, who had a lot of experi-

ence in business development as well as mergers and acquisitions. Also on our Board is Pierre Lapalme with vast experience in marketing pharmaceuticals. As you can see, we have a solid team with deep knowledge at all levels of the business.

CEO CFO: Why should potential investors pick Aeterna Zentaris out of the crowd?

Dr. Engel: First of all, we have a solid financial position. At the end of the 2nd Quarter 2010, we had more than \$ 45 million in cash with no debt. Our Phase 3 program with perifosine is sponsored by, our partner Keryx, which reduces our overall R&D costs. Our current and future partnerships could provide us with a

steady stream of upfront and milestone payments, as well as royalties on future sales of perifosine. AEZS-108 is yet unpartnered, so this could also be a subject of additional out-licensing activities, while retaining at least some co-marketing, co-promotion rights in order to achieve our goal of becoming a fully integrated company.

CEO CFO: It sounds like you are in a good position; what should people remember most about Aeterna Zentaris?

Dr. Engel: We have an experienced and dedicated team, a deep pipeline of innovative compounds in large market opportunities and a solid financial position. Indeed, we are in a good position.

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