



Quarterly Update: July 27, 2015

Company Description

Aeterna Zentaris Inc. (“Aeterna” or “the Company”) is transitioning into a specialty biopharmaceutical company. With a focus on establishing revenues and profitability while optimizing resources to reduce its burn rate, the Company co-promotes a non-patch estrogen replacement therapy, EstroGel®, in specific U.S. markets with partner, Ascend Therapeutics (“Ascend”), and has recently entered into an agreement to promote EMD Serono’s Saizen® for growth hormone deficiencies in the U.S. as well. Aeterna further holds a pipeline of candidates in varying stages of development and is working to acquire, in-license, or co-promote other commercial compounds. The Company’s most advanced wholly owned clinical candidate, zoptarelin doxorubicin (doxorubicin peptide conjugate targeting LHRH receptor-expressing tumors), is in a fully enrolled Phase 3 trial in advanced, recurrent, or metastatic endometrial cancer—a disease for which patients typically have a poor prognosis and there is no approved systemic therapy. Aeterna’s pipeline also includes Macrilen, which is in preparation for a Phase 3 confirmatory trial for the evaluation of Adult Growth Hormone Deficiency (AGHD), as well as other compounds in oncology, as the Company works to pursue strategic initiatives consistent with becoming a commercially operating specialty biopharmaceutical company.

Key Points

- Entering into an agreement with biopharmaceutical company, EMD Serono, Inc., marks the second promotional services agreement for Aeterna in recent months, as the Company accelerates its transition into a commercially operating specialty biopharma by leveraging its contractual sales force. The Company’s first co-promotion agreement was with Ascend for the sale of EstroGel® in 19 U.S. territories not already covered by Ascend.
- In the second quarter 2015, Aeterna reached two milestones in its Phase 3 clinical trial of zoptarelin doxorubicin in endometrial cancer (the ZoptEC study). The first interim futility analysis was completed favorably with the trial recommended to continue per an independent data safety monitoring board, and Aeterna completed its enrollment of all 500 participants into the trial. The study is on track for completion in 2016.
- Aeterna has established the infrastructure to grow through successful licensing, acquisition, and co-promotional opportunities of commercial compounds as it leverages its current sales force and brings in products that fit synergistically within its overall strategy.
- The Company’s leadership has experience and established ability in building significant value in the pharmaceutical industry. After raising approximately \$34.5 million in early 2015, Aeterna reported that it held cash and cash equivalents of \$53.3 million as of March 31, 2015.

Aeterna Zentaris

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Ticker (Exchange)	AEZS (NASDAQ) AEZ (TSX)
Recent Price (07/24/15)	\$0.20 (NASDAQ)
52-week Range	\$0.19 - \$1.54
Shares Outstanding	~140 million
Market Capitalization	~\$28 million
Average 3-mo. Volume	~4.09 million
Insider Ownership + >5%	0.69%
EPS (Qtr. ended 3/31/15)	(\$0.13)
Employees	51



Recent Events and Financial Results

Recent Events

- *On April 27, 2015*, Aeterna announced that the independent Data Safety Monitoring Board for the pivotal Phase 3 ZoptEC (Zoptarelin Doxorubicin in Endometrial Cancer) study with zoptarelin doxorubicin in women with advanced, recurrent, or metastatic endometrial cancer, completed a pre-specified first interim futility analysis. The Board recommended that the Phase 3 study continue as planned. This study is further detailed on pages 5-6.
- *On May 8, 2015*, the Company and EMD Serono, Inc., the U.S. and Canadian biopharmaceutical businesses of Merck KGaA, announced the finalization of a promotional services agreement that allows Aeterna to promote Saizen® [somatropin (rDNA origin) for injection] to designated medical professionals in specified territories in the United States. Saizen® is a recombinant human Growth Hormone (r-hGH) registered in the U.S. for the treatment of growth hormone deficiency (GHD) in children and adults. Greater details on this arrangement are provided on page 5.
- *On May 11, 2015*, Aeterna announced the results of the vote on directors held at its 2015 Shareholders' meeting on May 8, 2015. Each of the director nominees proposed by management for election was elected as director, without a vote by ballot being conducted. The Company received proxies with regard to voting on the six directors nominated for election: Marcel Aubut, David A. Dodd, Carolyn Egbert, Juergen Ernst, Pierre Lapalme, and Gérard Limoges. All other matters at the shareholders' meeting were also approved by shareholders.
- *On May 26, 2015*, the Company reported that it received written scientific advice from the European Medicines Agency (EMA) regarding the further development plan, including the study design, for the new confirmatory Phase 3 clinical study of Macrilen (macimorelin) for use in evaluating adult growth hormone deficiency (AGHD), following a Scientific Advice Meeting held earlier in May 2015. As a result of the advice, the Company believes that the confirmatory Phase 3 study that was reviewed with the U.S. Food & Drug Administration (FDA) last March meets the EMA's study-design expectations. Macrilen is detailed on page 7.
- *On June 18, 2015*, Aeterna announced that it received notice from the NASDAQ Listing Qualifications Department determining that the Company was eligible for an additional 180-calendar day period, until December 14, 2015, to regain compliance with the minimum \$1.00 per share required for continued listing under Listing Rule 5550(a)(2). The Company's shares continue to trade on the NASDAQ Capital Market under the symbol AEZS.
- *On June 25, 2015*, the Company executed a definitive agreement with Ergomed PLC, pursuant to which Ergomed is to manage the new, confirmatory Phase 3 clinical study to demonstrate the efficacy of Macrilen (macimorelin).
- *On June 30, 2015*, Aeterna announced it has reached its goal of recruiting 500 patients for its pivotal Phase 3 ZoptEC clinical study with zoptarelin doxorubicin in women with advanced, recurrent, or metastatic endometrial cancer (detailed on pages 5-6).
- *On July 27, 2015*, the Company announced that it has started promoting Saizen® in 25 territories in the U.S., pursuant to its co-promotion agreement with EMD Serono.

First Quarter 2015 Financial Results

All amounts are in U.S. dollars.

Aeterna reported its first quarter 2015 financial and operating results on May 7, 2015. The current period for the following information reflects the three months ended March 31, 2015.

Aeterna reported research and development (R&D) costs of \$4.5 versus \$5.8 million for the same quarter in 2014. This decrease is attributable to lower comparative employee compensation and benefits costs, facilities rent, and maintenance as well as other costs. A substantial portion of this decrease is due to the realization of cost savings in connection with the Company's global resource optimization program as well as the lower comparative exchange rate of the EUR against the U.S. dollar. This decrease was partly compensated by higher third-party costs, mostly related to the Company's ZoptEC Phase 3 clinical trial in endometrial cancer.

Selling, general, and administrative (SG&A) expenses were \$5.1 million for the three-month period ended March 31, 2015, versus \$2.4 million for the same period in 2014. This increase is attributable to the Company's increased selling activities, associated with the co-promotion efforts related to EstroGel[®], with \$1.1 million of first quarter 2015 expenses being related to higher costs associated with Aeterna's contracted sales force and sales and marketing staff. Additionally, approximately \$0.8 million of the quarter-over-quarter increase is attributable to transaction costs incurred in connection with the completion of the March 2015 offering. Other increases are attributable in large part to lower comparative foreign exchange gains.

Net loss for the current period was \$9.7 million, or (\$0.13) per basic and diluted share, versus \$4.4 million, or (\$0.08) per basic and diluted share, for the same period in 2014. This increase in net loss is due largely to higher comparative SG&A expenses and to higher comparative net finance costs, partially offset by lower comparative R&D costs.

As of March 31, 2015, Aeterna reported that it held cash and cash equivalents of \$53.3 million versus \$34.9 million as of December 31, 2014.

Company Background

Aeterna Zentaris Inc. (“Aeterna” or “the Company”) is a specialty biopharmaceutical company engaged in developing, commercializing, and promoting novel treatments in oncology and endocrinology via internal development programs as well as expanding its commercial portfolio through co-promotion, in-licensing, and the acquisition of products already on the market. With a focus on establishing revenues and profitability while optimizing resources and reducing its burn rate, the Company’s current commercial programs are for the co-promotion of a non-patch estrogen replacement therapy, EstroGel®, in conjunction with Ascend Therapeutics US, LLC, and for the promotion of a growth hormone deficiency product, EMD Serono, Inc.’s Saizen® [somatropin (rDNA origin) for injection], in specific U.S. geographies. Aeterna also holds a pipeline of candidates in varying stages of development.

The Company’s lead and wholly owned clinical candidate, zopectarelin doxorubicin (doxorubicin peptide conjugate), is undergoing a fully enrolled Phase 3 trial in advanced-stage endometrial cancer, where this compound has shown to reduce toxicity and improve effectiveness of cytotoxic drugs. Aeterna is also investigating various other compounds as potential treatments in oncology and endocrinology as it pursues strategic initiatives that are consistent with the operations of a commercial specialty biopharmaceutical company.

EstroGel®

Figure 1
ESTROGEL 0.06%

ESTROGel^{0.06%}
(estradiol gel)
Designed for a modern woman.*



Source: Aeterna Zentaris Inc.

As a part of the Company’s strategy of branding itself beyond a development-stage entity and into a commercial entity, Aeterna entered into a co-promotion agreement with Ascend Therapeutics for Ascend’s product, EstroGel® (a non-patch transdermal estrogen therapy)*. With over 100 years of success by its parent company, Besins Healthcare S.A., Ascend is a specialty pharmaceutical company exclusively focused on women’s healthcare.

Under this agreement, Aeterna’s contractual sales force is co-promoting EstroGel® within specific territories in the U.S. Sales commissions are payable to Aeterna based upon incremental EstroGel® sales volumes generated over certain pre-established thresholds. With 35 years of worldwide patient use, EstroGel® is approved in over 70 countries and is the top-prescribed estrogen product in Europe as well as the leading prescribed transdermal estrogen product in Canada. The estrogen replacement market, which generated \$3.6 billion in annual revenues in 2013, encompasses products delivered orally,

transdermally, vaginally, or intramuscularly (IM). In the non-patch arena of transdermal products where EstroGel® is positioned (which has proven to be a promotionally responsive market), there are currently only three brands on the market, which collectively generate roughly \$100 million in annual sales.

By co-promoting EstroGel®, Aeterna is gaining valuable experience for its sales force to utilize toward promoting any future commercial products that the Company acquires, in-licenses, or co-promotes. To that end, an established and experienced sales force may be a key asset in facilitating negotiations with companies that have commercial assets they may wish to out-license or co-promote. Greater details of EstroGel® and the respective co-promotion agreement in place are provided on page 16 of Crystal Research Associates’ Executive Informational Overview® (EIO) published on Aeterna and available at www.crystalra.com.

*Please see patient information and boxed warning for more details on EstroGel® at www.estrogel.com.

Promotional Agreement with Merck's EMD Serono, Inc. for Saizen®

In May 2015, Aeterna entered into a promotional services agreement with EMD Serono, Inc., the U.S. and Canadian biopharmaceutical businesses of Merck KGaA (MRK-NYSE). Under the agreement, Aeterna is promoting Saizen® [somatotropin (rDNA origin) for injection] to designated medical professionals in specified territories in the U.S. Aeterna works within the realm of field promotion of Saizen® by driving awareness of the product among medical professionals, and expects to be compensated on the basis of new, eligible patient starts on Saizen® above an agreed-upon baseline. Aeterna began promoting the product to 25 territories in the U.S. in July 2015. Financial terms of this agreement were not disclosed.

About Saizen® for Growth Hormone Deficiency

Saizen® is a recombinant human Growth Hormone (r-hGH) registered in the U.S. for the treatment of growth hormone deficiency (GHD) in both children and adults. A deficiency of growth hormone in the body can cause slow growth in children, and without treatment, few will reach their full height potential as an adult. It is a disorder affecting one in every 4,000 to 10,000 children and up to three in every 10,000 adults. Aeterna believes that Saizen® represents a good fit for the Company's endocrinology portfolio currently in development, which includes Aeterna's in-house product candidate Macrilen (macimorelin), a novel, orally available peptidomimetic ghrelin receptor agonist that stimulates the secretion of growth hormone and that is used to diagnose adult growth hormone deficiency (profiled on page 7).

*Please see full prescribing information and important risk information for Saizen® at www.saizenus.com/.

Zoptarelin Doxorubicin (Doxorubicin Peptide Conjugate)

Zoptarelin doxorubicin (doxorubicin peptide conjugate) represents a new concept in oncology using a hybrid molecule composed of a synthetic peptide carrier and a well-known chemotherapy agent, doxorubicin. As the first intravenous drug in a clinical study to direct a chemotherapy agent specifically to luteinizing hormone-releasing hormone (LHRH)-receptor expressing tumors, zoptarelin doxorubicin is believed to lead to a more targeted treatment with less damage to healthy tissue. The Company's most advanced indication is for advanced, recurrent, or metastatic endometrial cancer (noting that endometrial cancer is the most common of the gynecologic malignancies and is expected to affect 1 in 37 women during 2015). If the compound is approved for its first indication, the Company intends to develop it for other tumors expressing the LHRH-receptor, such as ovarian, prostate, and possibly additional cancer indications as part of zoptarelin doxorubicin's lifecycle management program. A Phase 2 trial in ovarian cancer has been completed and published, while an investigator-initiated Phase 1/2 trial in prostate cancer is currently underway.

Patients with advanced and recurrent endometrial cancer typical have a poor prognosis. There is no known or approved systemic therapy (except in Germany) for advanced (Stages III or IV) and recurrent metastatic endometrial cancer. Moreover, while response rates of up to 50% have been seen in patients receiving combination chemotherapy, the duration of the responses are short and the medications carry high toxicity. Due to the difficulty in treating women with late-stage endometrial cancer, new therapies are being developed to try and help better target and kill cancerous cells. As such, Aeterna is developing zoptarelin doxorubicin for an advanced form of endometrial cancer.

Phase 3 ZoptEC Study in Endometrial Cancer

The ZoptEC (Zoptarelin doxorubicin in Endometrial Cancer) Phase 3 study in women with advanced, recurrent, or metastatic endometrial cancer who have progressed and have received one chemotherapeutic regimen with platinum and taxane (either as adjuvant or first-line treatment) has completed enrollment of 500 patients. The first patient was dosed in July 2013, and the trial is being conducted at over 120 sites across North America, Europe, and Israel. The primary efficacy endpoint of the ZoptEC study is improvement in median overall survival as compared to standard therapy with doxorubicin. The first futility interim analysis occurred in April 2015, following which a Data and Safety Monitoring Board recommended that the ZoptEC Phase 3 study continue as planned. A second interim analysis is expected during the fourth quarter 2015 at approximately 192 events, with the final analysis planned at an anticipated 384 events. The trial is expected to be completed by the end of 2016.

If approved, zoptarelin doxorubicin could become the first FDA-approved medical therapy for treating recurrent endometrial cancer. Medical therapies used in treating recurrent endometrial cancer account for approximately \$300 million to \$400 million in the U.S. When considering additional indications in the U.S., the annual market opportunity could exceed \$1 billion to Aeterna's knowledge.

Aeterna holds global rights to zoptarelin doxorubicin, with the exception of China (including Hong Kong and Macau), where rights have been out-licensed to Sinopharm A-Think (a subsidiary of Sinopharm, the largest medical and healthcare group in China and on *Fortune's* Global 500 list). Greater details of the Sinopharm agreement are provided on page 21 of the EIO. In addition, in early 2015, Aeterna announced the filing of a new patent that is anticipated to reduce the API production costs by more than 50%, potentially providing a solid competitive advantage for the Company.

Ergomed Agreement

In April 2013, Aeterna announced that it had signed a co-development and profit-sharing agreement with UK-based Ergomed plc for zoptarelin doxorubicin in endometrial cancer. Ergomed was selected as the contract clinical development organization to conduct the ZoptEC Phase 3 trial. Under the terms of the agreement, Ergomed has agreed to assume 30% (up to \$10 million) of the clinical and regulatory costs for the trial (estimated at approximately \$32 million over the course of the study). As well, Ergomed is to receive its return on investment based on an agreed percentage of any net income received by Aeterna for zoptarelin doxorubicin in this indication (up to a maximum amount specified in the agreement).

In June 2015, Aeterna executed another agreement with Ergomed for the management of the Company's confirmatory Phase 3 clinical study of Macrilen (macimorelin) as well.

Additional Potential Indications for Zoptarelin Doxorubicin

Going forward, Aeterna is continuing to develop its commercialization plans regarding zoptarelin doxorubicin in endometrial cancer, including establishing additional partnerships in territories that the Company does not intend to pursue. In addition, contingent on the success of the ZoptEC program, the Company may have additional areas of interest for further therapeutic development, including ovarian, prostate, triple negative breast cancer, and potentially bladder cancer.

By and large, recurrent ovarian cancer is considered incurable, with therapies at this stage mainly seeking palliative treatment of symptoms, maintaining or improving quality of life, and increasing survival. Aeterna has completed a Phase 2 trial with zoptarelin doxorubicin in women with platinum-resistant ovarian cancer, a late-stage form of the disease during which refractory tumor growth is observed despite use of primary therapy. The compound has been granted orphan drug designation by the FDA and orphan medicinal product designation from the European Medicines Agency (EMA) in treating ovarian cancer.

Zoptarelin doxorubicin is also in development for prostate cancer by an independent investigator. An article on final data for the Phase 1 portion of the ongoing Phase 1/2 trial in prostate cancer with zoptarelin doxorubicin was published in the December 2014 issue of *Clinical Cancer Research*. The article outlines data previously disclosed in June 2013 at the ASCO Annual Meeting, which demonstrated the compound's safety profile and potential anti-tumor activity in men with castration- and taxane-resistant prostate cancer who have been heavily pre-treated. With encouraging Phase 1 data, the next milestone could be results from the current Phase 2 portion of this investigator-driven trial.

Other Preclinical Compounds

Aeterna also has a number of drugs in preclinical studies addressing various other cancers and endocrine disorders. In its oncology pipeline are earlier stage programs, including a highly potent and selective ATP competitive Erk inhibitor, which may represent new therapeutic opportunities in oncology; and LHRH disorazol Z, a next-generation zoptarelin doxorubicin, which is a cytotoxic conjugate of disorazol Z and a synthetic peptide carrier that targets the LHRH receptor (and may also have potential in solid tumors).

Macrilen

Macrilen (macimorelin) is an orally active ghrelin agonist for use in evaluating AGHD. On April 13, 2015, the Company announced plans to conduct a new, confirmatory clinical study to demonstrate the efficacy of Macrilen for use in AGHD, as well as a dedicated thorough QT study to evaluate the effect of Macrilen on myocardial repolarization. Aeterna has stated that this decision followed a positive and constructive meeting with the FDA regarding the New Drug Application (NDA) for Macrilen. The Company requested the meeting to gain clarity on the approval deficiencies described in a Complete Response Letter (CRL) that Aeterna had received on November 6, 2014. Following receipt of the CRL, the Company convened a panel of U.S. and EU endocrinology experts to advise it regarding the options for Macrilen. According to Aeterna, the panel advised the Company to continue to seek approval for the compound because of their confidence in its efficacy and because there is not currently an FDA-approved diagnostic test for AGHD.

Following an end-of-review meeting with the FDA on March 6, 2015, the Company and the FDA agreed on the general design of the confirmatory study as well as evaluation criteria. The study is to be conducted as a two-way crossover with the insulin tolerance test as the benchmark comparator. The study population is intended to consist of patients with a medical history documenting risk factors for AGHD and to include a spectrum of patients, ranging from those who have a low risk of AGHD to those with a high risk of the condition. Additionally, Aeterna received written scientific advice from the EMA in May 2015 suggesting that the Company’s plan for a new Phase 3 trial of Macrilen, as discussed with the FDA, would also be acceptable to the EMA (Source: Aeterna’s May 26, 2015, press release). The EMA did propose that Aeterna consider additional aspects regarding the demonstration of reproducibility of a diagnosis made using Macrilen, which would further enhance the profile of the compound.

The Company believes that completion of the confirmatory Phase 3 study and the QT study will likely require approximately 18 months and a combined expenditure of between \$5 million and \$6 million.

Pipeline Summary

Figure 2 summarizes the Company’s current product pipeline, which is described in greater detail on pages 16-30 of the EIO® available at www.crystalra.com.

Figure 2
PRODUCT PIPELINE

Product Candidate	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
Zoptarelin doxorubicin					Endometrial Cancer
Zoptarelin doxorubicin			Ovarian ⁽¹⁾ and Prostate ⁽²⁾ Cancer		
Macrilen™ (macimorelin)					AGHD ⁽³⁾
AEZS-120		Prostate Cancer ⁽⁴⁾			
Erk Inhibitor		Oncology ⁽⁵⁾			
LHRH – Disorazol Z		Oncology			
Compound Library – MUSC ⁽⁶⁾					

(1) Phase 2 in ovarian cancer completed.
 (2) Investigator-driven and sponsored.
 (3) Confirmatory Phase 3 efficacy clinical trial to be initiated in Q3 2015.
 (4) Oral prostate cancer vaccine available for out-licensing.
 (5) Available for out-licensing
 (6) Compound library transferred to MUSC, AEZS to access future candidates.

Source: Aeterna Zentaris Inc.

Global Resources Optimization Program

In April 2013, Aeterna named a new CEO, David Dodd, who commenced a strategic review of the Company's assets and development plan. Mr. Dodd implemented a "global resources optimization program" to shift the Company's strategic focus from drug discovery and R&D to commercial operations and developing product sales. Prior to this, Aeterna was working toward developing multiple ongoing early-stage drug discovery and development programs emerging from a prior R&D team. When perifosine, Aeterna's lead drug candidate in 2012/2013, failed in two Phase 3 trials in advanced colorectal cancer and in recurrent multiple myeloma, respectively, Mr. Dodd was hired as Aeterna's new president and CEO to conduct a strategic review of the Company and its assets.

As a senior-level manager at several pharmaceutical companies, including president and CEO or as a Board member, Mr. Dodd is believed to hold the experience needed to redirect the Company and turn it into a commercially viable and revenue-generating organization. Mr. Dodd's history involves accelerating growth and increasing the market capitalization of companies he has led, and in certain cases, leading to merger(s) or acquisition(s). Mr. Dodd also has a history of raising capital. Aeterna recently completed a public offering which generated net proceeds of \$34.5 million, for a total of over \$53 million in the bank as of March 31, 2015. Aeterna thus believes that it holds the means with which to implement its restructuring plan and fund continuing development of the Company's product candidates while moving into a commercial organization. The Company may from time to time need to raise additional capital to fund its operations.

Key Corporation Information

The Company was incorporated on September 12, 1990, under the Canada Business Corporations Act (CBCA) and continues to be governed by the CBCA. On December 30, 2002, it acquired Zentaris AG, a biopharmaceutical company based in Frankfurt, Germany. Zentaris was a spin-off of Asta Medica GmbH, a former pharmaceutical company affiliated with Degussa AG. In May 2004, the Company's name was changed to Aeterna Zentaris Inc. and on May 11, 2007, Zentaris GmbH was renamed Aeterna Zentaris GmbH. On October 2, 2012, Aeterna effected a 6-to-1 reverse stock split and on October 5, 2012, the common shares began trading on a consolidated and adjusted basis on both the NASDAQ and TSX.

The Company's corporate headquarters are based in Québec City, Canada, with offices in Charleston, South Carolina, and Frankfurt, Germany. Aeterna expanded into Charleston in May 2014 as its new location for North American business and global commercial operations. Over the next five years, the Company has stated that it expects to implement staff additions to support the areas of commercial operations, business development, regulatory and quality assurance, manufacturing management, clinical and product development, along with administrative functions. As well, the Coordinating Council for Economic Development of South Carolina has approved job development credits for the Company.

Aeterna trades on the NASDAQ under the ticker symbol AEZS and on the TSX under AEZ. Its three wholly owned direct and indirect subsidiaries include Aeterna Zentaris GmbH (Germany); Zentaris IVF GmbH, a direct wholly owned subsidiary of AEZS Germany based in Frankfurt, Germany; and Aeterna Zentaris, Inc., an entity incorporated in the State of Delaware with an office in Summerville, South Carolina.

Key Points to Consider

- **Aeterna is a specialty biopharmaceutical company in oncology, endocrinology, and women’s health, focused on establishing revenues and profitability while optimizing resources and reducing burn rate.** The Company is working to achieve a commercial presence and growth via licensing, acquisition, and co-promotional opportunities beginning with EstroGel®, a non-patch estrogen replacement therapy, and Saizen®, a growth hormone deficiency therapy. Aeterna also holds a pipeline of candidates in varying stages of development, including zoptarelin doxorubicin (doxorubicin peptide conjugate), a potential therapy for advanced, recurrent, or metastatic endometrial cancer; and Macrilen (macimorelin), an orally available peptidomimetic ghrelin receptor agonist that stimulates the secretion of growth hormone and may diagnose AGHD. Other potential indications for zoptarelin doxorubicin may include tumors expressing the LHRH receptor, such as prostate cancer, bladder cancer, breast cancer, or ovarian cancer.
- **Aeterna has promotion services agreements with Ascend Therapeutics US, LLC, for EstroGel® and with Merck’s EMD Serono, Inc. for Saizen® [somatropin (rDNA origin) for injection], enabling Aeterna to transition beyond the development stage and into a commercial entity.** In collaboration with Ascend’s sales representatives, Aeterna’s contractual sales representatives promote EstroGel® to designated medical professionals in 19 specific territories in the U.S. on a commission basis. EstroGel® is a top-prescribed product in Europe and the leading prescribed transdermal product in Canada, participating in the \$3.6 billion estrogen replacement market. Aeterna’s contractual sales representatives also promote Saizen® in 25 U.S. territories on a commission basis.
- **Zoptarelin doxorubicin is a new concept in oncology.** This hybrid molecule, which is delivered intravenously, is composed of a synthetic peptide carrier and doxorubicin, which directs the chemotherapy agent specifically to LHRH-receptor-expressing tumors. There is an indication from Phase 2 studies that the compound results in a more targeted treatment with less damage to healthy tissue and fewer overall side effects.
- **As an ongoing Phase 3 trial for endometrial cancer, the ZoptEC (Zoptarelin doxorubicin in Endometrial Cancer) study has enrolled 500 patients at over 120 sites in North America, Europe, and Israel.** The Company is working under a Special Protocol Assessment (SPA) with UK-based Ergomed plc where the two entities have a cost-sharing agreement in place. The trial is expected to be completed by the end of 2016. If approved, zoptarelin doxorubicin could become the first FDA-approved therapy for treating recurrent endometrial cancer. Sinopharm A-Think of China has development rights for China, Hong Kong, and Macau. Following the first indication in endometrial cancer, Aeterna has stated an intent to pursue other tumors expressing the LHRH-receptor, such as ovarian cancer as well as prostate cancer (with an investigator-initiated trial already underway in prostate cancer) as part of the product’s lifecycle management program. Additional cancer treatment indications are also under consideration.
- **The Company recently announced plans to conduct a new confirmatory Phase 3 clinical study to demonstrate the efficacy of Macrilen for use in evaluating AGHD, as well as a dedicated thorough QT study to evaluate the effect of Macrilen on myocardial repolarization.** This decision follows positive meetings with the U.S. FDA and the European Medicines Agency (EMA) regarding Macrilen. The Company requested the meeting with the FDA to gain clarity on the approval deficiencies described in the Complete Response Letter (CRL) the Company received from the agency on November 6, 2014. The confirmatory Phase 3 trial is expected to be initiated in the third quarter 2015, while the QT trial is expected to be initiated in early 2016.
- **In preclinical stages, Aeterna’s Erk inhibitor program for oncology was presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2014 and selected as one of the most exciting recent developments in RAS/RAF/EGFR research.** The Company recently completed an optimization of this molecule for development and expects to initiate discussions with potential partners and/or continue its development for further proof of concept.

- **Over the past year, Aeterna has assembled a strong leadership team with experience and demonstrated ability in building significant value in the pharmaceutical industry.** The Company is listed on both the NASDAQ and the TSX exchanges. After raising approximately \$34.5 million in early 2015, Aeterna reported that it held cash and cash equivalents of \$53.3 million as of March 31, 2015.

Risks and Disclosures

This Quarterly Update has been prepared by Crystal Research Associates, LLC (CRA) based upon information provided by Aeterna. CRA has not independently verified such information. Some of the information in this Update relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in Aeterna's statements in its public and investor materials as well as regulatory forms filed from time to time.

The content of this report with respect to Aeterna has been compiled primarily from information available to the public released by the Company through news releases, investor presentations, and other materials released from time to time. Aeterna is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Aeterna or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, CRA has been compensated by the Company in cash of thirty-nine thousand U.S. dollars for its services in creating the base report and updates. Investors should carefully consider the risks and information about Aeterna's business, as described in Crystal Research Associates' Executive Informational Overview® (EIO) published on April 21, 2015, and Aeterna's regulatory filings. Investors should not interpret the order in which considerations are presented in filings as an indication of their relative importance. The risks and uncertainties overviewed in the EIO are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Aeterna or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, Aeterna's business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company's shares could decline. This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. Additional information about Aeterna, as well as copies of this report, can be obtained by calling (418) 652-8525.



crystal research

a s s o c i a t e s

Facts Without Fiction

QUARTERLY UPDATE: July 27, 2015

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